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Dr. Jin's coauthors included Dr. Raghavan Murugan, Dr. Gilles Clermont, and Priyanka Priyanka (pictured from left to right).

COURTESY JIM RIEKER

Intense urine output monitoring beneficial in ICU

BY IAN LACY
Frontline Medical News

FROM CHEST ■ Intense monitoring of urine output could be a useful tool in detecting acute kidney injury (AKI), according to a study conducted at the University of Pittsburgh.

Kui Jin, MD, of the University of Pittsburgh and his associates found that, after adjustment for baseline characteristics, intensive monitoring of urine output (UO) was associated with higher rates of AKI, with an odds ratio of 1.22. Intensive UO monitoring also was strongly associated with improved 30-day survival among patients developing AKI.

“Treatment for AKI is focused on supportive

care and identification of the underlying etiology. Both of these priorities might be improved by earlier detection of AKI and closer monitoring of kidney function,” wrote Dr. Jin and his associates.

This retrospective cohort study included 15,724 adult patients admitted to the center's ICUs during 2000-2008. All patients had either their UO or serum creatinine (SC) monitored. These patients were then divided into subcohorts that were monitored at one of two different intensities. UO intensive monitoring was defined by hourly recordings, with gaps no greater than 3 hours for the first 48 hours after ICU admission. The group receiving less intensive UO monitoring comprised patients who did not

ACUTE KIDNEY INJURY DETECTED // *continued on page 6*

Regionalized STEMI care slashes in-hospital deaths

BY BRUCE JANCIN
Frontline Medical News

ANAHEIM, CALIF. – An American Heart Association program aimed at streamlining care of patients with ST-elevation MI resulted in a dramatic near-halving of in-hospital mortality, compared with STEMI patients treated in hospitals not participating in the project, James G. Jollis, MD, reported at the American Heart Association scientific sessions.

He presented the results of the STEMI ACCELERATOR 2 study, which involved 12 participating metropolitan regions across the United States, 132 percutaneous coronary intervention-capable hospitals, and 946 emergency medical services agencies. The ACCELERATOR 2 program entailed regional implementation of a structured STEMI care plan in which EMS personnel were trained to obtain prehospital ECGs and to activate cardiac catheterization labs prior to hospital arrival, bypassing the emergency department when appropriate.

Key elements of the project, which was part of the AHA's Mission: Lifeline program, included

TIME-TO-CARE MEASURES IMPROVED // *continued on page 4*

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Time-to-care measures improved // continued from page 1

having participating hospitals measure their performance of key processes and send that information as well as patient outcome data to the National Cardiovascular Data Registry's ACTION-Get With The Guidelines registry. The hospitals in turn received quarterly feedback reports containing

blinded hospital comparisons.

The impetus for the STEMI ACCELERATOR 2 project was simple: "Every day in the United States, people die because of the fragmented nature of emergency cardiac care," declared Dr. Jollis, a cardiologist at Duke University in Durham, N.C.

Dr. Jollis and his coinvestigators worked to obtain buy-in from local stakeholders, organize regional leadership, and help in drafting a central regional STEMI plan featuring pre-specified treatment protocols.

The STEMI ACCELERATOR 2 study was carried out in 2015-2017,

during which 10,730 patients with STEMI were transported directly to participating hospitals with PCI capability.

The primary study outcome was the change from the first to the final quarter of the study in the proportion of EMS-transported patients with a time

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from first medical contact to treatment in the cath lab of 90 minutes or less. This improved significantly, from 67% at baseline to 74% in the final quarter. Nine of the 12 participating regions reduced their time from first medical contact to treatment in the cath lab, and eight reached the national goal of having 75% of STEMI patients treated within 90 minutes.

The other key time-to-care measures improved, too: At baseline, only 38% of patients had a time from first medical contact to cath lab activation of 20 minutes or less; by the final quarter, this figure had climbed to 56%. That's an important metric, as evidenced by the study finding that in-hospital mortality occurred in 4.5% of patients with a time from

first medical contact to cath lab activation of more than 20 minutes, compared with 2.2% in those with a time of 20 minutes or less.

Also, the proportion of patients who spent 20 minutes or less in the emergency department improved from 33% to 43%.

In-hospital mortality improved from 4.4% in the baseline quarter to

2.3% in the final quarter. No similar improvement in in-hospital mortality occurred in a comparison group of 22,651 STEMI patients treated at hospitals not involved in ACCELERATOR 2.

