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MITCHEL L. ZOLER/IMNG MEDICAL MEDIA

Review for USPSTF backs CT screening for lung cancer

Draft guidelines open for comment.

BY SHARON WORCESTER
IMNG Medical News

Low-dose computed tomography reduces lung cancer mortality and all-cause mortality when used as a screening tool in asymptomatic adults at high risk for the disease, according to the results of a systematic review conducted for the U.S. Preventive Services Task Force.

In 2004, the USPSTF deemed the evidence insufficient for recommending for or against low-dose computed tomography (LDCT) for lung cancer screening in asymptomatic individuals, but the findings of the cur-

rent review suggest screening has a definite benefit in most patients, Dr. Linda L. Humphrey, of Oregon Health and Science University and the Portland Veterans Affairs Medical Center, and her colleagues reported.

A draft recommendation based on the findings, published online in *Annals of Internal Medicine* (2013 July 29 [doi: 10.7326/0003-4819-159-6-201309170-00690]), is available on the USPSTF website for public comment.

The researchers conducted a review of the literature published between 2000 and May 2013 and identified four trials that reported findings

See **Screening** • page 10

New pulmonary drug ups walk distance

BY MARY ANN MOON
IMNG Medical News

Riociguat, an agent from a new class of compounds known as soluble guanylate cyclase stimulators, was found effective and safe for treating two different types of pulmonary hypertension

in separate industry-sponsored phase III clinical trials.

Compared with placebo, daily oral riociguat significantly improved exercise capacity as measured by 6-minute walk distance, and also improved pulmonary vascular resistance and World Health Organization

(WHO) functional class. The results are from one international study involving 261 patients who had chronic inoperable thromboembolic pulmonary hypertension and another study involving 443 patients who had pulmonary

See **Pulmonary** • page 7

"We think the VTEs during follow-up are recurrences of clots that first formed during treatment," said Dr. Ketan P. Kulkarni.

VTE rate triples in young cancer survivors

BY MITCHEL L. ZOLER
IMNG Medical News

AMSTERDAM – Children, adolescents, and young adults who survived a diagnosis and treatment of cancer had a greater than threefold higher rate of acute venous thromboembolism during roughly 10 years of follow-up compared with matched controls from the general population in a study that included more than 30,000 Canadians.

The increased rate of VTE appeared to be linked to the chemotherapy and radiation treatments that patients received, because patients who were managed only by surgery had a substantially

reduced rate of VTE during follow-up.

"Our working hypothesis is that VTE that develops during [initial] treatment of childhood cancers then places these patients at an increased risk" for a second VTE later in their life, Dr. Ketan P. Kulkarni said at the congress of the International Society on Thrombosis and Haemostasis.

If a first episode of VTE during or soon after the initial therapy that young cancer patients receive can be clearly established as a major risk factor for a subsequent episode of VTE, the next step would be to test whether improved prophylaxis during

See **Young survivors** • page 5

INSIDE

News

Medicolegal Lessons

A death from PE leads to a lawsuit over a substandard prophylactic warfarin dose. • 8

Critical Care Medicine

Predicting embolism risk

IMPROVE VTE risk-assessment model has been validated. • 9

Sleep Medicine

CBT for insomnia?

A single session can help some patients ... especially if they want it to. • 14

News From the College

Pulmonary Perspectives

Two nonsurgical options for treating lung cancer • 20

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Is the change in 6MWD predictive of long-term outcomes in PAH?

CHANGEMI

It's time to move beyond short-term functional endpoints

The continued use of change in 6MWD as a primary endpoint in PAH clinical trials is being challenged by leading researchers.¹⁻³ Recent studies suggest this measure does not explain a large proportion of the treatment effect on clinical outcomes.^{1,3} While experts acknowledge the clinical importance of 6MWD, they suggest the exploration of alternative primary endpoints.^{1,2,4}

Now is the time for a new perspective on change in 6MWD as a primary endpoint. The PAH expert community has called for future PAH studies to deliver data on the long-term effect of therapy on clinical outcomes, such as hospitalizations and mortality.^{2,5,6} Actelion is committed to investigating this evolving perspective in PAH.

References: 1. Gabler NB, French B, Strom BL, et al. Validation of six-minute-walk distance as a surrogate endpoint in pulmonary arterial hypertension trials. *Circulation*. 2012;126:349-356. 2. McLaughlin VV, Badesch DB, Delcroix M, et al. End points and clinical trial design in pulmonary arterial hypertension. *J Am Coll Cardiol*. 2009;54:S97-S107. 3. Savarese G, Paolillo SP, Costanzo P, et al. Do changes of 6-minute walk distance predict clinical events in patients with pulmonary arterial hypertension? *J Am Coll Cardiol*. 2012;60:1192-1201. 4. Snow JL, Kawut SM. Surrogate end points in pulmonary arterial hypertension: assessing the response to therapy. *Clin Chest Med*. 2007;28:75-89. 5. Gomberg-Maitland M, Dufton C, Oudiz RJ, Benza RL. Compelling evidence of long-term outcomes in pulmonary arterial hypertension? *J Am Coll Cardiol*. 2011;57:1053-1061. 6. Galie N, Manes A, Negro L, Palazzini M, Bacchi-Reggiani M, Branzi A. A meta-analysis of randomized controlled trials in pulmonary arterial hypertension. *Eur Heart J*. 2009;30:394-403.

PERSPPECTIVE

Benefits and limitations of 6MWT endpoint^{2,4}

PROS

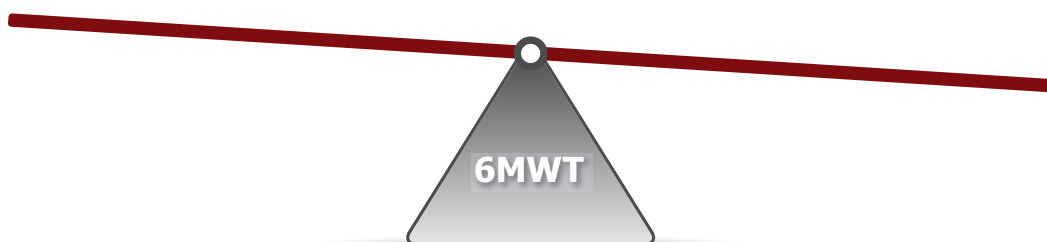
- Ease of use, low cost
- Allows assessment of daily functioning
- Accepted by regulatory agencies

CONS

- Results affected by musculoskeletal factors
- High within-subject variability
- May have a threshold effect
- Variability based on other activities on the day of testing



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PAHChangePerspective.com/6MWTTest



RSV hospitalization high in children under 1 month

BY M. ALEXANDER OTTO

IMNG Medical News

Being under a month old, living with children under 5 years old, and being born during peak respiratory syncytial virus season all increase the likelihood that young children will be hospitalized with the infection, according to a 5-year, prospective surveillance study of children up to 2 years old.

Investigators found 559 (26%) RSV-infected children among the 2,149 hospitalized with acute respiratory infections during 2000-2005 in counties that included Nashville, Tenn.; Rochester, N.Y.; and Cincinnati. Most of the children had been previously healthy, and most were born full term (Pediatrics 2013;132:e341-e348 [doi:10.1542/peds.2013-0303]).

VITALS

Major finding: The RSV hospitalization rate for children in their first month of life is 25.9 per 1,000.

Data source: Prospective study of children up to 2 years old hospitalized with acute respiratory infections during 2000-2005.

Disclosures: The Centers for Disease Control and prevention funded the work. Six of the 14 authors reported research funding from or speaking, advising, or consulting relationships with several companies, including GlaxoSmithKline, MedImmune, Merck, Sanofi Pasteur, Novartis, BD Diagnostics, Novavax, and Quidel. Some of those firms are involved with RSV vaccine development.

The findings suggest that preventive measures – including vaccines under development – should be aimed at all young children, not just premature infants and others traditionally thought of as being at high risk, according to Dr. Caroline Breese Hall of the University of Rochester (N.Y.) and her associates.

“These findings indicate that strategies for diminishing the health care burden from RSV infections should include appropriate prophylaxis and the development of vaccines that are effective in very young infants, even those within the first month of life. In addition, general infection control practices such as restrictions of visits from ill individuals and careful hand washing should be emphasized, espe-

cially during the peak months of RSV circulation,” which were December and January in this study, the authors reported.

The RSV hospitalization rate was 5.2 per 1,000 children less than 24 months old; infants in their first month of life had the highest rate at 25.9 per 1,000 children. Infection was confirmed in the study by reverse-transcriptase polymerase chain reaction.

Infants no older than 2 months had a hospitalization rate of 17.9 per 1,000 children and accounted for 44% of RSV hospitalizations.

Ten percent of hospitalized kids were born preterm, “but their risk of hospitalization was not significantly different from that for term infants.” It was a different story with very premature infants, that is, those born at less than 30 weeks’ gestation. They accounted for only 3% of RSV cases but had an RSV hospitalization rate of 18.7 per 1,000 children, about three times that of term infants, the authors noted.

Previous attempts to characterize children hospitalized with RSV have tended to rely on retrospective data – often discharge diagnoses – and have stratified risk by 6-month blocks of time. To increase precision, the authors used birth certificates to quantify risk by months of age.

About 21% of the children less than 12 months old had a comorbid condition, most often cardiopulmonary disease; coexisting medical conditions were even more common among older

children, occurring in 53% of those aged 12-23 months.

The proportion of hospitalized children less than 24 months old living with another child under 5 years old (57%) was more than twice that of children living with older children (19%).

Overall, gender and race did not affect hospitalization rates.

The team did not study the effects of palivizumab – a monoclonal antibody used to prevent RSV complications in premature infants and others generally thought to be at high risk – on hospitalization rates, which “was unlikely to be appreciable because only a small proportion (less than 5%) of our study population was eligible” to receive it, the team noted.

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IN THIS ISSUE

News From the College • 16

CHEST 2013

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CHEST PHYSICIAN Is Online

CHEST PHYSICIAN is available on the Web at www.chestnet.org/accp/chestphysician.

VIEW ON THE NEWS

Dr. Susan Millard, FCCP, comments:

This prospective study verifies what has been taught to pediatric residents – neonates (infants less than 30 days of age) are at high risk for RSV, especially if born during the RSV season!



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VTE risk high after cancer treatment

Young survivors from page 1

initial therapy can prevent a first episode and thereby also cut patients' risk for a second VTE several months or years later. Clinicians who manage children, adolescents, and young adults with cancer need increased awareness that VTE "is a major problem" during both initial treatment and follow-up, Dr. Kulkarni said in an interview. "We think the VTEs during follow-up are recurrences of clots that first formed during treatment." He and his associates have begun to review the medical records of each survivor to better determine how many of the VTEs seen during follow-up were recurrences.



"We should have a higher index of suspicion for VTE in pediatric cancer survivors."

DR. LESNICK

Another major finding from this analysis of people who survived at least 5 years following cancer diagnosis at age 0-24 years was that the entire range of cancers posed a VTE risk to patients, not just leukemia as some had previously thought. The VTE rate during follow-up was similar regardless of the type of cancer, said Dr. Kulkarni, a pediatric hematologist-oncologist at the University of Alberta in Edmonton.

The researchers used provincial health insurance records from British Columbia during 1981-1999 to identify 2,857 patients who were aged 0-24 years at the time of their initial cancer diagnosis and then lived for at least another 5 years. The survivors averaged about 14 years old at the time of their initial cancer diagnosis. The investigators also assembled a control group matched by age and sex from the general population, taking 10 controls for each case for a total of 28,570.

During follow-up that ranged from 5 to 21 years and averaged nearly 10 years, they found that 43 survivors had an episode of VTE, a 1.5% incidence rate, compared with a 0.5% rate among the controls. In a multivariate analysis that controlled for sex, socioeconomic status, and region of residence, patients who were cancer survivors had a statistically significant, 3.4-fold increased rate of VTE compared with the controls, Dr. Kulkarni reported. Among the survivors the incidence of deep vein

thrombosis was roughly 0.8%, the incidence of pulmonary embolism was roughly 0.5%, and VTE in other locations occurred in about 0.3% of the survivors. The incidence of VTEs was

highest during the first 6 months following cancer diagnosis.

Cancer survivors who had been treated by surgery alone had a statistically significant, 81% lower rate of developing a VTE compared with the patients treated by chemotherapy alone, radiation alone, or both.

Patients with relapses had a 2.5-fold

higher rate of VTE compared with survivors who did not have a relapse.

"Based on these compelling findings, we should have a higher index of suspicion for VTE in pediatric cancer survivors," Dr. Burt Lesnick, FCCP, of Georgia Pediatric Pulmonary Associates, remarked.

Dr. Kulkarni had no disclosures.



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Important Safety Information

Spiriva® HandiHaler® (tiotropium bromide inhalation powder) is contraindicated in patients with a history of hypersensitivity to tiotropium, ipratropium (atropine derivatives), or any components of SPIRIVA capsules.

SPIRIVA HandiHaler is not indicated for the initial treatment of acute episodes of bronchospasm, i.e., rescue therapy.

Immediate hypersensitivity reactions, including urticaria, angioedema (swelling of lips, tongue or throat), rash, bronchospasm, anaphylaxis, or itching may occur after administration of SPIRIVA. Additionally, inhaled medicines, including SPIRIVA, may cause paradoxical bronchospasm. If any of these occurs, treatment with SPIRIVA should be stopped and other treatments considered.

Use with caution in patients with severe hypersensitivity to milk proteins.

SPIRIVA HandiHaler should be used with caution in patients with narrow-angle glaucoma or urinary retention. Prescribers should instruct patients to consult a physician immediately should any signs or symptoms of narrow-angle glaucoma, or prostatic hyperplasia or bladder-neck obstruction occur.

SPIRIVA may interact additively with concomitantly used anticholinergic medications. Avoid coadministration with other anticholinergic-containing drugs.

The most common adverse reactions in the 1-year placebo-controlled trials were dry mouth, upper respiratory tract infection, sinusitis, pharyngitis, non-specific chest pain, and urinary tract infection. In addition, the most commonly reported adverse reactions from the 4-year trial not included above were headache, constipation, depression, insomnia, and arthralgia.

Indication

SPIRIVA HandiHaler is indicated for the long-term, once-daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema, and for reducing COPD exacerbations.

Please see accompanying Brief Summary of full Prescribing Information.

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References: 1. SPIRIVA Prescribing Information. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; 2012. 2. Data on file, Boehringer Ingelheim Pharmaceuticals, Inc.



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CMS non-face-to-face pay falls short for specialists

BY MARY ELLEN SCHNEIDER
IMNG Medical News

In a move away from the traditional visit-based payment system, of-

ficials at the Centers for Medicare and Medicaid Services are considering paying physicians for their non-face-to-face work in chronic disease management.

The proposal would create two

new G-codes for the non-face-to-face care management services for Medicare patients with two or more significant chronic conditions.

The services would include physician development and revision of a

care plan, communication with other treating physicians and health providers, and medication management. The CMS is proposing two G-codes for establishing a plan of care and for providing care management over 90-day periods.

Physicians could use the codes if their patients have had Medicare's Annual Wellness Visit or an Initial Preventive Physician Examination. The CMS also plans to establish practice standards for the codes, such as requiring the use an electronic health record at the time of service.