A significant reduction in the rate of in-hospital congestive heart failure occurred in the ACCELERATOR 2 centers, from 7.4% at baseline to 5.0%. In contrast, stroke, cardiogenic shock, and major bleeding rates were unchanged over time.

The ACCELERATOR 2 model of emergency cardiovascular care is designed to be highly generalizable, according to Dr. Jollis.

“This study supports the implementation of regionally coordinated systems across the United States to abort heart attacks, save lives, and enable heart attack victims to return to their families and productive lives,” he said.

The ACCELERATOR 2 operations manual – essentially a blueprint for organizing a regional STEMI system of care – is available gratis.

Discussant Larry A. Allen, MD, applauded the investigators for shifting the focus of quality improvement efforts in STEMI care away from a fixation on door-to-balloon time. That measure, while important, constitutes only one element in the STEMI care system. The clock really ought to start ticking at the time of first medical contact. And emergency department waiting time is an important indicator of coordination of care between paramedics and hospitals.

Dr. Allen, a cardiologist at the University of Colorado, Denver, said the ACCELERATOR 2 model has been successful because it is consistent with a fundamental principle of implementation science as described by Carolyn Clancy, MD, Executive in Charge at the Veterans Health Affairs Administration, who has said it's a matter of making the right thing to do the easy thing to do. Gregg C. Fonarow, MD, founder of the Get With The Guidelines program and professor and cochief of cardiology at the University of California, Los Angeles, predicted that the success of this program will lead to a ramping up of efforts to regionalize and coordinate STEMI care across the country. Simultaneous with the presentation at the AHA conference, the results of STEMI ACCELERATOR 2 were published online in *Circulation* (2017 Nov 14. doi: 0.1161/CIRCULATIONAHA.117.032446).

The trial was sponsored by research and educational grants from AstraZeneca and The Medicines Company. Dr. Jollis reported having no financial conflicts of interest.

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meet intensive monitoring criteria, regardless of their UO in the 7 days following ICU admission. The patients who had their SC intensively monitored had 3 calendar days of samples taken after their ICU admissions. Those who did not meet SC intensive monitoring criteria were placed into the less intensive SC monitoring group.

To understand the effect of the monitoring strategies on detecting the development of AKI, the researchers determined each patient's baseline, admission, and reference serum creatinine levels. Baseline creatinine was defined as the lowest value in the year prior to hospital admission. The source for a patient's reference creatinine varied; for example, for some patients reference creatinine represented the lowest creatinine level recorded within 24 hours after ICU admission or the baseline value.

The crude rates of stage 2-3 AKI 7 days after admission to the ICU were similar between patients from both groups who had their UO monitored; 62.5% of intensive and 63.9% of less intensive patients displayed symptoms. After the researchers adjusted for baseline characteristics,

however, intensive monitoring of UO was associated with greater rates of stage 2-3 AKI (OR, 1.22; *P* less than .001). Crude rates were higher in the patients who received intensive monitoring for SC, compared with patients who received less intensive monitoring for SC.

Ultimately, Dr. Jin and his associates found when caring for patients with or without AKI, fluid management is one of the most important factors. Patients who underwent intensive UO monitoring received less fluid in their first 24 hours (3.6 L) in the ICU, compared with patients who received less intense UO monitoring (4.2 L). Patients who received intensive monitoring of their UO also were less likely to use vasopressors (29.9% vs. 43.3%; *P* less than .001), suggesting these patients were more hemodynamically stable. Further, the percentage of patients at or above 10% of fluid overload was lower in the group who received intensive monitoring of their UO (2.49% vs. 5.68%; *P* less than .001) during the first 72 hours in the ICU. C.R. Bard provided partial funding for this study.

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VIEW ON THE NEWS

Nikita Desai, MD, and William S. Bender, MD, of Emory University School of Medicine, comment: Dr. Jin and colleagues seek to answer several important clinical questions: "Do people live longer if we monitor their urine output closely? Is this because we are detecting acute kidney injury sooner? Does managing fluid balance seem to be the critical intervention in impacting mortality?" In an era where hospital reimbursements are diminishing with the diagnosis of catheter-associated urinary tract infection, these are laudable inquiries.

In this study, patients who presented with acute kidney injury and had their urine output monitored hourly had a lower hazard for 30-day mortality when compared to those patients who did not have urine output monitored closely (HR 0.85 [0.77 - 0.94] versus HR 0.90 [0.81 - 0.99]). The authors posit this may be secondary to better management of fluid balance since the former group had less total fluid accumulation. However, in patients without acute kidney injury, this difference is not detected, and the authors do not include the HR for this subset of patients.

The authors reveal that those patients without acute kidney injury who have their serum creatinine monitored daily seem to have a hazard ratio of 30-day mortality of 0.70 (0.60 - 0.80). However, when these same patients are adjusted for age and acuity of illness, this difference in mortality seems to disappear (HR 1.20 [1.18 - 1.21]). While adjusted outcomes are often altered when managing so many co-variables, this trend toward worsening mortality lessens confidence in the authors' conclusions.

In studies which examine such a large cohort of patients, some differences in mortality and morbidity will inevitably be detected. However, clinicians should be very cautious to make changes in clinical practice based on the results of trends in these data sets. These studies are not designed to demonstrate causality for any meaningful associations, and should be confirmed with clinical trials. Database studies such as this one continue to have their value in hypothesis generation, which will guide future critical care research.

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CardioMEMS shows real-world success as use expands

BY MITCHEL L. ZOLER

Frontline Medical News

DALLAS – Management of outpatients with advanced heart failure using an implanted pulmonary artery pressure monitor continues to show real-world efficacy and safety at least as impressive as in the pivotal trial for the device.

Data from the first waves of patients to receive the CardioMEMS implanted pulmonary artery



Dr. J. Thomas Heywood

pressure (PAP) monitor since it got Food and Drug Administration marketing approval in May 2014 also showed steady uptake of this fluid volume management strategy for patients with advanced heart failure, despite Medicare reimbursement issues in some U.S. regions, J. Thomas Heywood, MD, said at the annual scientific meeting of the Heart Failure Society of America. He estimated that more than 6,000 U.S. heart failure patients have now had a CardioMEMS PAP monitor implanted.

“PAP monitoring seems to work in the real world,” said Dr. Heywood, a heart failure cardiologist at the Scripps Clinic in La Jolla, Calif. An apparent signal of better patient outcomes during routine use, compared with outcomes in the pivotal CHAMPION trial (*Lancet*. 2011 Feb 19;377[9766]:658-66), may reflect a real change in how clinicians use the data from implanted PAP monitors, he speculated.

“The clinicians using CardioMEMS now have a lot more experience” than they had during the trial, he said in an interview. “They have more experience using the device, they know what treatments to use to lower PAP more effectively, and they are now convinced that patients will benefit from reducing diastolic PAP.”

Dr. Heywood estimated that tens of thousands more U.S. heart failure patients with New York Heart Association class III disease and a recent history of at least one heart failure hospitalization are eligible to receive an implanted PAP monitor, dwarfing the more than 6,000 patients who received a device so far.

The postapproval study

The newest efficacy data come from the first 300 patients enrolled in the CardioMEMS HF System Post Approval Study, a registry of patients receiving an implanted PAP monitor funded by the

device’s manufacturer and scheduled to include a total of 1,200 patients. Dr. Heywood said full enrollment was on track for completion by the end of October 2017.

The first 300 patients enrolled in the postapproval study were older than the CHAMPION cohort. They averaged about 69 years of age, compared with about 62 years in CHAMPION; were more often women (38% vs. 28% in CHAMPION); and were more likely to have heart failure with



Dr. Joanna M. Joly

preserved ejection fraction (41% vs. about 22%).

Follow-up data showed that, during the first 6 months with PAP monitoring, the 300 patients averaged 0.20 hospitalizations for worsening heart failure, with 56 hospitalizations in 43 patients (14%), reported Nirav Y. Raval, MD, a cardiologist at Florida Hospital in Orlando. In contrast, in CHAMPION the average heart failure hospitalization rate during 6 months was 0.44 in control patients and 0.32 in those managed using frequent monitoring of an implanted PAP device.

A similar pattern existed for the 6-month cumulative tally of PAP area under the curve, which showed an average rise of 42 mm Hg/day in the CHAMPION control patients, an average drop of 160 mm Hg/day in the CHAMPION patients managed using their CardioMEMS data, and a drop of 281 mm Hg/day in the 300 postapproval study patients.

“We’re now using the implanted sensor in a broader population of patients, and one wonders whether the effect will be diluted. What we see is at least as good as in the CHAMPION trial. This is just an early snapshot, but it is exciting that we see no erosion of the benefit. It’s a great indication that the correct patients are receiving it,” Dr. Raval said while presenting a poster at the meeting.