The new codes would go into effect Jan. 1, 2015.

Currently, Medicare pays for primary care management that occurs during an office visit. Last year the agency established codes for transitional care management services for patients moving from a hospital or a skilled nursing facility to home, which included some non-face-to-face activities. The transitional care codes went into effect in January 2013.

The new codes are among policy changes being floated as part of the proposed 2014 Medicare Physician Fee Schedule. The proposed rule was published in the Federal Register July 19. The CMS will accept public comment until Sept. 6 and a final rule is expected in November.

Continued on page 8

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BRIEF SUMMARY OF PRESCRIBING INFORMATION

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CONTRAINDICATIONS: SPIRIVA HandiHaler is contraindicated in patients with a hypersensitivity to tiotropium, ipratropium, or any components of SPIRIVA capsules [see WARNINGS AND PRECAUTIONS]. In clinical trials and postmarketing experience with SPIRIVA HandiHaler, immediate hypersensitivity reactions, including angioedema (including swelling of the lips, tongue, or throat), itching, or rash have been reported.

WARNINGS AND PRECAUTIONS: Not for Acute Use: SPIRIVA HandiHaler is intended as a once-daily maintenance treatment for COPD and is not indicated for the initial treatment of acute episodes of bronchospasm (i.e., rescue therapy). **Immediate Hypersensitivity Reactions:** Immediate hypersensitivity reactions, including urticaria, angioedema (including swelling of the lips, tongue, or throat), rash, bronchospasm, anaphylaxis, or itching, may occur after administration of SPIRIVA HandiHaler. If such a reaction occurs, therapy with SPIRIVA HandiHaler should be stopped at once and alternative treatments should be considered. Given the similar structural formula of atropine to tiotropium, patients with a history of hypersensitivity reactions to atropine should be closely monitored for similar hypersensitivity reactions to SPIRIVA HandiHaler. In addition, SPIRIVA HandiHaler should be used with caution in patients with severe hypersensitivity to milk proteins. **Paradoxical Bronchospasm:** Inhaled medicines, including SPIRIVA HandiHaler, can produce paradoxical bronchospasm. If this occurs, treatment with SPIRIVA HandiHaler should be stopped and other treatments considered. **Worsening of Narrow-Angle Glaucoma:** SPIRIVA HandiHaler should be used with caution in patients with narrow-angle glaucoma. Prescribers and patients should be alert for signs and symptoms of acute narrow-angle glaucoma (e.g., eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema). Instruct patients to consult a physician immediately should any of these signs or symptoms develop. **Worsening of Urinary Retention:** SPIRIVA HandiHaler should be used with caution in patients with urinary retention. Prescribers and patients should be alert for signs and symptoms of prostatic hyperplasia or bladder-neck obstruction (e.g., difficulty passing urine, painful urination). Instruct patients to consult a physician immediately should any of these signs or symptoms develop. **Renal Impairment:** As a predominantly renally excreted drug, patients with moderate to severe renal impairment (creatinine clearance of ≤ 50 mL/min) treated with SPIRIVA HandiHaler should be monitored closely for anticholinergic side effects.

ADVERSE REACTIONS: The following adverse reactions are described, or described in greater detail, in other sections: Immediate hypersensitivity reactions [see Warnings and Precautions]; Paradoxical bronchospasm [see Warnings and Precautions]; Worsening of narrow-angle glaucoma [see Warnings and Precautions]; Worsening of urinary retention [see Warnings and Precautions]. **Clinical Trials Experience:** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. **6-Month to 1-Year Trials:** The data described below reflect exposure to SPIRIVA HandiHaler in 2663 patients. SPIRIVA HandiHaler was studied in two 1-year placebo-controlled trials, two 1-year active-controlled trials, and two 6-month placebo-controlled trials in patients with COPD. In these trials, 1308 patients were treated with SPIRIVA HandiHaler at the recommended dose of 18 mcg once a day. The population had an age ranging from 39 to 87 years with 65% to 85% males, 95% Caucasian, and had COPD with a mean pre-bronchodilator forced expiratory volume in one second (FEV₁) percent predicted of 39% to 43%. Patients with narrow-angle glaucoma, or symptomatic prostatic hypertrophy or bladder outlet obstruction were excluded from these trials. An additional 6-month trial conducted in a Veteran's Affairs setting is not included in this safety database because only serious adverse events were collected. The most commonly reported adverse drug reaction was dry mouth. Dry mouth was usually mild and often resolved during continued treatment. Other reactions reported in individual patients and consistent with possible anticholinergic effects included constipation, tachycardia, blurred vision, glaucoma (new onset or worsening), dysuria, and urinary retention. Four multicenter, 1-year, placebo-controlled and active-controlled trials evaluated SPIRIVA HandiHaler in patients with COPD. Table 1 shows all adverse reactions that occurred with a frequency of $\geq 3\%$ in the SPIRIVA HandiHaler group in the 1-year placebo-controlled trials where the rates in the SPIRIVA HandiHaler group exceeded placebo by $\geq 1\%$. The frequency of corresponding reactions in the ipratropium-controlled trials is included for comparison.

Table 1 Adverse Reactions (% Patients) in One-Year COPD Clinical Trials

Body System (Event)	Placebo-Controlled Trials		Ipratropium-Controlled Trials	
	SPIRIVA (n = 550)	Placebo (n = 371)	SPIRIVA (n = 356)	Ipratropium (n = 179)
Body as a Whole				
Chest Pain (non-specific)	7	5	5	2
Edema, Dependent	5	4	3	5
Gastrointestinal System Disorders				
Dry Mouth	16	3	12	6
Dyspepsia	6	5	1	1
Abdominal Pain	5	3	6	6
Constipation	4	2	1	1
Vomiting	4	2	1	2
Musculoskeletal System				
Myalgia	4	3	4	3
Resistance Mechanism Disorders				
Infection	4	3	1	3
Moniliasis	4	2	3	2
Respiratory System (Upper)				
Upper Respiratory Tract Infection	41	37	43	35
Sinusitis	11	9	3	2
Pharyngitis	9	7	7	3
Rhinitis	6	5	3	2
Epistaxis	4	2	1	1
Skin and Appendage Disorders				
Rash	4	2	2	2
Urinary System				
Urinary Tract Infection	7	5	4	2

Rx only

Arthritis, coughing, and influenza-like symptoms occurred at a rate of $\geq 3\%$ in the SPIRIVA HandiHaler treatment group, but were $< 1\%$ in excess of the placebo group. Other reactions that occurred in the SPIRIVA HandiHaler group at a frequency of 1% to 3% in the placebo-controlled trials where the rates exceeded that in the placebo group include: *Body as a Whole:* allergic reaction, leg pain; *Central and Peripheral Nervous System:* dysphonia, paresthesia; *Gastrointestinal System Disorders:* gastrointestinal disorder not otherwise specified (NOS), gastroesophageal reflux, stomatitis (including ulcerative stomatitis); *Metabolic and Nutritional Disorders:* hypercholesterolemia, hyperglycemia; *Musculoskeletal System Disorders:* skeletal pain; *Cardiac Events:* angina pectoris (including aggravated angina pectoris); *Psychiatric Disorder:* depression; *Infections:* herpes zoster; *Respiratory System Disorder (Upper):* laryngitis; *Vision Disorder:* cataract. In addition, among the adverse reactions observed in the clinical trials with an incidence of $< 1\%$ were atrial fibrillation, supraventricular tachycardia, angioedema, and urinary retention. In the 1-year trials, the incidence of dry mouth, constipation, and urinary tract infection increased with age [see Use in Specific Populations]. Two multicenter, 6-month, controlled studies evaluated SPIRIVA HandiHaler in patients with COPD. The adverse reactions and the incidence rates were similar to those seen in the 1-year controlled trials. **4-Year Trial:** The data described below reflect exposure to SPIRIVA HandiHaler in 5992 COPD patients in a 4-year placebo-controlled trial. In this trial, 2986 patients were treated with SPIRIVA HandiHaler at the recommended dose of 18 mcg once a day. The population had an age range from 40 to 88 years, was 75% male, 90% Caucasian, and had COPD with a mean pre-bronchodilator FEV₁ percent predicted of 40%. Patients with narrow-angle glaucoma, or symptomatic prostatic hypertrophy or bladder outlet obstruction were excluded from these trials. When the adverse reactions were analyzed with a frequency of $\geq 3\%$ in the SPIRIVA HandiHaler group where the rates in the SPIRIVA HandiHaler group exceeded placebo by $\geq 1\%$, adverse reactions included (SPIRIVA HandiHaler, placebo): pharyngitis (12.5%, 10.8%), sinusitis (6.5%, 5.3%), headache (5.7%, 4.5%), constipation (5.1%, 3.7%), dry mouth (5.1%, 2.7%), depression (4.4%, 3.3%), insomnia (4.4%, 3.0%), and arthralgia (4.2%, 3.1%). **Additional Adverse Reactions:** Other adverse reactions not previously listed that were reported more frequently in COPD patients treated with SPIRIVA HandiHaler than placebo include: dehydration, skin ulcer, stomatitis, gingivitis, oropharyngeal candidiasis, dry skin, skin infection, and joint swelling. **Postmarketing Experience:** Adverse reactions have been identified during worldwide post-approval use of SPIRIVA HandiHaler. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These adverse reactions are: application site irritation (glossitis, mouth ulceration, and pharyngolaryngeal pain), dizziness, dysphagia, hoarseness, intestinal obstruction including ileus paralytic, intraocular pressure increased, oral candidiasis, palpitations, pruritus, tachycardia, throat irritation, and urticaria.

DRUG INTERACTIONS: Sympathomimetics, Methylxanthines, Steroids: SPIRIVA HandiHaler has been used concomitantly with short-acting and long-acting sympathomimetic (beta-agonists) bronchodilators, methylxanthines, and oral and inhaled steroids without increases in adverse drug reactions. **Anticholinergics:** There is potential for an additive interaction with concomitantly used anticholinergic medications. Therefore, avoid coadministration of SPIRIVA HandiHaler with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic adverse effects [see Warnings and Precautions and Adverse Reactions]. **Cimetidine, Ranitidine:** No clinically significant interaction occurred between tiotropium and cimetidine or ranitidine.

USE IN SPECIFIC POPULATIONS: Pregnancy: Teratogenic Effects, Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. SPIRIVA HandiHaler should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. No evidence of structural alterations was observed in rats and rabbits at inhalation tiotropium doses of up to approximately 660 and 6 times the recommended human daily inhalation dose (RHDID) on a mg/m² basis, respectively. However, in rats, tiotropium caused fetal resorption, litter loss, decreases in the number of live pups at birth and the mean pup weights, and a delay in pup sexual maturation at inhalation tiotropium doses of approximately 35 times the RHDID on a mg/m² basis. In rabbits, tiotropium caused an increase in post-implantation loss at an inhalation dose of approximately 360 times the RHDID on a mg/m² basis. Such effects were not observed at inhalation doses of approximately 4 and 80 times the RHDID on a mg/m² basis in rats and rabbits, respectively. These dose multiples may be over-estimated due to difficulties in measuring deposited doses in animal inhalation studies. **Labor and Delivery:** The safety and effectiveness of SPIRIVA HandiHaler has not been studied during labor and delivery. **Nursing Mothers:** Clinical data from nursing women exposed to tiotropium are not available. Based on lactating rodent studies, tiotropium is excreted into breast milk. It is not known whether tiotropium is excreted in human milk, but because many drugs are excreted in human milk and given these findings in rats, caution should be exercised if SPIRIVA HandiHaler is administered to a nursing woman. **Pediatric Use:** SPIRIVA HandiHaler is approved for use in the maintenance treatment of bronchospasm associated with COPD and for the reduction of COPD exacerbations. COPD does not normally occur in children. The safety and effectiveness of SPIRIVA HandiHaler in pediatric patients have not been established. **Geriatric Use:** Of the total number of patients who received SPIRIVA HandiHaler in the 1-year clinical trials, 426 were < 65 years, 375 were 65 to 74 years, and 105 were ≥ 75 years of age. Within each age subgroup, there were no differences between the proportion of patients with adverse events in the SPIRIVA HandiHaler and the comparator groups for most events. Dry mouth increased with age in the SPIRIVA HandiHaler group (differences from placebo were 9.0%, 17.1%, and 16.2% in the aforementioned age subgroups). A higher frequency of constipation and urinary tract infections with increasing age was observed in the SPIRIVA HandiHaler group in the placebo-controlled studies. The differences from placebo for constipation were 0%, 1.8%, and 7.8% for each of the age groups. The differences from placebo for urinary tract infections were -0.6%, 4.6%, and 4.5%. No overall differences in effectiveness were observed among these groups. Based on available data, no adjustment of SPIRIVA HandiHaler dosage in geriatric patients is warranted. **Renal Impairment:** Patients with moderate to severe renal impairment (creatinine clearance of ≤ 50 mL/min) treated with SPIRIVA HandiHaler should be monitored closely for anticholinergic side effects [see Warnings and Precautions]. **Hepatic Impairment:** The effects of hepatic impairment on the pharmacokinetics of tiotropium were not studied.

OVERDOSAGE: High doses of tiotropium may lead to anticholinergic signs and symptoms. However, there were no systemic anticholinergic adverse effects following a single inhaled dose of up to 282 mcg tiotropium in 6 healthy volunteers. In a study of 12 healthy volunteers, bilateral conjunctivitis and dry mouth were seen following repeated once-daily inhalation of 141 mcg of tiotropium. **Accidental Ingestion: Acute intoxication by inadvertent oral ingestion of SPIRIVA capsules is unlikely since it is not well-absorbed systemically.** A case of overdose has been reported from postmarketing experience. A female patient was reported to have inhaled 30 capsules over a 2.5 day period, and developed altered mental status, tremors, abdominal pain, and severe constipation. The patient was hospitalized, SPIRIVA HandiHaler was discontinued, and the constipation was treated with an enema. The patient recovered and was discharged on the same day. No mortality was observed at inhalation tiotropium doses up to 32.4 mg/kg in mice, 267.7 mg/kg in rats, and 0.6 mg/kg in dogs. These doses correspond to 7300, 120,000, and 850 times the recommended human daily inhalation dose on a mg/m² basis, respectively. These dose multiples may be over-estimated due to difficulties in measuring deposited doses in animal inhalation studies.

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VIEW ON THE NEWS

Dr. Stuart M. Garay, FCCP, comments: In an effort to better coordinate patient care, the CMS is proposing two new G-codes for non-face-to-face care to be used primarily by primary care physicians. While this is a major concession that physicians provide and should be reimbursed for this type of care, this effort falls short for both primary and specialty care. As proposed, specialists cannot be compensated for their behind-the-scenes efforts. Furthermore, the SGR formula will undermine all attempts to adequately compensate physicians.



The final rule on these codes is scheduled for November 2013. Public comment is welcomed until Sept. 6. Make your voice count!

Riociguat proves promising

Pulmonary from page 1

arterial hypertension. The magnitude of the improvement was greater than that reported for existing medications such as endothelin-receptor antagonists and prostanoids, both groups of researchers said.

In early August, the FDA's Cardiovascular and Renal Drugs Advisory Committee voted unanimously that riociguat should be approved for the two patient groups.

The pathogenesis of pulmonary hypertension involves impairment of both nitric oxide synthesis and signaling through the nitric oxide-soluble guanylate cyclase-cyclic guanosine monophosphate pathway. Riociguat directly stimulates soluble guanylate cyclase independently of nitric oxide and also increases the enzyme's sensitivity to nitric oxide. The drug also raises levels of cyclic guanosine monophosphate, which induces vasorelaxation and has additional antiproliferative and antifibrotic effects.

The CHEST-1 trial

In the CHEST-1 (Chronic Thromboembolic Pulmonary Hypertension Soluble Guanylate Cyclase-Stimulator) trial, funded by Bayer HealthCare, the drug was assessed in adults with chronic thromboembolic pulmonary hypertension who were either ineligible for the standard surgical treatment (pulmonary endarterectomy) or whose condition persisted or recurred after they underwent the surgery. It is estimated that 63% of patients with this disorder are ineligible for endarterectomy, which is the only potentially curative treatment available, and that thromboembolic pulmonary hypertension persists or recurs in 35% of patients who do have the procedure. So an alternative approach is clearly needed, said Dr. Hossein-Ardeschir Ghofrani of University Hospital Giessen and Marburg, Germany, and his associates.

The CHEST-1 study subjects, who were treated and followed at 89 medical centers in 26 countries, were randomly assigned to receive either riociguat (173 patients) or matching placebo (88 patients) for 16 weeks.

The primary endpoint was change in 6-minute walk distance. In the intention-to-treat analysis, this increased by a mean of 39 m in patients taking riociguat, compared with a decrease of 6 m in those taking placebo. The benefit was similar in a per-protocol analysis, the investigators reported (*N. Engl. J. Med.* 2013 July 25 [doi: 10.1056/NEJMoa1209657]).

Riociguat improved 6-minute walk

distance by 54 m in the patients who were ineligible for surgery and by 26 m in those who had persistent or recurrent disease after surgery. The drug's beneficial effect on exercise capacity was consistent across several subgroups of patients.

In addition, the active drug significantly reduced pulmonary vascular resistance; improved other hemodynamic factors, including mean pulmonary artery pressure and cardiac

Riociguat improved 6-minute walk distance by 54 m in the patients who were ineligible for surgery and by 26 m in those who had persistent or recurrent disease after surgery.

output; improved WHO functional class, which is known to correlate with survival; and decreased levels of N-terminal pro-brain natriuretic peptide (NT-proBNP).

In exploratory analyses, riociguat also improved scores on the Borg dyspnea index when compared with placebo, and nominally bettered scores on one measure of quality of life but not on a disease-specific QOL tool.

Drug-related serious adverse effects included three cases of syncope and one case each of gastritis, acute renal failure, and hypotension with riociguat, and one case each of syncope and trauma with placebo. Three percent of the riociguat group and 2% of the placebo group dropped out of the study owing to adverse events, and another 2% of each group dropped out because of serious adverse events that were not considered to be related to the study drug. There were two deaths in the riociguat group and three in the placebo group.

A total of 237 of these study subjects elected to enroll in an extended study of the long-term safety and efficacy of riociguat (the CHEST-2 clinical trial). An exploratory analysis of data from the first 12 weeks of that study showed further increases of 51-63 m in the 6-minute walk distance, Dr. Ghofrani and his associates said.

The PATENT-1 trial

The other phase III clinical trial reported in the *New England Journal of Medicine* was the PATENT-1 (Pulmonary Arterial Hypertension Soluble Guanylate Cyclase-Stimulator) study. This trial also was funded by Bayer HealthCare and headed

by Dr. Ghofrani.

In it, 443 patients who had symptomatic pulmonary arterial hypertension were treated and followed up at 124 medical centers in 30 countries. These subjects had idiopathic or familial disease, or pulmonary arterial hypertension associated with connective-tissue disease, congenital heart disease, portal hypertension with liver cirrhosis, anorexigen use, or amphetamine use.

A total of 44% of patients were already receiving an endothelin-receptor antagonist (usually bosentan), and 6% were taking prostanoids (usually inhaled iloprost) for the disorder, and the other half of the study population was not receiving any other treatments. Concomitant therapy with oral anticoagulants, diuretics, and supplemental oxygen was permitted during the study.

These study subjects were randomly assigned to receive high-dose riociguat capped at 2.5 mg three times daily (254 patients), low-dose riociguat capped at 1.5 mg three times daily (63 patients), or placebo (126 patients) for 12 weeks. The analysis of data from the low-dose group was considered exploratory and was reported separately.

The primary endpoint – change from baseline in 6-minute walk distance – increased by a mean of 30 m in the high-dose group but decreased by a mean of 6 m in the placebo group in the intention-to-treat analysis. The results were similar in the per-protocol analysis, the investigators reported (*N. Engl. J. Med.* 2013 July 25

[doi: 10.1056/NEJMoa1209655]).

This treatment benefit was consistent across several subgroups of patients. In addition, the active drug significantly decreased pulmonary vascular resistance, improved mean pulmonary artery pressure and cardiac output, lengthened the interval to clinical worsening, improved NT-proBNP levels, improved WHO functional class, and improved scores on the Borg dyspnea scale.

Drug-related serious adverse events occurred in 1.4% of patients receiving high-dose riociguat and 1% of those receiving placebo. A total of 3% of patients in the riociguat group and 7% of those in the placebo group discontinued the study drug because of adverse events.

Serious or drug-related adverse events in both groups included increased hepatic enzyme levels, acute renal failure, syncope, esophageal pain and swelling, supraventricular tachycardia, hypotension, generalized edema, hypoxemia, dyspnea, and worsening of pulmonary hypertension. There were two deaths in the riociguat group and three in the placebo group, none of which were considered to be related to the study drug.

A total of 396 of the subjects in the PATENT-1 study elected to enroll in an extended study of the long-term safety and efficacy of riociguat (the PATENT-2 clinical trial). An exploratory analysis of data from the first 12 weeks of that study showed a further mean increase of 53 m in 6-minute walk distance with high-dose riociguat.

VIEW ON THE NEWS

Riociguat “is poised for examination by the Food and Drug Administration as a therapy for pulmonary hypertension and, if approved, has the potential to generate substantial revenue” for the sponsor of these two clinical trials, said Dr. Stephen L. Archer.

Both CHEST-1 and PATENT-1 were sponsored by Bayer HealthCare, which also provided statistical and editorial support for both trials. “In light of the financial stakes, both real and apparent investigator autonomy remain key to ensuring the delivery of new drugs for pulmonary hypertension for patients,” he noted.

Although riociguat yielded only “modest” gains in exercise capacity, it looks promising and may prove to be the first effective oral therapy for inoperable Group 4 pulmonary hypertension, Dr. Archer added.

However, he noted limitations in both studies. The CHEST-1 trial was limited by its “failure to examine the

effects of the study drug on the right ventricle. The 6-minute walk distance is as reflective of right ventricular or skeletal-muscle function as it is of reduction in pulmonary vascular resistance, the authors’ presumed mechanism of benefit.”

PATENT-1 was limited by its modest effect size, he added. “This is particularly important, since 50% of the patients were receiving no other treatment for pulmonary arterial hypertension, and the rate of response to treatment among such patients is usually higher than the rate among patients who are receiving concomitant treatment for pulmonary arterial hypertension,” Dr. Archer said.

Dr. Archer is in the department of medicine, Queen's University, Kingston, Ont. He reported having no financial conflicts. These remarks were made in his editorial accompanying Dr. Ghofrani's reports (N. Engl. J. Med. 2013 July 25 [doi: 10.1056/NEJMe1306684]).

MEDICOLEGAL LESSONS: VTE and a debatable dose

BY FRANKLIN A. MICHOTA, M.D.
IMNG Medical News

Mr. SS was a 48-year-old man who presented to the emergency department with complaints of right calf and ankle swelling for 1 day associated with mild shortness of breath. Lower extremity ultrasound quickly confirmed an acute right femoral and popliteal deep vein thrombosis. CT angiogram of the chest was negative for pulmonary embolus (PE). Two weeks earlier, Mr. SS had suffered a traumatic right intertrochanteric hip fracture when he fell off a ladder at home. At that time, he underwent open reduction and internal fixation of the right hip without complication. He was discharged home on warfarin for venous thromboembolism (VTE) prophylaxis. At the time of his return to the hospital, his INR was 1.4 and his current level of activity was touch toe weight-bearing of the right leg.

The ED physician paged the hospitalist on call, who was already at home for the evening. Following a telephone discussion, Mr. SS was given 7.5 mg of subcutaneous fondaparinux (Arixtra) in the ED. Mr. SS was then transferred up to the regular nursing floor and admitted by a house doctor employed by the hospital. The house doctor continued the fondaparinux at a dose of 7.5 mg daily.

At approximately 10 a.m. the following day, Mr. SS was up in the bathroom. He became acutely short of breath and called out for help. Before he could return to bed, he was noted to be ashen in appearance, and he lost consciousness along with his

pulse and respirations. A code blue was called, but despite more than an hour of resuscitation, Mr. SS expired. An autopsy was performed and con-



DR. MICHOTA

firmed a large saddle pulmonary embolism as the cause of death. The hospitalist on call never saw Mr. SS before he died.

Complaint

Mr. SS was an English professor at the local university. He left behind a wife and four children. A relation in the medical field reviewed the records and discovered that Mr. SS received only 7.5 mg of fondaparinux despite the fact that Mr. SS weighed more than 100 kg (265 pounds). The Food and Drug Administration–approved dose of Arixtra for the treatment of acute venous thromboembolism is based on tertile of weight (5 mg if less than 50 kg; 7.5 mg if between 50-100 kg; and 10 mg if more than 100 kg). The complaint alleged that Mr. SS was underdosed and therefore needlessly developed a pulmonary embolism. Had Mr. SS received the FDA-approved dose of fondaparinux based on his weight, he would be alive and well today.

The complaint was filed against the ED physician, the hospitalist on call, and the house doctor.

Scientific principles

Outcome studies confirm that the vast majority of patients (more than 95%) who receive adequate anticoagulation in the setting of acute venous

thromboembolism will be alive at discharge, 30 days, and at 1 year. In fact, of all the variables possibly associated with VTE recurrence, the only one demonstrated by logistic regression to be statistically significant with respect to VTE recurrence is the failure to achieve and maintain adequate anticoagulation. Properly conducted phase II dose ranging studies with Arixtra (REMBRANDT) ultimately led to the tertile weight-based dosing regimen that was studied in the phase III trial (MATISSE) that led to Arixtra's FDA approval and the recommendations for dosing in the Arixtra package insert.

Complaint rebuttal and discussion

The defense argued that the dosing recommendations in the Arixtra package insert were guidelines and not in and of themselves the standard of care. Mr. SS did not have a normal INR on presentation and the defense argued it was reasonable clinical judgment on behalf of the providers involved to use that dose that best balanced efficacy and safety. The defense further argued that based on the timing of the PE (approximately 12 hours after the 7.5-mg fondaparinux dose), Mr. SS should have been in a therapeutic range in regard to drug concentration.

In other words, Mr. SS still would have had more drug in his body 12 hours after a 7.5-mg dose than he would at 24 hours following a 10-mg dose. As such, Mr. SS would have had a fatal PE regardless. The plaintiff attacked the clinical judgment defense as unreasonable. There simply was no reason not to use the proven and recommended dose for SS. To do anything less was unnecessary experi-

mentation on Mr. SS by the physicians involved.

Ironically, during deposition testimony, the hospitalist on call confirmed that he never discussed the Arixtra dose with the ED physician. He further testified that had he known that the ED physician was going to give only 7.5 mg, he would have increased the dose to 10 mg himself.

Conclusion

It is commonplace for hospitalists to discuss admission plans of care with our ED colleagues. Rarely, however, do we have such discussions with the same granularity as if we were writing the actual orders ourselves. It is important to remember that if we rely on our ED colleagues (or a house doctor) to fulfill our responsibilities in that regard, we can get trapped by a clinical judgment decision that doesn't really match what we would have done under the same circumstances. The hospitalist in this case never even saw Mr. SS and he didn't write the Arixtra order, yet he was deemed culpable for the outcome. Based on deposition testimony, it was readily apparent that the ED physician simply did not know the appropriate Arixtra dosing schedule for a patient weighing more than 100 kg. The jury, however, was ultimately persuaded by the defense arguments and returned a full defense verdict in this case.

Dr. Michota is director of academic affairs in the hospital medicine department at the Cleveland Clinic. He has relationships with oral anticoagulant makers Janssen, Boehringer Ingelheim, and Daiichi Sankyo.

Continued from page 6

In addition to payment changes proposed by the CMS, physicians face a 24.4% across-the-board pay cut in 2015 due to the Sustainable Growth Rate (SGR) formula. Congressional action is required to avoid the steep pay cut. Members of Congress are drafting legislation that would permanently eliminate the SGR formula but it is unclear if the bill would be voted on this year.

Dr. Jeffrey Cain, president of the American Academy of Family Physicians, said the CMS can make only so much progress on payment reform within the current system.

"In light of the SGR's mandate that CMS slash Medicare physician payment by 24.4%, these in-

cremental increases do nothing to sustain primary medical care, much less build the primary care physician workforce," he said in a statement. "The SGR-required payment cut shines a bright light on the need for Congress to replace this dysfunctional system."

'As proposed, specialists cannot be compensated for their behind-the-scenes efforts.' Also, the SGR will undermine all attempts for adequate compensation.

The fee schedule proposal offers more specifics for rolling out the physician value-based payment modifier, an Affordable Care Act program that will pay physicians based on both the quality and cost of the care they provide to Medicare beneficiaries. The program is being phased in, but will apply to all physicians by Jan. 1, 2017.

Since the program is "budget neutral," higher payments for some physicians mean pay cuts for others. Under the program, physician groups could

see a payment cut of between 1% and 2% in 2016 based on their performance on quality and cost.

The latest fee schedule proposal sets out an implementation schedule for the value modifier program.

Physician groups with 100 or more eligible professionals will be subject to the modifier starting in 2015. In 2016, the program will apply to physician groups of 10 or more. However, Medicare officials will begin measuring their performance on cost and quality in 2014 to determine the payments in 2016. The expansion of the program to groups of 10 or more will mean that nearly 60% of physicians will be affected by the modifier in 2016, according to the CMS.

The remainder of physicians will see their payments affected by the modifier in 2017, based on performance during 2015.

Embolism risk-prediction formula gains validation

BY MITCHEL L. ZOLER

IMNG Medical News

AMSTERDAM – A simple formula for calculating the risk faced by acutely ill, hospitalized patients for venous thromboembolism was validated in a case-control study with more than 400 patients.

This VTE risk-calculator formula “is the first [risk-assessment model (RAM)] to be validated on a large scale in hospitalized medical patients,” Charles E. Mahan, Pharm.D., said at the congress of the International Society on Thrombosis and Haemostasis.

“Applying this RAM could spare 20%-30% of these patients from getting unnecessary prophylaxis” with an anticoagulant, said Dr. Mahan, director of outcomes research at the New Mexico Heart Institute, Albuquerque.