Further scrutiny of the same 300 patients showed another feature of the impact of PAP monitoring on patient outcomes: The first 90 days with the PAP monitor in place led to a greater number of tweaks in patient treatment and a steady fall in PAP. During days 91-180, PAP tended to level off, the number of medication adjustments dropped, and heart failure hospitalizations fell even more than in the first 90 days, Joanna M. Joly, MD, reported in a separate poster at the meeting.

During days 0-90, heart failure hospitalizations averaged a 6-month rate of 0.29, but during days 91-180 this dropped to an average 6-month rate of

0.11, said Dr. Joly, a cardiologist at Brigham and Women’s Hospital in Boston. Also during the first 90 days, the 300 patients underwent 1,226 medication changes, most often drug up-titrations with a diuretic or with nitrates. During days 91-180, this fell by nearly half, to 660 medication changes, a rate of 2.2 changes per patient during the second set of 90 days or fewer than 1 medication change per month in each patient, she reported.

The data showed “effective reduction” of PAP during the second half of the study despite fewer medication adjustments. How was that possible? Patients who transmit data on their PAPs undergo “modeling of their behavior” based on the feedback they receive from the device, Dr. Joly suggested. Regular measurement of their PAP and seeing how the number relates to their clinical status helps patients “understand the impact of their nonadherence to diet and their medications.” Another factor could be the growing familiarity clinicians develop over time with PAP fluctuations that individual patients display repeatedly that are usually self-correcting. Also, patients may undergo “hemodynamic remodeling” that results in improved self-correction of minor shifts in fluid volume and vascular tone, she said.

This pattern of a reduced need for interventions after the first 90 days with a PAP implant suggests that many patients managed this way may be able to transition to care largely delivered by local providers, or even play a greater role in their own self-care once their PAP and clinical state stabilizes, Dr. Joly said.

The findings imply that by the end of the first 90 days, “patients accept the device and manage themselves better. It becomes basically a behavioral device” that helps patients better optimize their diet and behavior, Dr. Raval observed.

Safety holds steady

Continued real-world use of PAP monitoring has also resulted in new safety insights. During the first 3 years when the CardioMEMS device was on the U.S. market, May 2014–May 2017, the FDA’s adverse event reporting system for devices, the Manufacturer and User Facility Device Experience (MAUDE), received reports on 177 unique adverse events in 155 patients implanted with a PAP monitor, Muthiah Vaduganathan, MD, reported at the meeting. During the same 3-year period, he estimated that at least 5,500 U.S. patients had received a CardioMEMS device, based on data Dr. Vaduganathan obtained from the manufacturer, Abbott. This works out to an adverse event rate of about 2.8%, virtually identical to the rate reported from CHAMPION, noted Dr. Vaduganathan, a cardiologist also at Brigham and Women’s.

The most common adverse event was a sensor failure, malfunction, or migration, which happened in 26% of the patients, followed by pulmonary artery injury or hemoptysis, which occurred in 16%. MAUDE reports for the device included 22 deaths, including six patients who died as a result of pulmonary artery injury or hemoptysis, four patients who died from a heart failure–related

Continued on following page

Bilateral ACP shown similar to unilateral in study

BY RICHARD MARK KIRKNER

Frontline Medical News

What may be the largest study comparing unilateral and bilateral antegrade cerebral perfusion during total arch replacement (ACP) for type A aortic dissection has reported that outcomes between the two approaches are comparable, although the bilateral approach showed some advantages during the operation itself, investigators from China reported in the *Journal of Thoracic and Cardiovascular Surgery* (2017;154:767-75).

The effectiveness of bilateral antegrade cerebral perfusion (b-ACP) vs. unilateral antegrade cerebral perfusion (u-ACP) has been the focus of extensive debate, lead study author Guang Tong, MD, of the Guangzhou (China) General Hospital, and coauthors said.

They compared outcomes in six different metrics, ranging from cardiopulmonary bypass time to length of stay (LOS) in the ICU and hospital, in 203 patients with type A aortic dissection who had total aortic arch replacement with hypothermic circulatory arrest over an 8-year period ending in August 2014; 121 had b-ACP and 82 had u-ACP. “The issue of u-ACP vs. b-ACP has been examined in aortic arch surgery, but few reports have focused on type A aortic dissection,” Dr. Tong and coauthors wrote.

They acknowledged that some surgeons are reluctant to use b-ACP because of its complexity, but their study found no increase in cross-clamp time, cardiopulmonary bypass time, or surgery time in the b-ACP group. They cited another reason surgeons give for avoiding b-ACP: the risk of embolic injury

caused by cannulating the left common carotid artery in an atheromatous aorta. “In the present study, this risk was avoided by attaching the left common carotid artery to the four-branched prosthetic graft for left hemisphere perfusion,” Dr. Tong and coauthors wrote.