He cautioned that the new evidence he presented still needs to be published, and a prospective test of the risk formula should also be done, but the new findings give this risk-scoring method a leg up over the several other risk-assessment methods that are out there.

“This gives us some information that we can comfortably use,” said Dr. Mahan in an interview. Other formulas for estimating VTE risk in pa-

VITALS

Major finding: A validation analysis confirmed a venous thromboembolism risk-assessment formula as sensitive and specific for predicting VTE.

Data source: A retrospective case-control study with 417 cases and controls from a single Canadian health system.

Disclosures: Dr. Mahan said that he has been a consultant to or speaker for several drug companies including Janssen, Sanofi-Aventis, Boehringer Ingelheim, Bristol-Myers Squibb, and Pfizer.

tients hospitalized for medical reasons include the Padua Prediction Score (J. Thromb. Haemost. 2010;8:2450-7), but the RAM tested by Dr. Mahan now “has the best evidence base for hospitalized, acutely ill patients.”

The validation used the risk formula developed by the IMPROVE (International Medical Prevention Registry in Venous Thromboembolism) study, which included over 15,000 medical patients at 52 hospitals in 12 countries (Chest 2011;140:705-14).

The IMPROVE RAM includes seven risk factors that each score from 1 to 3 points (see box). A history of VTE scores 3 points; immobilization for a week or more, ICU stay, and age over 60 each score 1 point; and three other factors each score 2 points. The validation cohort came from the more than 130,000 patients aged 18 years or older who were hospitalized for at least 3

days during 2005-2011 at a McMaster University-affiliated hospital in Hamilton, Ont. After excluding pregnant patients, patients with recent surgery, and patients with VTE at admission, the researchers identified 139 patients who developed VTE within 90 days of hospital admission and matched them with 278 patients who did not develop a VTE as controls. Matching was by gender, hospital, and date of admission.

The IMPROVE RAM showed “good” discrimination in the validation cohort, Dr. Mahan said. The incidence of VTE during the 90 days after hospitalization in the validation cohort was 0.20% in patients with low scores, 0 or 1; 1.04% in patients with moderate scores, 2 or 3; and 4.15% in those with high scores, 4 or greater. By comparison, in the first IMPROVE

cohort the VTE rates were 0.45% in patients with low scores, 1.30% in those with moderate scores, and 4.74% in those with high scores.

Analysis showed that in the new cohort, the IMPROVE formula could account for about 77% of the variability in VTE incidence, performance that was also similar to that of the derivation cohort. But the formula failed to predict a VTE in several patients: 26 patients (19%) who had a VTE during follow-up had an IMPROVE score of 0 or 1 at the time of their hospitalization.

The data showed that a score cut-point of 2 had a sensitivity of 81% and a specificity of 60%, whereas a cut-point of 3 had a sensitivity of 63% and a specificity of 78%.

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The IMPROVE risk-assessment model

Risk factor	Points
Prior venous thromboembolism	3
Diagnosed thrombophilia	2
Current lower-limb paralysis	2
Current cancer	2
Immobilized for at least 7 days	1
Stay in the ICU or coronary care unit	1
More than 60 years old	1

Note: In 2011, the authors of IMPROVE set a total score of 0 or 1 as low risk and not needing anticoagulant prophylaxis and a score of 2 or more as appropriate for prophylaxis.

Source: Chest 2011;140:705-14

IMNG Medical Media

VIEW ON THE NEWS

Dr. Steven Q. Simpson, FCCP, comments: Given the characterization of VTE as a so-called “never event” for hospitalized patients, most hospitals are placing emphasis on ensuring that higher risk patients are uniformly receiving VTE prophylaxis. To achieve that goal, some lower risk individuals will likely receive unnecessary prophylactic treatment. It is interesting to see research aimed at reducing the number of patients who receive prophylaxis. Clearly, our goal as clinicians should be to treat those patients who need it and not treat those patient who don't. Nevertheless, one wonders whether we have yet fulfilled our obligations to the former well enough to pay significant attention to the latter.



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CT benefits outweigh risks

Screening from page 1

on the efficacy of LDCT screening in patients with smoking exposure for both intervention and control groups. Three small trials showed varying degrees of benefit, but were underpowered; one large trial – the National Lung Screening Trial (NLST) – showed a significant 20% reduction in lung cancer mortality among those screened, as well as a 6.7% reduction in all-cause mortality.

The randomized multicenter NLST compared annual LDCT scans with annual sin-

gle-view posterior-anterior chest radiographs for 3 years in more than 53,000 current or former smokers aged 55-74 years with at least a 30-pack-year history of smoking (N. Engl. J. Med. 2013;368:1980-91). One cancer death was prevented for every 320 patients who completed one screening, and one death from any cause was prevented for every 219 patients screened in that study; the trial was stopped early after 6.5 years of follow-up based on the findings.

The benefits of LDCT for lung cancer screening in this population outweighed the risks, Dr. Humphrey and her colleagues noted.

Harms associated with LDCT, according to findings from 7 trials and 13 cohort studies that reported on such outcomes, included radiation exposure, overdiagnosis, and a high rate of false-positive findings that were resolved by further imaging in most cases. False negatives were reported in six studies, and the rates ranged from 0% to 20%, but none of the studies evaluated the harm of false reassurance, the investigators noted. The benefits of



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Lung cancer is the leading cause of cancer-related deaths, accounting for nearly 27%.

screening must be weighed against these potential harms.

Lung cancer is the third most common cancer among men and women in the United States, but is the leading cause of cancer-related deaths, accounting for nearly 27%.

The studies included in this review were conducted in patients at high risk for lung cancer based on current or former smoking. However, patients at an increased risk for lung cancer, including older adults and those with a family history of lung cancer, chronic obstructive pulmonary disease, pulmonary fibrosis, and certain environmental and occupational exposures, may also benefit from screening.

“Future research to identify methods for focusing

LDCT screening on persons at highest risk for disease, to improve discrimination between benign and malignant pulmonary nodules, and to find early indicators of aggressive disease is warranted,” the investigators noted.

The review was funded by grants from the Agency for Healthcare Research and Quality and the Portland Veterans Affairs Medical Center. Dr. Humphrey is employed by the Department of Veterans Affairs, and she and her coauthors disclosed ties with UpToDate, the USPSTF, AHRQ, the Department of Veterans Affairs, the American Lung Association, the Chest/LUNgevity Foundation, the National Lung Cancer Partnership, and/or the American College of Chest Physicians.

VIEW ON THE NEWS

Dr. W. Michael Alberts, FCCP, comments: The potential benefits of screening for lung cancer are easily understood. The detection of a cancer earlier in the course might permit more resections for cure. The very real risks of screening, however, are not so apparent. Maybe the cancer would never cause problems (overdiagnosis). Maybe the screening CT findings are not cancer (false positives). Maybe repeated imaging procedures are required to document stability (radiation exposure).

The heretofore unknown risk/benefit calculation has not allowed the ACCP (or most

other organizations) to recommend CT screening for lung cancer in the past. Everyone wants screening to work; we just didn't have confirmation of a mortality benefit until publication of the National Lung Screening Trial results in 2011.

It is hoped that the systematic review of the literature by the USPSTF (reported on here) and the draft recommendations (based on the review) will weather the public comment period and lead to incorporation of this procedure into the “best practice” management of the high-risk patient and to insurance coverage for this lifesaving procedure.



Afatinib approved for tumors with growth factor mutations

BY M. ALEXANDER OTTO
IMNG Medical News

The tyrosine kinase inhibitor afatinib received Food and Drug Administration approval in July for the first-line treatment of metastatic non-small cell lung cancers that express epidermal growth factor exon 19 deletions or exon 21 L858R substitution gene mutations. Its brand name is Gilotrif, and it will be marketed by Boehringer Ingelheim.

The agency also approved a kit to detect those mutations, Qiagen's therascreen EGFR RGQ PCR Kit; they occur in most of the 10% of NSCLC tumors that have epidermal growth factor receptor mutations.

Genentech's erlotinib (Tarceva), was approved for the same indication in May, along with its own mutation screening tool, Roche's cobas EGFR Mutation Test.

In the study that won approval for afatinib, 230 NSCLC patients with the mutations were randomized to afatinib 40 mg orally; 115 others were randomized to up to six cycles of pemetrexed and cisplatin. Median progression-free survival was 11.1 months in the afatinib group and 6.9 months in the chemotherapy group. There was no significant difference in overall survival. The therascreen kit was validated in that trial.

Gilotrif's side effects include diarrhea, which can lead to kidney failure and severe dehydration; liver toxicity; lung inflammation; and severe rashes. Less serious side effects include acne-like skin eruptions, dry skin, pruritus, mouth inflammation, paronychia, and decreased appetite.

In a phase II Japanese study, afatinib 50 mg/day showed “modest but noteworthy efficacy” in NSCLC patients who progressed after being on

erlotinib or gefitinib, or both, for 12 or more weeks. Of 62 treated patients, 45 (72.6%) were EGFR mutation positive in their primary tumor; 51 (82.3%) patients had developed resistance to erlotinib or gefitinib.

Median values for progression-free and overall survival were 4.4 and 19.0 months (J. Clin. Oncol. 2013 July 1 [doi: 10.1200/JCO.2012.45.0981]).

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VIEW ON THE NEWS

Dr. Lary Robinson, FCCP, comments: A new tyrosine kinase inhibitor, afatinib, was approved for first line clinical use in patients with stage IV lung cancer who have an EGFR mutation. This drug joins erlotinib and gefitinib, two other currently used tyrosine kinase inhibitors (TKIs). However, this new drug might have a very modest additional advantage with



an 8% response rate in second-line treatment in patients who have become resistant to the older TKI drugs. Most intriguing is the just-published, preliminary data suggesting that combining afatinib with cetuximab (Erbix), a monoclonal antibody that binds to the EGFR receptor, offers a much improved 30% response rate in patients with metastatic lung cancer.

Validation is key in medical marijuana prescribing

BY BRUCE JANCIN

IMNG Medical News

ORLANDO – An essential element in prescribing medical marijuana responsibly is to insist that the patient must demonstrate improved functional status to be allowed to continue, one expert has advised.

“If cannabis is going to be used as a medicine, we have to see improvement in function: return to work, improvement in daily activities, engagement in society. I tell patients, ‘If this drug is really helping you, then show me. Show me that you can come off this other medication or reduce the dose. Show me you can go out and do volunteer work or join a club. Prove to me that this is valuable to you, because I cannot continue to authorize access to a substance if you cannot show me that it’s actually helping you improve your quality of life,’” Dr. Mark A. Ware said at the fifth Cooperative Meeting sponsored by the Consortium of Multiple Sclerosis Centers and the Americas Committee for Treatment and Research in Multiple Sclerosis.

Through this requirement, a physician can validate that a patient is not merely using the prescription recreationally, sitting around the house in a fog watching “M*A*S*H” reruns on television all day, explained Dr. Ware, a family physician and anesthesiologist who is director of clinical research at the Alan Edwards Pain Management Unit at McGill University in Montreal.

Canada has had a federal program for medical marijuana in place for a dozen years. Dr. Ware has extensive experience in prescribing marijuana in the pain clinic, where many patients report improvement not only in pain, but in spasticity, sleep, and/or mood. Also, he has led randomized clinical trials that found that smoked cannabis reduced pain and improved sleep quality in patients with chronic neuropathic pain (CMAJ 2010;182:E694-701) and that oral nabilone (Cesamet), a synthetic cannabinoid, improved sleep and was well tolerated in patients with fibromyalgia (Anesth. Analg. 2010;110:604-10).

He offered these tips for physicians who have patients asking about medical marijuana:

The doses used are modest. A World Health Organization report estimated that the average joint contains 0.5 g of cannabis, and that the average dose in patients using marijuana medically is four joints per day, or roughly 2 g of cannabis. That equates to 20-50 mg/day of tetrahydrocannabinol, the

active molecule, which is consistent with the results of clinical trials using standardized extracts.

“A watchful dose is 5 g of cannabis per day. I would be very, very cautious about anybody who’s asking for more than 5 g/day. The likelihood of



‘A watchful dose is 5 g of cannabis per day. I would be very, very cautious about anybody who’s asking for more.’

DR. WARE

diversion goes way up. There’s very little reason on pharmacologic grounds why a patient would need that much,” Dr. Ware advised.

Not everyone responds to medical marijuana. As with any other medication, there are nonresponders. Because cannabis has been widely available recreationally for so long, an individual’s past recreational experience can be used as a rough predictor of the likelihood of response.

“One of the tests I use when a patient with a chronic medical illness comes in asking if maybe a cannabis-based drug could be useful is I ask if they’ve ever used the drug before, say, in college or high school. If they say they did and got anxious and paranoid and hated it, that tells me they’re not cannabinoid responders. I have no scientific evidence for this, it’s just a clinical tool I use,” Dr. Ware continued.

Most patients are more concerned about medical marijuana’s safety than effectiveness. Medical cannabinoids are “overall quite safe,” according to Dr. Ware, who with coauthors has published a systemic review of the adverse effects (CMAJ 2008;178:1669-78). Cannabis has no associated toxicity even at extremely high doses. The prescription oral cannabinoids have no apparent abuse potential. While dependence is seen in some recreational marijuana smokers, it doesn’t seem to occur with clinical use.

And regarding the key safety concern for most patients and physicians – the question of smoked marijuana’s effects on the lung – a new analysis of the published literature by Dr. Donald P. Tashkin, FCCP, emeritus professor of medicine and medical director of the pulmonary function laboratory of the University of California, Los Angeles, concluded that “the accumulated weight of evidence” suggests regular smoking of marijuana alone doesn’t increase the risk of lung or up-

per airway cancer or [chronic obstructive pulmonary disease], and the evidence is inconclusive regarding a possible associated risk of lower respiratory tract infection (Ann. Am. Thorac. Soc. 2013;10:239-47).

Medical marijuana is contraindicated in adolescents and patients with unstable ischemic heart disease or a personal or family history of psychosis. All of the clinical trials have screened for and excluded patients with a history of psychosis, either personally or in a first-degree relative. So there is no evidence supporting its safe use in such individuals.

A growing number of case reports suggest recreational cannabis use in young adolescents can trigger a latent psychotic episode in susceptible individuals. This is a major concern.

Cannabis is a powerful peripheral vasodilator. “The way to remember that is the red eyes of Bob Marley,” Dr. Ware suggested. Peripheral vasodilation results in an increased heart rate, which could trigger an MI in a patient with unstable ischemic heart disease.

Always ask about legal issues. A surprisingly large number of patients inquiring about medical marijuana are under investigation for a crime and are seeking a stay-out-of-jail card. They won’t mention it if they’re not asked.

Consider the prescription alternatives to medical pot. Nabilone and Marinol (dronabinol, which is tetrahydrocannabinol) are approved for prescription use in the United States. The beneficial effects last longer than with smoked cannabis, and there is no uncertainty about the concentration, source, or possible contaminants.

Keep an eye out for improved technology. Smoking is a dirty delivery system for marijuana. While it’s not nearly as harmful to the lungs as smoking tobacco, as Dr. Tashkin recently concluded, cannabis smoke nevertheless does contain carcinogens and toxins. Vaporization devices are now commercially available as an alternative: a smokeless marijuana delivery system. This approach has recently been shown effective in a randomized, double-blind, placebo-controlled, crossover clinical trial conducted in patients with neuropathic pain (J. Pain 2013;14:136-48).

Dr. Ware has received lecture fees from the Canadian Consortium for the Investigation of the Cannabinoids and a research grant and honoraria from Valeant for conducting a randomized trial of nabilone in fibromyalgia patients.

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Marijuana’s effects on lungs reviewed

LOS ANGELES – The pulmonary consequences of regularly smoking marijuana are far less than for tobacco, according a review of the published evidence conducted by Dr. Donald P. Tashkin, FCCP, emeritus professor of medicine and medical director of the pulmonary function laboratory at the University of California, Los Angeles. Habitual use of marijuana alone doesn’t appear to lead to significant abnormalities in lung function, nor does it increase the risks of COPD or either lung or upper airway cancer. It is associated with an increase in symptoms of chronic bronchitis; however the symptoms go away upon discontinuation of use, according to Dr. Tashkin (Ann. Am. Thorac. Soc. 2013;10:239-47).

“The accumulated weight of evidence implies far lower risks for pulmonary complications of even regular heavy use of marijuana, compared with the grave pulmonary consequences of tobacco,” he concluded.

In an accompanying editorial, Dr. Mark A. Ware called Dr. Tashkin’s article “the most comprehensive and authoritative review of the subject ever published.”

Dr. Tashkin’s conclusion that smoking marijuana is not a major risk factor for airway cancer or COPD “will affect the way health professionals interact with patients, parents with teenagers, and policy makers with their constituents,” predicted Dr. Ware, a family physician and anesthesiologist who is director of clinical research at the Alan Edwards Pain Management Unit at McGill University in Montreal.

Dr. Tashkin reported having no conflicts of interest.

Dr. Ware has reported receiving lecture fees from the Canadian Consortium for the Investigation of the Cannabinoids and a research grant and honoraria from Valeant for conducting a randomized trial of nabilone in fibromyalgia patients.

Sickle cell disease linked to sixfold rise in VTEs

BY MITCHEL L. ZOLER

IMNG Medical News

AMSTERDAM – Adult patients who become hospitalized and have sickle cell disease have about a sixfold increased risk of developing venous

on Thrombosis and Haemostasis.

Relative immobilization during hospitalization may also play a role in triggering VTE in these patients, suggesting that “robust” thromboprophylaxis be applied to patients with

sickle cell disease who enter a hospital, said Dr. Wun, professor of medicine and chief of hematology and oncology at the University of California, Davis, in Sacramento.

The analysis showed the impact of

VTE episodes. After 10 years of follow-up, cumulative mortality was just under 20% in patients with sickle cell disease who did not have a VTE, and more than 40% in patients who had a VTE, a statistically significant

VITALS

Major finding: Having sickle cell disease linked with a sixfold higher rate of venous thromboembolism during follow-up in hospitalized patients.

Data source: Data came from a case-control study with a total of 25,680 patients hospitalized or seen at an emergency department in California during 1990-2010.

Disclosures: Dr. Wun had no disclosures.

thromboembolism during the following weeks and months, compared with hospitalized patients without sickle cell disease, in a case-control study of more than 25,000 people admitted to or seen at California hospitals during 1990-2010.



At 10 years, the rate of cumulative mortality more than doubled in the patients who had VTE.

DR. WUN

Since 46% of the venous thromboembolism (VTE) episodes in patients with sickle cell disease happened within 30 days of a hospitalization or emergency department visit, the painful, inflammatory episodes that often drive patients with sickle cell disease to seek hospitalization may also provoke VTE said Dr. Ted Wun and his associates in a poster presented at a congress of the International Society

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Pulmonary Hypertension

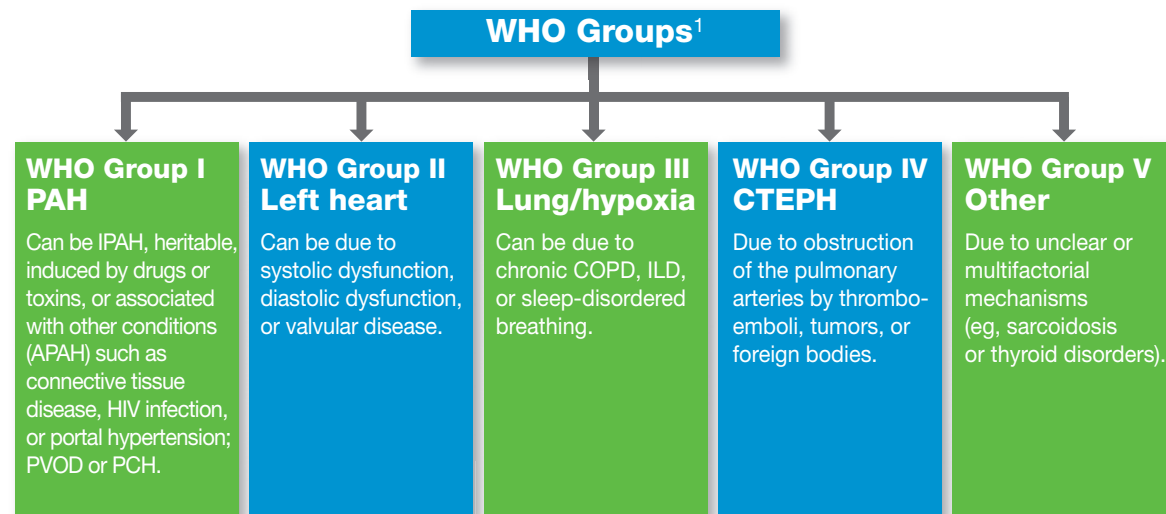
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COPD=chronic obstructive pulmonary disease; CTEPH=chronic thromboembolic pulmonary hypertension; HIV=human immunodeficiency virus; ILD=interstitial lung disease; IPAH=idiopathic pulmonary arterial hypertension; PAH=pulmonary arterial hypertension; PCH=pulmonary capillary hemangiomatosis; PH=pulmonary hypertension; PVOD=pulmonary veno-occlusive disease; WHO=World Health Organization.

References: 1. Simonneau G, Robbins IM, Beghetti M, et al. Updated clinical classification of pulmonary hypertension. *J Am Coll Cardiol*. 2009;54(1)(suppl S):S43-S54. 2. McLaughlin VV, Archer SL, Badesch DB, et al. ACCF/AHA 2009 expert consensus document on pulmonary hypertension. A report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents and the American Heart Association. Developed in collaboration with the American College of Chest Physicians; American Thoracic Society, Inc.; and the Pulmonary Hypertension Association. *J Am Coll Cardiol*. 2009;53(17):1573-1619.



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difference in an actuarial analysis.

The risk for VTE posed by sickle cell disease was even higher in the 42% of patients with severe sickle cell disease, defined as patients who had three or more hospitalizations or emergency department visits during the prior year. Patients in the severe subgroup had a 9.5-fold higher rate

of VTE, compared with controls who had no sickle cell disease.

Among the 58% of sickle cell patients without severe disease, the incidence of VTE was fourfold greater than among those without sickle cell disease.

Dr. Wun and his associates used data collected in the California Pa-

tient Discharge Dataset and in California's Emergency Department Utilization database. They identified 4,280 patients 18-65 years old with sickle cell disease who were either hospitalized or seen at an emergency department during 1990-2010. They matched each of these sickle cell patients with five patients hospitalized

or seen at emergency departments who did not have sickle cell disease. Matching included age, sex, race, ethnicity, and year of index event. The researchers could track each of the more than 25,000 total patients through subsequent hospitalizations and emergency department visits by their unique identifier codes.

The patients with sickle cell disease averaged 28 years old, 91% were black, and during follow-up they had an 8% incidence of VTE.

The analysis also showed that comorbidities increased the risk for VTE, although not as strongly as sickle cell disease. For the entire

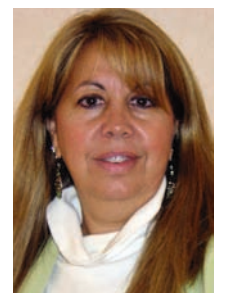
Among only patients with sickle cell disease, three or more comorbidities boosted the VTE rate by a statistically significant 67%, compared with those who had no comorbidities.

group of more than 25,000 patients having three or more comorbidities linked with a threefold higher rate of VTEs, compared with those without any comorbidities. Among only patients with sickle cell disease, having three or more comorbidities boosted the VTE rate by a statistically significant 67%, compared with sickle cell patients without any comorbidities. Female sex also significantly linked with a boosted VTE rate among patients with sickle cell disease. Women with sickle cell disease had 43% more VTE episodes than did men with sickle cell disease in the adjusted analysis.

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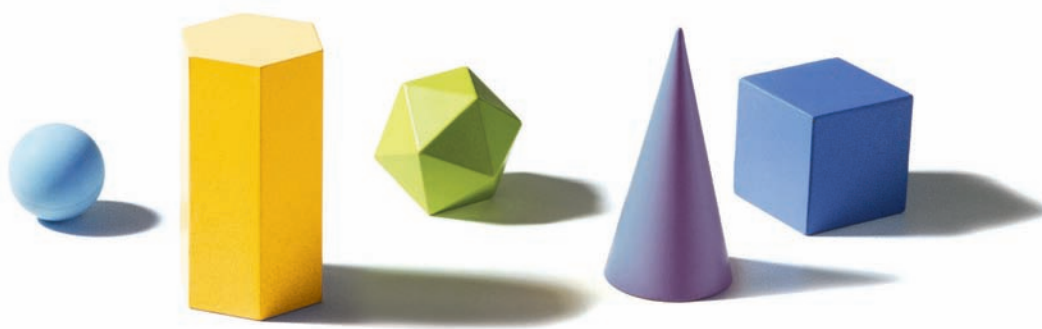
VIEW ON THE NEWS

Dr. Vera DePalo, FCCP, comments: Risk factor assessment has been a powerful tool used together with clinical presentation to determine the level of suspicion for venous thromboembolic disease (VTE). The work presented helps clinicians with additional stratification of a patient's risk. Having other medical conditions in addition to the hematologic disease further increases the likelihood of VTE.



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Single CBT session helps cure insomnia for some

BY KAREN BLUM

IMNG Medical News

BALTIMORE – A single session of cognitive-behavioral therapy for insomnia, given in a large group format, may effectively improve sleep conditions for many healthy adults, California researchers have found.

Nearly 90% of 363 insomnia patients who attended the session reported improvements in their sleep

VIEW ON THE NEWS

Dr. Paul A. Selecky, FCCP, comments:

Patients with insomnia can often benefit from a simple helping hand to achieve good quality sleep. Utilizing allied personnel for this purpose can be very successful. Note the high

no-show rate of 30%-40%, which may not be unusual in this sleep disorder population. If the patient thinks that CBT will not help him/her, then it won't. Many patients want the quick fix of a hypnotic.



patterns, of whom nearly a third said their insomnia had resolved, said Dr. Dennis Hwang, director of the Sleep Disorders Center at Kaiser Permanente Fontana (Calif.) Medical Center.

He reported results of a retrospective analysis from his center at the annual meeting of the Associated Professional Sleep Societies.

To offer cognitive-behavioral therapy (CBT) efficiently, Dr. Hwang and his colleagues created a 2.5-hour CBT session, taught by a physician assistant (PA) to groups of 20 patients at a time.

In the first 2 hours of the class, the discussion covers proper sleep hygiene, sleep beliefs, relaxation techniques, and sleep restriction, and offers patients a chance to create an individual plan of action and sleep diary.

In the next 15 minutes of the class, a PA or pharmacist goes over basic insomnia medication education, including how to wean off insomnia medications.

In the last 15-minute section of the class, a PA or physical therapist demonstrates optimal sleep positions.

"We teach patients how to sleep better by positioning pillows in certain areas and really try to get them into a neutral spine position," Dr. Hwang said. Many patients report

VITALS

Major finding: A single session of cognitive-behavioral therapy for insomnia was enough to help improve sleep conditions for the majority (90%) of 363 patients enrolling in the program. A total of 30% said their insomnia resolved.

Data source: Retrospective analysis of patients participating in the CBT program.

Disclosures: None; the study was funded by the medical center.

that doing that alone helps their insomnia, he said.

Individual telephone follow-up calls are scheduled between the PA and the participants as needed, until there is an improvement in sleep patterns or the patient declines further participation.

Dr. Hwang's group reviewed responses from patients participating between December 2010 and December 2011. There were 230 women and 133 men with an average age of 56 years. Among them, 117 had obstructive sleep apnea, 20 had restless legs syndrome, and 20 were night-shift workers; 134 took medications for insomnia and 102 took medications for depression or anxiety.

After completing the program, 321 (88%) patients said they had at least

some improvement in their insomnia, and 110 (30%) said their insomnia had resolved. Twenty-five patients said they had no improvement.

Statistically significant improvements were seen in the following sleep parameters before and after the program: sleep latency (57 vs. 26 minutes); awakenings (3 vs. 1.4); and total sleep time (5 hours vs. 6.5 hours). The patients taking sleep medications decreased their use from 6.1 to 3.9 nights/week. And there was a decrease in primary care office visits in the year following the program, compared with the year before the program, from 4.3 to 3.5, an adjusted average of 1 full visit.

Most patients completed the program within 2.5 months, needing only one follow-up telephone call, Dr. Hwang said, indicating that "the class itself is effective even without follow-up." He cautioned that he could not find a good control group to match to those in the CBT program and that the office had a 30%-40% no-show rate for sessions.

An online program and weekly/bi-weekly interactive voice response questionnaire have been added to the therapy program since the study was completed, he said, allowing providers to single out those in need of additional follow-up.

Circadian regulator resets blind patients' internal clocks

BY M. ALEXANDER OTTO

IMNG Medical News

SAN FRANCISCO – Tasimelteon, an experimental melatonin receptor agonist, reset the internal clocks of blind patients to a 24-hour cycle in a randomized trial by Vanda Pharmaceuticals, its maker.

The 84 totally blind subjects had non-24-hour sleep-wake disorder, meaning that their circadian rhythms were out of synch with the external world, causing sleep and daytime performance problems. That's not uncommon in blindness; without the regulating effects of perceived light, internal clocks revert to their intrinsic rhythm of about 24.5 hours.



Forty-two patients were randomized to 20 mg of tasimelteon 1 hour before bedtime for 6 months, and 42 others to placebo. Entrainment to a 24-hour cycle was gauged by the timing of peak urinary excretions of cortisol and 6-sulfatoxymelatonin, a melatonin metabolite.

'The medication is able to replace the time cue usually provided by light and synchronize the circadian clock.' Eight patients on tasimelteon synched up to the 24-hour clock, and 10 both entrained and had improvements in various sleep and function measures. One placebo patient entrained during the trial, and none had improvements in sleep or function.

DR. LOCKLEY

In a follow-up study, 10 entrained tasimelteon patients were randomized to continue the drug, and 10 others to switch to placebo. One tasimelteon patient, but eight placebo patients, reverted to a non-24-hour cycle. "Maintenance is required to maintain entrainment and clinical benefit," said lead investigator Steven Lockley, Ph.D., a neuroscientist in the division of sleep medicine at Brigham and Women's Hospital in Boston.