Key outcomes that the researchers found not statistically significant were:

- Overall 30-day mortality (11.6% for b-ACP vs. 20.7% for u-ACP; $P = .075$).
- Prevalence of postoperative permanent neurologic dysfunction (8.4% vs. 16.9%; $P = .091$).
- Average ICU LOS (16 ± 17.75 days vs. 17 ± 11.5 days, $P = .454$).
- Average hospital LOS (26.5 ± 20.6 days vs. 24.8 ± 10.3 days, $P = .434$).

However, average ventilation time was lower in the b-ACP group (95.5 hours vs. 147 hours; P less

than or equal to .001).

Dr. Tong and coauthors used an aggressive approach, as advocated by Dhaval Trivedi, MD, and colleagues (*Ann Thorac Surg*. 2016;101:896-903), and had a total arch replacement rate of 57.8%. This rate is higher than most published series in the West but comparable to other studies from China, perhaps because of the relatively young age of this study cohort – an average age of 51 years – compared to data sets other studies have used. Dr. Tong and coauthors used a b-ACP strategy that established both cerebral perfusion routes before circulatory arrest.

Rates of the following complications were also not significantly different across the study population: paraplegia (2.8% for b-ACP vs. 3.1% for u-ACP), temporary neurologic dysfunction (4.7% vs. 9.2%), permanent neurologic dysfunction (TND) (8.4% vs. 16.9%), renal failure (18% vs. 23.1%), reoperation for bleeding (2.8% vs. 4.6%), and mediastinal infection (3.7% vs. 6.2%).

While b-ACP patients did not have a statistically significant lower incidence of TND, Dr. Tong and coauthors noted the shorter time on ventilation and significantly lower tracheostomy rates for the b-ACP patients, 3.7% vs. 16.9% for the u-ACP group ($P = .003$). “In our institute, protocols to wean patients from ventilation were normally initiated as soon as consciousness was regained,” Dr. Tong and coauthors wrote. Among the study limits were its retrospective, nonrandomized, single-center nature.

The investigators reported having no relevant financial disclosures.

VIEW ON THE NEWS

Still waiting for an answer

The study by Dr. Tong and coauthors adds to the discussion between the “bilateralists” and “unilateralists,” as Jean Bachet, MD, called the two prevailing camps on cerebral perfusion strategies in his invited commentary (*J Thorac Cardiovasc Surg*. 2017;154:765-6). And while most clinical reports find outcomes similar between the two approaches, the evidence favors the bilateral approach for total arch replacement.

Citing how the study implied mortality and neurologic morbidity rates almost half those for unilateral perfusion, but not reaching statistical significance, Dr. Bachet said, “The statisticians would say that this is only a trend and no proof,

but some trends might be indicative, and significance might only be a matter of number in each arm of the comparison.”

Dr. Bachet raised a question about the unilateral approach – that once the arch is opened it takes a minute or so to insert the small balloon canula into the origin of the left carotid artery or divided vessel and start bilateral perfusion. “A major question arises,” said Dr. Bachet: “Why should we expose our patients to any undue risk just to avoid a simple maneuver, to spare a little time, or for any other fancy and questionable reason?”

Cardiologists have raised that question for more than 20 years. Said Dr. Bachet, “We still wait for the answer.”

Dr. Bachet is a cardiac surgeon in Surgenes, France. He reported having no financial relationships to disclose.

Continued from previous page

cause, and 12 patients with death from an unknown cause or a cause unrelated to their heart failure or CardioMEMS placement.

Analysis of both the 22 deaths as well as the episodes of pulmonary artery injury or hemoptysis showed that the preponderance occurred relatively early after introduction for U.S. use, suggesting that “a learning curve may exist for the most serious complications,” he said. “Improved safety and device durability may result from careful patient selection, increased operator training, and refined technologies.”

Dr. Vaduganathan cautioned that the MAUDE database is limited by its bias toward serious adverse events, selective reporting, and lack of adjudication for the reported events. Concurrently with his report at the meeting, a written version appeared online (*JAMA Cardiol*. 2017 Sep 18. doi:10.1001/jamacardio.2017.3791).

“The adverse event rate was reassuringly low,

well below the accepted threshold for device safety. It bodes favorably for the device,” he said in an interview.