"The medication is able to replace the time cue usually provided by light and synchronize the cir-

VITALS

Major finding: Tasimelteon, an experimental melatonin receptor agonist, entrained about half of totally blind patients to a 24-hour circadian rhythm.

Data source: Randomized, blinded, placebo-controlled trial of 84 patients.

Disclosures: The lead researcher is an investigator for Vanda Pharmaceuticals, which makes the drug and funded the study. Another investigator is a consultant to the company, and the remaining six are employees.

cadian clock in totally blind people. None of the traditional medications used to treat sleep disorders or sleepiness have this ability," he said at the Endocrine Society's annual meeting.

Vanda filed with the Food and Drug Administration in May for an indication to treat non-24-hour sleep-wake disorder in totally blind patients. The drug might also prove useful for other circadian problems, Dr. Lockley said.

Side effects included nausea, headache, and sleepiness, but were uncommon and not significantly more frequent than with placebo. Subjects were aged 21-84 years, and 34 were women.

VIEW ON THE NEWS

Dr. Paul A. Selecky, FCCP, comments: The study design and outcome are fascinating. The question remains as to whether and how this might be utilized in nonblind patients.

COPD: Pneumonia risk high after thoracic surgery

BY DOUG BRUNK
IMNG Medical News

SAN DIEGO – For thoracic surgery patients, being on neoadjuvant chemotherapy, having chronic obstructive pulmonary disease, and a weight loss of greater than 10% were all associated with postoperative pneumonia, results from a single-center study showed.

At the national conference of the American College of Surgeons/National Surgical Quality Improvement Program, Dr. Elisabeth Dexter noted that after the first ACS/NSQIP data harvest at the Roswell Park Cancer Institute in Buffalo, N.Y., the risk of postoperative pneumonia was 4.4%, compared with a rate of 1.1% in all other NSQIP hospitals.

“The thoracic surgery service had a high incidence of 13.2%,” said Dr. Dexter, an attending surgeon in the department of thoracic surgery at the cancer institute. “The high incidence of our postoperative pneumonia was likely [affected] by our thoracic surgery service because our thoracic surgery service had an increased percentage of the abstracted NSQIP data in our cohort, from 12%

to 14%, compared with other NSQIP hospitals of similar academic size abstracting 2%. When we found this high postoperative pneumonia rate, we decided to query our NSQIP data and our tumor registry between July 1, 2011, and Oct. 8, 2012, to ask the question: Is there an increased inci-



‘Our thoracic surgery service had an increased percentage of the abstracted NSQIP data in our cohort.’

DR. DEXTER

dence of postoperative pneumonia in thoracic surgery patients who received neoadjuvant chemotherapy compared with those who did not?”

She and her associates cross-referenced ACS/NSQIP data on 1,723 patients at the cancer center with the tumor registry. Of the 1,723 patients, 1,645 had no postoperative pneumonia; 78 did. Compared with the non-pneumonia patients, those who had pneumonia were more likely to be older (a mean of 67 vs. 60 years, re-

spectively; odds ratio, 1.05; P less than .001); be male (59% vs. 37%; OR, 2.48; P less than .001); have chronic obstructive pulmonary disease (35% vs. 9%; OR, 5.08; P less than .001); be smokers (36% vs. 24%; OR, 1.75; $P = .021$); have lost more than 10% of body weight (10% vs. 2.5%; OR, 4.47; P less than .001).

On univariate analysis, postoperative pneumonia was associated with being on neoadjuvant chemotherapy (4.2% vs. 14%; OR, 3.75; P less than .001).

Certain surgical subspecialties at the institute had a high incidence of postoperative pneumonia: thoracic surgery (46%), GI surgery (21%), and gynecology (12%).

When the researchers included the entire cohort, those on neoadjuvant therapy had an increased incidence of postoperative pneumonia, compared with those not on neoadjuvant chemotherapy ($P = .001$). When thoracic surgery patients were excluded, non-thoracic surgery patients on neoadjuvant chemotherapy had no increased incidence of postop pneumonia, compared with patients not on neoadjuvant chemotherapy ($P = .681$). On multivariate analysis, significant variables associated with postop pneu-

VITALS

Major finding: On multivariate analysis, significant variables associated with postoperative pneumonia were being on neoadjuvant chemotherapy ($P = .001$), having COPD (P less than .0001), and having weight loss of greater than 10% ($P = .004$).

Data source: A study of 1,723 patients who underwent surgery at Roswell Park Cancer Institute in Buffalo, N.Y. Of the postoperative pneumonia cases that developed, 46% were from the thoracic surgery service.

Disclosures: Dr. Dexter said that she had no relevant financial disclosures to make.

monia were being on neoadjuvant chemotherapy ($P = .001$), having chronic obstructive pulmonary disease (P less than .0001), and having weight loss of greater than 10% ($P = .004$).

“Institutions with disproportionately busy complex thoracic surgery programs may have rates of postoperative pneumonia skewed higher than predicted by NSQIP models,” Dr. Dexter concluded.

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Fluid, sodium restriction during heart failure questioned

BY DR. JUN CHIONG, FCCP; AND KYLE TRINIDAD

Acute decompensated heart failure (ADHF) is traditionally managed by restricting fluid and sodium intake. However, the benefit of this intervention is unclear and has not been tested scientifically but has served as a necessary procedure for patients hospitalized.

Aliti and colleagues (*JAMA* 2013;173:1058) tested this hypothesis. The investigators randomly assigned the subjects into a control group [CG] ($n = 37$) that maintained a typical hospital diet with liberal fluid and sodium intake and an intervention group [IG] ($n = 38$) that restricted fluid intake to 800 mL per day and sodium intake to 800 mg per day. Seventy-five patients were observed during hospitalization; all of them had systolic dysfunction with a mean ejection fraction of 27% and were similar in their baseline characteristics.

Throughout their stay, the clinical congestion score (CCS), body

weight, B-type natriuretic peptide (BNP), and perceived thirst of each patient were measured and recorded; IV drugs, including diuretics, vasodilators, and inotropes, were also recorded. After hospitalization, patients were followed up within 30 days. There were no significant differences in weight loss in the CG (means of 82.4 kg \pm 12.8 kg) and IG (means of 78 kg \pm 12.6 kg) and clinical stability (CCS). In addition, as a secondary end point, perceived thirst was more detrimental in the IG (5.1) compared with the CG (3.44), based

on scores determined by a visual analog scale; more patients also had BNP levels over 700 pg/mL in the IG. Furthermore, during follow-up, patients demonstrated a higher mean CCS (7.9) in the IG than in the CG (6.0). No significant changes in IV drugs were observed between the two groups. As a result, the authors concluded that fluid and sodium intake restrictions are not necessary.

This study explains that the reverse of the traditional view on

sodium intake is actually true: an increase in sodium intake benefits a patient with HF. With the increase of sodium in the intravascular lumen, osmosis diffuses extravascular fluid into the lumen, increasing the fluid volume and allowing for adequate diuresis. All in all, restriction of fluid and sodium intake reveals a weak correlation with body weight loss and clinical stability.



DR. CHIONG

Dr. Chiong is CEO, Hospital to Home Medical Specialists, Inc.; and Associate Clinical Professor of Medicine, Pharmacy and Outcomes, Loma Linda University, Loma Linda, CA. Mr. Trinidad is a research assistant at Hospital to Home Medical Specialists, Inc. The authors reported having no conflicts related to the material presented in this article.

The CHEST Foundation award project is empowering

Designed to educate people about palliative care and what it offers, the website Palliative Care Services of Nebraska, www.palliativecarenebraska.com, states: "Palliative care is specialized medical care for people with serious life-limiting illnesses. Its focus lies in providing patients with relief from the symptoms, pain, and stress of illness, whatever the diagnosis. The goal is to improve quality of life for both the patient and the family."

That definition is one piece of a wealth of information available on the website, which was founded by Dr. Lisa Mansur, FCCP, recipient of The CHEST Foundation's Roger C. Bone Advances in End-of-Life Care Award. In this instance, the term "end-of-life" care is slightly misleading because, as the website points out, "Palliative care is appropriate at any age and any stage in a serious illness and can be provided along with curative treatments." In this way it is different from its close cousin, hospice care, which is solely dedicated to comfort care when curative treatments are no longer appropriate or desired.

"The goal of the Palliative Care Services of Nebraska website is to empower people to learn and understand both the scientific and humanistic aspects of palliative care and to help them make informed decisions," she said. The site provides links to a wide array of articles, podcasts, and videos; a glossary of terms; and other resources for patients, families, caregivers, and medical professionals.

"Communication is a key tenet of palliative care," says Dr. Mansur. "Better communication equals better medicine." Emphasis on communication between patients, families, and doctors helps ensure that all needs – medical, emotional, spiritual, and practical – are met. In fact, Dr. Mansur calls what she and her colleagues practice "narrative medicine," with an empha-

sis on talking and listening rather than diagnosing and prescribing. That is not to say that patients do not receive treatment for their illness. If so desired, palliative care can work in concert with treatments meant to cure. But the focus is on the alleviation of symptoms, such as pain, fatigue, shortness of breath, loss of appetite, and anxiety or depression. Treatment might include medications along with things like massage and relaxation training. Palliative care focuses on the entire person, not just the illness. And it puts more choices in the patient's hands.

A critical care specialist, Dr. Mansur recognized the need for palliative care in the critical care unit early in her career. She developed Palliative Care Services of Nebraska in 2010 in concert with Bryan Medical Center, where she is Director of Palliative Care, first as a hospital service with only one or two consultations a week. Since then, the program has grown to accommodate up to 65 patients a week and includes an outpatient clinic, a staff of four advanced-practice nurses, and in-home visits for people who are too ill to come to the clinic. With her award from The CHEST Foundation, Dr. Mansur was able to greatly expand the website, which was launched in 2012.

The Roger C. Bone award supports leadership in end-of-life care that stresses the importance of communication, compassion, and effective listening. The award honors the late Roger C. Bone, MD, Master FCCP, who wrote about ethical and humanistic issues surrounding end-of-life decisions and stressed the importance of communication between physicians and patients. For more information about The CHEST Foundation grants and awards program, contact Lee Ann Fulton at lfulton@chestnet.org.

New Guidelines Now Available

Diagnosis and Management of Lung Cancer, 3rd Edition

New and updated lung cancer guidelines are now available, published in May 2013 as a supplement to *CHEST*. The 3rd edition includes innovative procedural and methodological advancements that have changed previous recommendations, including:

- The most recent staging system and methods for staging.
- Recommendations for tobacco dependence treatment in lung cancer patients.
- A more critical approach to guideline development, employing the latest standards of evidence-based medicine.
- Focus on advancements in symptom management and palliative and end-of-life care.
- Focus on outcomes deemed patient-important.

The **print version** of the guidelines includes the executive summary, introduction, and methodology for the development.

The **online version** features the complete guidelines, including articles on individual topics, evidence profile tables, and more.

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NETWORKS: NW featured lectures, women in medicine, and more

Practice Operations

The ACCP Practice Operations Network members are looking forward to the upcoming CHEST 2013 in the Windy City! We encourage any physicians or practice administrators interested in delivering quality, customer-focused care that maximizes reimbursement and optimizes efficiency to learn more about how to get involved with our NetWork at the NetWork Featured Lectures session on Tuesday, October 29, from 11:30 AM to 12:30 PM. There you can meet with steering committee members and attend the NetWork Featured Lecture “To Sell or Not To Sell ... Is That the Question? The Quest for Meaningful Clinical Integration in the Accountable Care Era and How to Gauge Its Impact in Your Market Place: A Pro/Con Debate.” We anticipate a lively exchange on how to assess and prepare for the converging market forces that are impacting physician’s practices and health-care networks. Hear about the lessons learned thus far from fundamental alterations in existing health-care markets and advice on the changes ahead.

Further your understanding of how to stay competitive in the digital age and leverage technology to your benefit with “Getting Your Practice Online With Social Media” on Tuesday, October 29, from 2:45 PM to 4:15 PM. Also, don’t forget to join us for the latest guidance on the changing landscape of sleep medicine on Wednesday, October 30, from 11:30 AM to 12:30 PM for the session: “Home Sleep Testing: Should I Institute It in My Practice?”

We hope to see you there!

Dr. Chad Case, FCCP
Steering Committee Member

Disaster Response

The ethics of disaster engagement

The decisions that limit access to fundamental and even life-or-death treatments are fraught with controversy. These decisions are difficult for the medical provider to make and are even more difficult for the patient to understand. Medical providers are poorly trained to address the numerous factors involved in triage decisions under the pressure of limited time (Repine et al. *Mil Med.* 2005;170[6]:505).

Correct decision-making may have far-reaching consequences. Triage is an area in which decision-makers must know what they are doing, why they are doing it, and which actions to take to achieve a satisfactory out-

come. Triage has its origins in military history and is used in a variety of medical settings. In an article in *Annals of Emergency Medicine* (Kennedy et al. *Ann Emerg Med.* 1996;28[2]:136), the focus is on the role of triage in disaster situations, its application in military settings, and its use in disaster medicine. Correct decision-making by the team leader will be different than that of his or her decision-making in the ED or ICU. The dynamic nature of triage and the role of ethics will be different, depending on the nature of the complex humanitarian emergency. The ethical consideration goes well beyond the nature of the injury. Leadership in disaster management may come from some very unexpected individuals who have the capacity and training to understand the global picture that continues to change.

Come to the NetWork meeting on Monday, October 28, from 11:30 AM to 12:30 PM at CHEST 2013, and engage in the discussion and hear the speaker Dr. Thomas Novotny discuss “Global Health in the Coming Age: Ethics in Disaster Response.”

Alan Roth, MS, MBA
Steering Committee Member

Transplant

The lung allocation score (LAS) was implemented in May 2005 by the Organ Procurement and Transplant Network as the primary method for allocation of lungs from deceased donors for transplantation in individuals aged >12 years in the United States. Compared with the older method, the LAS was intended to provide a more objective basis for lung allocation than the previous criteria, which were based largely on accrual of time on the waiting list. The LAS is a numeric value derived from a candidate’s clinical information (such as lab values, test results, and disease diagnosis) and is used by the United Network for Organ Sharing (UNOS) to assign relative priority for distributing donated lungs for transplantation in the United States. The LAS determines a candidate’s position on the waiting list and, therefore, the order in which lung offers are made to candidates. This numeric score reflects the net transplant benefit and is derived from estimates of medical urgency prior to transplant and the probability of survival following transplant. When an organ match is run, the LAS is used, along with ABO blood group and distance from the donor’s location, to deter-



mine the order for offering lungs to candidates. Studies evaluating the LAS suggest that waiting time for transplant and wait list mortality have both decreased, and the total number of organs transplanted has increased. Also, posttransplant survival has not significantly changed following implementation of the LAS. While candidates aged 0 to 11 years still receive pediatric organs based largely on priority and waiting time, transplant programs may now also request adolescent classification and an LAS, thereby expanding the donor pool for these individuals. Until donor availability can match the number of candidates awaiting transplant, the LAS offers more equitable access to organs while still attempting to maximize net transplant benefit. Additional information on the LAS and transplantation may be found at www.unos.org.