“But with a passive surveillance system like MAUDE, adverse events are likely underreported; we see in MAUDE the most severe adverse events. There is certainly a larger spectrum of more minor events that we are not seeing, but I think these numbers accurately reflect serious events.” A full registry of every U.S. patient who receives the device, similar to what’s in place for U.S. patients who undergo transcatheter aortic valve replacement, would provide a more complete picture of the risks, Dr. Vaduganathan suggested.

He also voiced some surprise about the frequency of pulmonary artery injury, which was not as apparent in the 550 total patients enrolled in CHAMPION. Clinicians who place the PAP monitor are required to first take a training program, but the manufacturer has no mandated minimum number of placements an

operator must assist on before launching a new CardioMEMS practice, Dr. Vaduganathan said. Many of the pulmonary artery injuries reported to MAUDE resulted from wire perforations that resulted from loss of wire control, he noted. Dr. Heywood said that, in addition to the standard criteria of NYHA class III symptoms and a recent history of a heart failure hospitalization, the other clinical feature he looks for in a patient who is a possible CardioMEMS recipient is a persistently elevated systolic PAP as measured using echocardiography.

The CardioMEMS HF System Post Approval Study is sponsored by Abbott, which markets CardioMEMS. Dr. Heywood has been a consultant to and/or has received research funding from Abbott as well as Impedimed, Medtronic, Novartis, and Otsuka. Dr. Raval has been a consultant to Abbott. Dr. Joly and Dr. Vaduganathan had no disclosures.

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Knowledge Check-In redo allowed in all subspecialties

BY GREGORY TWACHTMAN

Frontline Medical News

The American Board of Internal Medicine is extending its “no consequence” Knowledge Check-In attempt to all subspecialties.

ABIM previously announced that, beginning in 2018, physicians taking the Knowledge Check-In in 2018 would get another chance to take it in 2 years if they were unsuccessful, even if they were due to pass the maintenance of certification (MOC) exam later that year. In 2018, Knowledge Check-Ins will

be offered in internal medicine and nephrology.

“Based on feedback ABIM has received from the physician community, we are happy to let you know that we are extending this policy to include all other internal medicine subspecialties in the future,” ABIM said in a Dec. 4 announcement on its website. “This means that if a physician takes the Knowledge Check-In in the first year it is offered in their subspecialty and is unsuccessful, they will get at least one additional opportunity to take and pass it 2 years later.”

The Knowledge Check-In is an

alternative to the traditional MOC process, and is administered every 2 years rather than the standard decade between MOC exams. ABIM

“[We] are happy to let you know that we are extending this policy to include all other internal medicine subspecialties in the future.”

noted that a single failure on a Knowledge Check-In will not result in a status change to a physician’s

certification status.

Separately, ABIM also announced that it will continue to make practice assessment activities (part IV of the MOC program) a part of the portfolio of options that can be used to satisfy MOC requirements.

“Our intent is to support physicians completing MOC activities that are most meaningful to their practice, including those that enhance and improve medical knowledge, as well as many existing quality improvement activities, and those that blend both,” ABIM said in its announcement.

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Drug prices a key focus of Senate HELP interview of Azar

BY GREGORY TWACHTMAN

Frontline Medical News

AT A SENATE HELP COMMITTEE HEARING

WASHINGTON - Escalating drug prices topped the agenda as members of the Senate Health, Education, Labor & Pensions Committee interviewed Alex Azar regarding his nomination as secretary of the Department of Health & Human Services.

Mr. Azar, a former HHS deputy secretary and general counsel during the Bush administration and a former president of Eli Lilly’s U.S. operations, outlined his priorities to the Senate HELP Committee during a hearing.

“With a department the size of HHS, it is often difficult to prioritize. Nonetheless, should I be confirmed, I do envision focusing my personal efforts in four critical areas,” including lowering drug prices, improving health care access and affordability, paying for outcomes, and tackling the opioid crisis.

Drug prices were the focus of many senators’ questions, and while many contentious questions came from panel Democrats, Sen. Rand Paul (R-Ky.) signaled he was not yet on board with his approval for Mr. Azar’s nomination.

“I think many [Americans] perceive [that drug companies use] their economic might to manipulate the system to maximize profits,” Sen. Paul said. “It’s not like they are selling a cheaper product to more people. They are using government to maximize their profits. Do you acknowledge that, under the current system, Big Pharma uses their economic clout to manipulate the patent system to increase drug prices?”

“There are clearly abuses, Senator, in the system, and that is why one of the steps that I mentioned ... that I believe we have to go after, is the gaming of that,” Mr. Azar responded. He suggested that although Hatch-Waxman rules give innovators a time frame to exclusively sell products “there should be a certain moment” when full

generic competition should begin.

Sen. Paul also challenged Mr. Azar on the notion of drug importation.

There has not been a successful path to certify that drugs being imported are “safe and reliable,” Mr. Azar noted.

Sen. Paul countered that “you would have to sit there and say that the European Union has unsafe drugs. It would be unsafe for Americans to buy drugs from the European Union or from Canada or Australia. It’s just frankly not true.”

Sen. Paul told Mr. Azar that if he cannot come up with a way to reimport drugs as a means of addressing the high cost of pharmaceuticals in the United States, “I can’t support you.”

Sen. Paul continued that a lot of people have talked about how they are going to change the system, particularly patent issues that stand in the way of generic competition, and “you’ve got some convincing to make me believe

that you are going to represent the American people and not Big Pharma, and I know that’s insulting, and I don’t mean it to be because I am sure you are an honest and upright person. But we all have our doubts because Big Pharma manipulates the system to keep prices high. ... We’ve got to fix it. We can’t tepidly go at it. We have to really fix it, and you need to convince those of us who are skeptical that you will be part of fixing it and won’t be beholden to Big Pharma.”

Regarding his other priorities, Mr. Azar noted that, through his “experience helping to implement [Medicare] Part D and with my extensive knowledge of how insurance, manufacturers, pharmacy, and government programs work together, I believe I can bring the skills and experiences to the table that can help us address these issues, while still encouraging discovery so Americans have access to high-quality care.”

He called for making health care “more affordable, more available, and more tailored to what individuals want and need. ... Under the status quo, premiums have been skyrocketing year after

year, and choices have been dwindling. We must address these challenges for those who have insurance coverage and for those who have been pushed out or left out of the insurance market by the Affordable Care Act.”

Mr. Azar signaled that he will continue the push toward value-based care and will use the power of Medicare to lead the rest of the health care delivery system to follow suit.

“We can better channel the power of health information technology and leverage what is best in our programs and in the private competitive marketplace to ensure the individual patient is the center of decision making and his or her needs are being met with greater transparency and accountability.”

Regarding the opioid crisis, Mr. Azar said that “we must heed President Trump’s call to action and tackle the scourge of the opioid epidemic that is destroying so many individuals, families, and communities. We need aggressive prevention, education, regulatory, and enforcement efforts to stop overprescribing and overuse of these legal and illegal drugs. And we need compassionate treatment for those suffering from dependence and addiction.”

Mr. Azar also was challenged on women’s health issues, particularly the ability of employers to exclude health insurance coverage of contraception because of religious objections. He noted that there needs to be a balance between the medical needs of the patient and the rights of an organization to follow its conscience.

Mr. Azar also committed during the hearing to working with improving interoperability of electronic health records as well as working with physicians to reduce the associated documentation burden.

Mr. Azar’s appearance before the HELP Committee was a courtesy as the Senate Finance Committee holds jurisdiction over his nomination. No confirmation hearing had been scheduled at press time.

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MR. AZAR

Evidence mounts for pulmonary embolism benefit from catheter thrombolysis

BY MITCHEL L. ZOLER

Frontline Medical News

AT CHEST 2017 ■ TORONTO – Catheter-directed thrombolysis of pulmonary embolism using an ultrasound-assisted device led to significantly better outcomes in patients hospitalized for pulmonary embolism, compared with conventional systemic thrombolytic treatment, in a propensity score–adjusted analysis of nearly 3,400 patients.

Catheter-directed thrombolysis

EKOS endovascular system that uses ultrasound to facilitate pulmonary embolism (PE) thrombolysis, received FDA approval for U.S. marketing in 2014, the trials that have compared it with systemic thrombolysis have been small, noted Dr. Mishra, and none have looked at whether CDT improves patient survival, compared with standard treatments. The largest report on CDT treatment of PE came from a single-arm, uncontrolled study with 150 patients who received ultrasound-facilitated

ed with thrombolytic therapy, they used propensity score matching to compare 2,256 patients treated with systemic thrombolysis with 1,128 matched patients treated with CDT using tissue plasminogen activator.

The analysis showed that in-hospital death was 15% in the systemic patients and 6% in the CDT group, a relative risk reduction of 63%, and 30-day readmissions occurred in 11% of the systemic patients and in 8% of those treated with CDT, a 30% relative risk reduction. Both were statistically significant differences for the study's two primary endpoints, Dr. Mishra reported at the meeting. Rates of intracerebral hemorrhage and gastrointestinal bleeds were both numerically lower with CDT, and significantly lower for gastrointestinal bleeds.