Dr. Keith Wille, FCCP
Steering Committee Member

Women’s Health

After 1849, when Elizabeth Blackwell became the first woman to receive a medical degree in the United States, there was a steady increase in the number of women physicians. By the end of the 19th century, the number of women physicians increased to approximately 7,000. Until the 1970s, there was a slow increase in the numbers of women in medicine, but women still remained underrepresented in the profession. Women made up 8% of the physician workforce in the 1970s and 17% in the 1990s.

An important strategy to address this disparity in the physician workforce is to increase the training of women in medicine. Recently, the American Association of Medical Colleges’ publication, *Diversity in*

Medical Education Facts and Figures,¹ included the latest data regarding the trends of women in medical schools in the United States. According to the report, the number of women graduates from US medical schools showed a tremendous increase in the past 50 years. In the early 1970s, only 11% to 15% of medical school applicants were women. By the early 1980s, this number increased to around 30%. Over the next 2 decades, there was a steady increase in the number of medical school applicants and matriculates, reaching 49% in 2002. In the past decade since then, the number of white and Asian women graduates in 2011 rose 17.3% and 42.1%, respectively, as compared with 2002. There was a 54%, 14.3%, and 4.4% increase respectively in Hispanic or Latino, American Indian or Alaska Native, and black or African American women graduates.

With overall gender parity in medical school graduates reached, this report also highlights the current problem facing women in medicine. It showed that among US medical schools in 2011, male faculty members were the majority across every racial and ethnic group for the professor and associate professor ranks (57.5% or greater). Women comprised less than 31% of full professors across all racial and ethnic groups. Other studies have also shown that in academic medical institutions, women reported less satisfaction with career advancement; perceived less gender equity; and fared worse in salary, promotions, and receipt of peer-reviewed grants.^{2,3}

These data underscore the continuing need for mentoring programs for women faculty members in academic medical institutions and for these institutions to examine their organizational culture to bring parity to women in medicine in all ways.

Dr. Suryakanta Velamuri, FCCP
Steering Committee Member

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1. Diversity in Medical Education: Facts & Figures 2012. American Association of Medical Colleges.
2. Carr PL, Ash AS, Friedman RH, et al. Faculty perceptions of gender discrimination and sexual harassment in academic medicine. *Ann Intern Med.* 2000;132(11):889-896.
3. Pololi LH, Civian JT, Brennan RT, et al. Experiencing the culture of academic medicine: gender matters, a national study. *J Gen Intern Med.* 2013;28(2):201-207.

This Month in *CHEST*: Editor's Picks

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

Quality Assessment of Asthma Clinical Practice Guidelines: A Systematic Appraisal. By Dr. A. Acuña-Izcaray et al.

Asymmetric Dimethylarginine in Exhaled Breath Condensate and Serum of Children With Asthma. By Dr. S. Carraro et al.

Safety and Feasibility of Interventional Pulmonologists Performing Bedside Percutaneous Endoscopic Gastrostomy Tube Placement. By Dr. L. Yarmus, FCCP, et al.

TOPICS IN PRACTICE MANAGEMENT

Endobronchial Valve Placement and Balloon Occlusion for Persistent Air Leak: Procedure Overview and New Current Procedural Terminology Codes for 2013. By Dr. K. L. Kovitz, FCCP; and Ms. K. D. French.

ULTRASOUND CORNER

ONLINE ONLY. Worsening Dyspnea and Cough Following Thoracentesis. By Dr. G. Volpicelli et al.



Coding information you should know

BY DR. STEVE G. PETERS, FCCP
ACCP CPT Advisor

The Centers for Medicare & Medicaid Services (CMS) is planning to add edits to the National Correct Coding Initiative (NCCI). These edits typically define which procedures may or may not be performed or coded together. The new edits clarify that pulmonary function testing codes (94010-94799) include laboratory procedure(s) and interpretation of test results. If a separate evaluation and management service is performed, the appropriate E&M service code may be reported in addition to 94010-94799.

Specifically, if a provider performs a significant and separately identifiable E&M service on the same date as the pulmonary diagnostic testing or therapy, the provider may append modifier 25 to the E&M code which will bypass the NCCI edit.



DR. PETERS

IN MEMORIAM: Stephen P. Mikles

The Commission on Accreditation for Respiratory Care (CoARC) President, Stephen P. Mikles, EdS, RRT, FAARC, died on July 4, 2013.

Mr. Mikles was a respiratory care educator – a volunteer in respiratory care accreditation services during almost 20 years of service to CoARC and its predecessor organization. He was a member of the AARC continuously since 1973. He was a tireless promoter of excellence in education and the credentialing process. Steve Mikles' extensive history with CoARC and his countless volunteer hours working with other state and national organizations over the past 2 decades have served as an invaluable resource to many students and colleagues, to CoARC, and to the profession.

In 2008, the AARC bestowed one of its highest honors on Mr. Mikles by recognizing him as a Fellow of the American Association for Respiratory Care for his outstanding character, dedication, and service. He considered his work in the classroom as his greatest contribution to the profession. Services for Mr. Mikles were held in Clearwater, FL.

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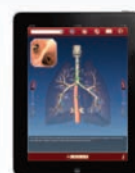


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ACCP Clinical Trials Registry announcement

The ACCP Clinical Trials Registry is a free service that helps connect physicians and their patients with ongoing clinical trials in respiratory disease being conducted by participating pharmaceutical companies.

Participation in clinical trials provides an opportunity to advance and accelerate medical research and contribute to improved and effective care for patients.

ACCP announces the Xolair Pregnancy Registry
The Xolair Pregnancy Registry: An Observational



Study of the Use and Safety of Xolair® (omalizumab) During Pregnancy (EXPECT) is a new clinical trial that is part of the ACCP Clinical Trials Registry.

The Xolair Pregnancy Registry (EXPECT) is an observational study established by Genentech to obtain data on pregnancy outcomes in women who are exposed to Xolair® (omalizumab) during their pregnancy. Women who have been exposed to at least one dose of Xolair within 8 weeks prior to conception or during pregnancy may be included in this registry.

Learn more about the ACCP Clinical Trials Registry and how to participate in the Xolair Pregnancy Registry at www.chestnet.org/About-ACCP/Industry-Support/ACCP-Clinical-Trials-Registry.

CHEST 2013: Inspire Chicago – arts, culture, and more

You could spend a lifetime exploring Chicago's unique arts, culture, and entertainment. But, since you'll likely be in town for just a short time, here are some great places to start.

Museums, galleries, and exhibitions

From the bottom of the sea up to the stars, Chicago has it all on display. Start at the famous Museum Campus along Lake Michigan, where you'll find three world-renowned museums: The Adler Planetarium & Astronomy Museum, The Field Museum, and The Shedd Aquarium. For art lovers, the Art Institute of Chicago offers masterpieces from ancient to ultramodern, and cultural institutions cover everything from famous historical events to current issues. And, don't miss the International Museum of Surgical Science.



The Art Institute of Chicago offers many masterpieces.

Theater and performing arts

Soak up story lines, take in dazzling sights and sounds, journey through fairy tale wonderlands, and laugh or cry until it hurts. On any given night, Chicago's 200+ theaters

present everything from Broadway world premieres to edgy original plays. Beyond theater are renowned dance companies, opera that will make you want to take up singing lessons, and the Chicago Symphony Orchestra, a musical force of over 100 talented musicians.

Music and comedy

Chicago is famous for legendary blues and jazz, heard nightly in venues throughout the city. Chicago's music scene can also offer up indie, hip-hop, electronic, or just plain rock n' roll. Whatever is on your iPod® is also in Chicago. If you like to laugh, you'll be in the right place. Chicago's comedy scene launched the careers of John Belushi, Steve Carrell, Stephen Colbert, Tina Fey, and many others.

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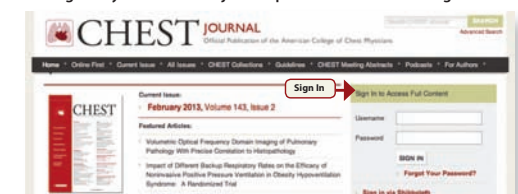
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PULMONARY PERSPECTIVES: Nonsurgical options for treating lung cancer

BY DR. IGOR BRICHKOV

Division of Thoracic Surgery
Maimonides Medical Center
Brooklyn, NY

Lung cancer is currently the most common cause of adult cancer related to mortality in the United States. Surgical resection remains the gold standard for resectable disease and offers the best chance for a cure. Unfortunately, age, poor lung function, and significant comorbidity preclude many patients with otherwise resectable lung cancer from surgical therapy. A conventional option for medically inoperable patients with lung cancer includes external beam radiation therapy. Long-term survival with this treatment modality is poor, with reported 5-year survival rates from 10% to 30% and 13% for stage I non-small cell lung cancer (NSCLC) (Sibley et al. *Int J Radiat Oncol Biol Phys.* 1998;40[1]:149).

The need to improve the treatment of this high-risk group of patients with lung cancer has prompted the development of newer treatment modalities as alternatives to conventional therapy. Radiofrequency ablation (RFA) and stereotactic radiosurgery (SRS) are two such alternative modalities that have emerged in the arena of lung cancer treatment in recent years. RFA has historically been used as an adjunct for treatment of tumors of solid abdominal viscera, and its use for pulmonary malignancy was first reported in 2000. Since that time, multiple case series have been published establishing the safety and efficacy of this treatment modality for pulmonary malignancies in high-risk patients.

SRS was a term originally coined by Leksell to describe a radiation delivery system in which multiple convergent beams of radiation could be delivered to a tumor, utilizing a three-dimensional imaging localization technique. This modality was originally applied to intracranial malignancies, and in 1994, was adapted to treat extracranial lesions as well (Song et al. *Oncology.* 2004;18[11]:1419). Several reports of its use for pulmonary malignancies began to emerge in the early 2000s; and since that time, refinement of imaging, tracking, and radiation delivery systems has given rise to several different commercially available SRS systems. One such system, the CyberKnife® System (Accuray, Sunnyvale, CA), has shown success in the treatment of pulmonary malignancy.

Radiofrequency ablation

RFA utilizes heat-induced cellular necrosis and is administered by means of an alternating current applied via an electrode. The current is supplied by a radiofrequency generator and is transferred through the patient and completed via two grounding pads. The alternating current, when applied to tissue, results in agitation of water molecules and frictional release of thermal energy within the immediate area of the electrode. At 46°C cell death occurs within 60 minutes, at 50°C to 52°C irreversible cell death occurs at 4 to 6 minutes, and at 60°C there is instantaneous irreversible cell death.

The goal of RFA is to ablate the tumor with a 0.5- to 1.0-cm margin of surrounding lung tissue. The RFA electrode, with or without tines deployed, ablates a spherical target area of tissue. The target temperature during a conventional pulmonary RFA treatment protocol is 105°C. For an electrode with multiple tines, the temperature is typically averaged across all tines, which each provide accurate real-time temperature readings at their respective locations within the tissue.

Indications for pulmonary RFA include otherwise resectable pulmonary nodules in patients who either refuse surgery or are at high risk for surgical resection. This includes patients with poor pulmonary reserve and/or medically inoperable patients, such as those who have severe coronary/valvular disease, uncompensated congestive heart failure, or other severe comorbidities, who are candidates for RFA. Patients who have failed prior modalities, including surgical resection with or without chemoradiation, would also qualify.

The only absolute contraindication to RFA is a central location of a nodule, defined as being within 3 cm of the hilum. Central nodules are close to large blood vessels, which function as heat sinks, limiting the therapeutic effect of RFA. Also, the presence of larger airways with corresponding pulmonary vessels near the hilum increases the risk of potentially deadly bronchovascular fistula formation from ablation. Relative contraindications include large nodules (>3 cm) that would require multiple ablations within the same nodule as well as multiple nodules. The latter may be cumbersome to treat and may not be technically feasible, although multiple staged treatments for bilateral pulmonary nodules are possible.

The procedure of RFA for pulmonary lesions with regard to electrode placement and treatment

algorithm varies according to the protocols supplied by the individual RFA system manufacturers. Either general endotracheal anesthesia or local with IV sedation may be used. The latter generally decreases the risk of pneumothorax with the trade-off that the patient is more likely to move spontaneously during the procedure. Typically, the electrode is placed under image guidance into the center of the nodule after a small skin incision is made to accommodate the 14-gauge needle. Imaging

The 2- and 4-year survival rates after RFA were 78% and 47%, respectively. Median overall survival was 30 months. Tumors larger than 3 cm were more likely to recur locally.

should be repeated between every repositioning to confirm placement. In the event of a periprocedural pneumothorax, a pleural drainage catheter should be placed immediately to evacuate it, as this may cause the lung and nodule to fall away from the chest wall and impede adequate placement of the electrode. A completion CT scan is performed after treatment to visualize the adequacy of the ablation as well as to visualize delayed pneumothorax formation. Occasionally, fiber-optic bronchoscopy may be required to clear endobronchial secretions, which can be blood-tinged after treatment.

Postoperatively, the patient is typically admitted for observation overnight. Chest radiographs are obtained at 6 h postoperatively and the following morning to assess for delayed pneumothorax. If a chest pigtail was required during or after the procedure, a clamp trial is usually performed the following day prior to removal. Rarely, a patient will require a chest drain for a longer period of time, resulting in a prolonged hospital stay. A follow-up chest CT scan may be done the next morning to more accurately assess the post ablation lung but is not required. Patients are typically followed with CT/PET scans at 3- to 4-month intervals.

The most common complication of pulmonary RFA is pneumothorax, occurring in 59% of patients in a recent series. This is largely attributed to the size of the electrode used and is less frequent when positive pressure ventilation is avoided. Prolonged air leak (>5 days) occurred in 7% of patients.

Other complications included hemoptysis requiring bronchoscopy, myocardial infarction, deep vein thrombosis, and respiratory failure, which occurred in 1% of patients. In addition, 3% of patients required subsequent drainage of pleural effusions. No intraoperative or in-hospital mortality was observed (Pennathur et al. *Ann Thorac Surg.* 2009[5];88:1601).

Local recurrence for stage I NSCLC after RFA was confirmed radiographically by CT scan, PET scan, or both after 31.5% of treatments (12/38). Two patients were successfully retreated for technical failures related to pneumothorax; three underwent radiotherapy with stable disease. Three patients died of metastatic disease; five died of pneumonia remote from treatment. The 2- and 4-year survivals were 78% and 47%, respectively. Median overall survival was 30 months. Tumors larger than 3 cm were more likely to recur locally (Pennathur et al. *Ann Thorac Surg.* 2009[5];88:1601).

CyberKnife® System

The rationale for SRS is based on the notion that higher doses of radiation improve local control and disease-related survival at the expense of increased toxicity in normal tissues (Sibley et al. *Int J Radiat Oncol Biol Phys.* 1998;40[1]:149). Initially described for the treatment of intracranial lesions, SRS utilized a rigid frame to immobilize a patient, stereotactically localize a lesion, and deliver a higher dose to a specific point with minimal dosing of surrounding normal tissue, using multiple convergent beams of radiation (Song et al. *Oncology.* 2004;18[11]:1419). As technology evolved, this technique was adapted for extracranial lesions. However, due to the presence of multiple critical structures in the thorax, as well as the intrinsic movement of the lung, there was little interest in SRS for pulmonary lesions. Recent advances in SRS led to the development of CyberKnife, which overcame the limitations of conventional SRS in the thorax.

CyberKnife utilizes a frameless system in which the patient needs to not be immobilized. Instead, the CyberKnife System depends on tracking a tumor in real time and adjusting radiation beams accordingly, thus overcoming the limitations of respiratory movement and minimizing toxic exposure to nearby critical structures. It utilizes a 6-MV linear accelerator mounted on a robotic arm. Beams can be emitted in 12 directions from 110 arm positions. The CyberKnife System relies on internally placed radio-opaque

Continued on following page

Continued from previous page

fiducial markers that are implanted and allow tumor tracking based on internal rather than external reference points, thus eliminating the need for rigid immobilization (Pennathur et al. *Ann Thorac Surg.* 2007;83[5]:1820).

Indications for CyberKnife treatment are similar to those of RFA. Unlike those with RFA, patients with central nodules are also candidates for CyberKnife as there are no heat-sinking limitations. There are no absolute contraindications to CyberKnife. Relative contraindications are similar to those of RFA. Multiple bulky nodules may be difficult to treat without surrounding radiation toxicity and may lead to treatment failure. Central lesions limit the total allowable dose.

The procedure for CyberKnife treatment begins with placement of one to four fiducials in and around the tumor. These are gold tumor markers that are 1 to 2 mm in size and allow for real-time tracking of the tumor. They are placed under image guidance, typically in an outpatient setting. Usually, a total of three fiducials (within, superior, and inferior to the tumor) will suffice. It is critical that the fiducials be placed within the lung parenchyma, as placement within the pleural space

or in the fissures will allow migration, compromising tumor tracking.

A week after placement of fiducials, the patient is brought back for a contrast-enhanced CT scan of the chest and upper abdomen with 1.25-mm sections. The treatment plan is then jointly formulated by a thoracic surgeon and radiation oncologist. The tumor volume as well as a 0.5- to 1.0-cm margin of surrounding tissue is outlined using dosimetry software. The treatment area need not be spherical and, in fact, may be molded to encompass irregularly shaped nodules to avoid neighboring critical structures. Precise doses at each point within and away from the planned treatment area may be calculated, thus avoiding reaching toxic thresholds in nearby critical structures.

During the treatment phase, the patient is typically positioned according to the previously formulated treatment plan. Fiducials are tracked in real time using two ceiling-mounted radiographic fluoroscopes, and these oblique dual images are combined with the CT scan data, using tracking software to direct or readjust the beams of radiation at frequent intervals. For peripheral lesions, 60 Gy is delivered in three fractions; and for central lesions, 48 Gy is delivered in four fractions to minimize toxicity to surrounding

critical structures (Pennathur et al. *Ann Thorac Surg.* 2009;88[5]:1594).

Patients are followed at 3- to 4-month intervals with PET/CT scans. Nodules are assessed for response/progression based on size, mass quality (cavitation, replacement with scar, etc.), and PET avidity. In addition, treatment-related toxicity is assessed with each follow-up visit with pulmonary function testing and quality-of-life assessment.

Early complications of treatment are mainly related to placement of fiducials. In a recent series, 26% of patients developed a pneumothorax requiring tube thoracostomy. Late complications are mainly due to treatment-related toxicity. This is particularly true for central tumors (Pennathur et al. *Ann Thorac Surg.* 2009;88[5]:1594). In a phase II trial of 70 patients treated with 60 to 66 Gy in three fractions, only 54% of patients with central tumors were free from severe toxicity compared with 83% of patients with peripheral tumors at 2 years. In summary, 8.6% of patients died of treatment-related toxicity (Timmerman et al. *J Clin Oncol.* 2006[30];24:4833).

Therefore, lower doses are required for central tumors, particularly those near larger central airways.

Using this modality, the overall 2-year survival for primary lung cancer

(all stages) was 44%. The median overall survival was 22 months. In conclusion, 62% of patients had progression, which was observed at a median time of 9 months. Patients treated with 60-Gy doses (ie, those with peripheral lesions) showed significantly improved survival and time to disease progression compared with those treated with 20-Gy doses (Pennathur et al. *J Thorac Cardiovasc Surg.* 2009;137[3]:597).

Conclusion

RFA and SRS each provide a minimally invasive alternative for high-risk patients with pulmonary malignancy. Studies are ongoing in their application to pulmonary metastases and as part of multimodality treatment protocols. As technology improves, RFA delivery probes will be smaller and can potentially be delivered endobronchially. Tumor-tracking technology in the spontaneously ventilating lung continues to improve, and fiducial placement may soon be unnecessary in SRS. As the technology evolves, the use of these modalities may expand beyond use only for the high-risk patients.

Dr. Brichkov has disclosed that he has no significant relationships with the companies/organizations whose products or services are discussed within this Pulmonary Perspectives.

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BRONSON

Pulmonologist

Bronson Healthcare Midwest has an exciting opportunity for a Board Certified Pulmonologist to join an established pulmonary group. Group provides inpatient consults and maintains an outpatient pulmonary practice, which is located on the campus of Bronson Methodist Hospital. Evening coverage is provided by the Bronson Adult Critical Care service. This would be an employed position offering a competitive salary and bonus structure with comprehensive benefits and relocation.

Bronson Healthcare Midwest is a subsidiary of Bronson Healthcare Group in Kalamazoo, Michigan. The practice operates within Bronson Methodist Hospital which is an award winning, tertiary healthcare system serving 10 counties in southwest Michigan. With a workforce of more than 7,000, Bronson is one of the area's largest employers. We offer a full range of services from primary care to advanced critical care and have multiple service locations in Kalamazoo, Calhoun and Van Buren counties.

Kalamazoo, located midway between Detroit and Chicago, is a diverse university town with highly rated public schools and affordable real estate. Offering art, symphony, theater, museums and year round festivals, there are many activities for the whole family including numerous parks, lakes, fine dining and Lake Michigan is less than an hour's drive away.

For more information about Bronson or Kalamazoo visit www.bronsonhealth.com or www.kalamazoomi.com

Interested candidates may contact Cadace Lee at 269-341-8631 or leeca@bronsonhg.org

UCSF Medical Center

UCSF FRESNO PULMONARY/ CRITICAL CARE FACULTY POSITION WITH FOCUS ON LUNG CANCER AND INTERVENTIONAL BRONCHOSCOPY

The UCSF Fresno Medical Education Program and the Central California Faculty Medical Group (CCFMG) are seeking faculty members for the Adult Pulmonary and Critical Care Division at the assistant or associate professor level. Applicants should be board certified or board eligible in Pulmonary Medicine and in Critical Care Medicine, have excellent clinical skills, be willing to actively participate in medical education, and have experience and interest in clinical research. Clinical research opportunities are available in both critical care and pulmonary medicine. We are seeking a faculty member with an interest in lung cancer and interventional bronchoscopy to join a busy lung nodule referral program. Faculty appointment with UCSF will be commensurate with the applicant's background and accomplishments. UCSF Fresno has an active residency program in Internal Medicine and an ACGME accredited Pulmonary Fellowship. The UCSF Fresno Medical Education Program has recently transitioned to a new \$150 Million Regional Medical Center and initiated successful faculty practice sites. The program is located in Fresno, California, a vibrant, growing, but affordable community in the Central California Valley just a short drive from Yosemite and other national parks.

E-mail or FAX CV & 3 references to:
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FAX: (559) 443-2691

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NEW MEXICO Albuquerque

Presbyterian Healthcare Services is seeking BE/BC Pulmonary/Critical Care trained physicians to join Presbyterian Medical Group.

Our medical group employs more than 600 primary care and specialty providers and is the fastest growing employed physician group in New Mexico. Presbyterian Healthcare Services is a locally owned, not-for-profit organization based in Albuquerque. We have been proudly providing care to New Mexicans for 103 years.

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Albuquerque thrives as New Mexico's largest metropolitan center and has been listed as one of the best places to live in the United States by several major publications. Albuquerque is also home to the University of New Mexico, a world renowned institution.

For more information, e-mail Kelly Herrera at kherrera@pshs.org or call 1-505-823-8771. Visit our website at www.pshs.org

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McLeod, SC

McLeod Health is seeking Pulm/CC Physician to join McLeod Pulm/CC Associates. McLeod Health is looking to employ a Pulm/CC Physician to join McLeod Pulm/CC Associates in Florence, SC.

The elements of this opportunity are as follows: 50/50 inpatient/outpatient work. The Intensive Care units are "open" and there is a mid-level (NP/PA) that covers the ICUs in the evening. They serve as the front line staff, and therefore, the MDs only serve as "triage" type call coverage. Busy practice, 20+ patients/day and call schedule is 1/4 will be 1/5 nights and weekends, call is triage call. We are seeking for a long term fit. Good support within practice as there are 3 Physician's; 1 RN, office manager and support staff. The new office space will be in the New Cancer Center when completed.

Michelle Pittelli
McLeod Physician Recruiter
mpittelli@mcleodhealth.org
www.mcleodhealth.org
843-777-7140 (office)
843-360-9340 (cell)

PENNSYLVANIA

The VA Pittsburgh Healthcare System (VAPHS) has an immediate opening for a full-time BC/BE Cardiac Surgeon.

Training and experience in minimally invasive surgical techniques are required; robotic surgery experience required. Responsibilities also include resident and medical student teaching. An academic appointment at the University of Pittsburgh may be available. Research support may be available for qualified individuals. Competitive salary and benefits. VAPHS is one of the largest healthcare systems in the United States with state-of-the-art surgical technologies and serves as the acute tertiary care referral center for a large veteran population in Western Pennsylvania and surrounding areas. VAPHS is closely affiliated with the University of Pittsburgh.

We offer excellent benefits, including Federal Employees Retirement System (FERS), Federal Employees Health Benefits (FEHB) Program, Flexible Spending Accounts (FSA), Federal Employees Dental and Vision Insurance Program (FED-VIP), Federal Long Term Care Insurance (FLTCL) Program, Federal Employees' Group Life Insurance (FEGLI) Program, and Thrift Savings Plan (TSP). We offer competitive salary, commensurate with education and experience.

Interested candidates should fax or e-mail a current CV and cover letter to Karen Proffitt, HR Specialist, at 412-822-3559 or karen.proffitt@va.gov. The VA Pittsburgh Healthcare System is an equal opportunity employer.

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Academic Pulmonologist

The University of Tennessee Health Science Center has a tenure track faculty opening, academic rank based on qualifications, in its Pulmonary, Critical Care and Sleep Medicine Division.

Applicant must have an MD degree and be eligible for Tennessee licensure. BE/BC in internal medicine, pulmonary diseases, critical care medicine are minimal requirements.


Teaching and service activities of this position will be performed at The Regional Medical Center; an educational institution of the UTHSC College of Medicine.

The qualified individual will participate in inpatient and outpatient fellowship training and is expected to develop clinical and/or basic science investigation.

Send curriculum vitae and three recommendation letters to

**Amado X. Freire, MD, MPH, D-ABSM,
Division Chief, Pulmonary Critical Care
and Sleep Medicine
956 Court Ave. Room G-228
Memphis, TN 38163
Phone 901-448-5757, Fax 901-448-7726;
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GEORGIA, Atlanta

The Atlanta VA Medical Center and Division of Pulmonary, Allergy & Critical Care Medicine at Emory University are seeking a physician-scientist or clinician-investigator to lead the VA Pulmonary Section. Candidates should be Assistant or Associate Professor with demonstrated success in laboratory or clinical research and a strong commitment to mentoring fellows and junior faculty. The VA Pulmonary Section includes 7 physicians with NIH and VA funded research and 3 VA career development awardees. The successful candidate will assume a leadership role integrating clinical and academic functions with the 50 full-time faculty and NIH funded training program of the Pulmonary Division in the Department of Medicine. Atlanta is a thriving metropolitan area. The VA Medical Center is adjacent to the campuses of Emory University and the Centers for Disease Control. Interested applicants should contact:

David M. Guidot, MD, Division Director, at 404-712-2970 or dguidot@emory.edu and apply online at www.usajobs.gov, announcement JV-13-238CW-874134 for consideration.

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COMMENTARY: 'Teach back' sends the right message both ways

BY MICHAEL PISTORIA,
D.O.

IMNG Medical News

We need to speak a language our patients understand. I'm not talking about cultural competence, although that is important. I'm talking about speaking in plain language about diseases and treatments. Those in our care need to understand the information we've shared with them.



DR. PISTORIA

Several years ago, my family was on vacation and I found myself watching (at the behest of my then 13-year-old) "So You Think You Can Dance." Ordinarily, it would take a four-point restraint that would make The Joint Commission blush to get me to watch the show. I prefer sports or history. But my daughter loves dancing, so we watched.

During the show, my wife and older daughter talked about the piercings and tattoos of the contestants. On one level, the conversation completely

freaked me out because, you know, my then 13-year-old daughter was discussing this stuff! On another level, I simply listened. I realized their knowledge of this stuff was way beyond mine. They were basically talking another language and I was just along for the ride.

That moment made me think about some of the conversations we have with our patients and their families. Too often, we use language and terms familiar to us but completely foreign to those in our care. We talk *at* patients rather than *with* them and then wonder why they do not adhere to the plans we outlined.

At my former hospital, I was involved in a project to change this dynamic. Working with a talented multidisciplinary team, we started to change how we talked with our patients. We began having our patients "teach back" to us the information we needed them to know.

Using simple questions, teach back allows a provider to ensure that the patient or family member understands the disease process, treatments, and follow-up plans. The lead-in is simple, but the questions are powerful – "To be sure I did a good job of explaining your medications to you, it will be very helpful to

have you describe to me why you take your Lasix – your water pill." In

We subtly increase the likelihood that the patient will view the relationship as a partnership where we are all working toward the same goal – the patient's continued health.

framing the question this way, we change the dynamic, giving patients permission to say they do not understand what we tell them. We subtly increase the likelihood that the pa-

tient will view the relationship as a partnership where we are all working toward the same goal – the patient's continued health.

Speak at the patient's level of understanding – change your language as the situation warrants. I would describe heart failure differently to a patient who has been a nurse for 20 years than I would to my parents. It is not difficult – it takes practice. It works. Try to incorporate it into your care.

Dr. Pistoria is chief of hospital medicine at Coordinated Health in Bethlehem, Pa. He says the best care is always personal.

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Sunday, October 27
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Keynote Speaker: Jim Collins
Author of *Great by Choice* and Bestseller *Good to Great*

For more than 20 years, Jim Collins has studied how companies grow from good to great. Attend this session to hear Jim's principles on how companies attain superior performance and corporate success, and apply these concepts to your personal and professional advancement.



Monday, October 28
9:15 AM – 10:30 AM

Keynote Speaker: Chris Draft
Former NFL Linebacker, Author, Community Activist, and Founder of the Chris Draft Family Foundation

Chris Draft has been personally touched by pulmonary disease. He suffers from asthma and watched his wife battle and lose her life to lung cancer. Hear how he now works to inspire others and empower families to live their best, healthy lives.

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