A multivariate analysis showed CDT was linked with significant relative reductions of about 60% for both in-hospital death and 30-day readmissions, compared with patients on systemic therapy. The results Dr. Mishra reported also appeared in a published report (*Am J Cardiol.* 2017 Nov 1;120[9]:1653-61).

These findings help buttress the case for using CDT for at least some PE patients. “The key is which patients need it,” said Victor F. Tapson, MD, a pulmonologist at Cedars-Sinai Medical Center in Los Angeles.

“Patients with PE and a normal right ventricle generally don't need anything more aggressive than antico-

agulation, and really sick patients with massive PE need systemic thrombolytics. Intermediate-risk patients” are best suited to CDT, but “the problem is that intermediate-risk patients are heterogeneous,” Dr. Tapson said in a video interview, available at mddedg.com/chestphysician.

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Dr. Abhishek Mishra

(CDT) “represents an opportunity to locally treat pulmonary embolism with significant thrombus burden with lower bleeding complications,” Abhishek Mishra, MD, said at the CHEST annual meeting. “I think we are underusing CDT,” said Dr. Mishra, a cardiovascular disease physician at Guthrie Robert Packer Hospital in Sayre, Pa.

Although one CDT device, the



Dr. Victor F. Tapson

CDT (*JACC Cardiovasc Interv.* 2015 Aug;8[10]:1382-92).

To better document the incremental benefit from CDT, Dr. Mishra and his associates used data collected by the Nationwide Readmissions Database during 2013 and 2014, both before and after a CDT device became available for U.S. use. From among 4,426 patients hospitalized with a primary diagnosis of PE and treat-

on sex, age, and an episode of medical care within 1 year of the case event date. The case population consisted of 55.6% women, compared with the control population consisting of 55.4% women.

Five hundred thirteen (39.4%) cases and 189 (12.7%) controls had an infection within the previous 92 days (odds ratio, 4.5; *P* less than .0001). Known VTE risk factors and potentially confounding variables were used in the adjusted univariate and multivariate models, as reported in the *American Journal of Medicine* (2017. doi: 10.1016/j.amjmed.2017.09.015).

Dr. Cohoon and his colleagues reported that univariate analysis showed “most infection sites were strongly associated with venous thromboembolism” and the adjusted multivariate model resulted in 2.4-fold (*P* less than .0001) higher odds for VTE incidence, compared with uninfected controls.

Adjusted multivariate analysis ranked the odds of VTE according to specific infections. Dr. Cohoon and his colleagues reported that this modeling showed that the “highest magnitude of risk, compared with no infection, was imparted by intra-abdominal infection (OR, 18) followed by oral infection (OR, 12), systematic blood stream infection (OR, 11), lower respiratory infection such as pneumonia (OR, 3.6), and symptomatic urinary tract infection (OR, 2.2).”

The researchers concluded that their findings may allow for further refinement of inpatient VTE risk-prediction models such as the Padua prediction score and “future studies are required to assess the utility of venous thromboembolism prophylaxis among outpatients with high venous thromboembolism risk infections.”

The authors reported that they had no conflicts of interest.

VIEW ON THE NEWS

Daniel Ouellette, MD, FCCP, comments: Recently, practitioners

at my hospital have become interested in the use of catheter-directed thrombolysis to treat patients with hemodynamically

significant pulmonary embolus. We developed an on-call, multidisciplinary team to make treatment decisions for patients with a significant pulmonary embolus based on institutional protocols. While we await definitive data concerning outcomes for these exciting new technologies, the team approach to this process has led to judicious and well-thought-out plans for our patients.



Infections increase risk of idiopathic VTE

BY TERRY L. KAMPS

Frontline Medical News

Infection and infection sites have been found to be associated with a significant increased risk of venous thromboembolism, according to results of a population-based, matched, case-control analysis of medical records covering the 13-year period 1988-2000.

Dr. Kevin P. Cohoon and his colleagues at the Mayo Clinic, Rochester, Minn., developed models using conditional logistic regression analysis to stratify the risk associated with specific infections and infection sites.

A total of 1,303 individuals, mean age of 65.2 years, with a first lifetime objectively diagnosed deep vein thrombosis and/or pulmonary embolism were identified and paired with 1,494 controls without venous thromboembolism (VTE), mean age of 64.9 years. The matches were based

Red cell age: No impact on mortality after transfusion

BY ANDREW D. BOWSER

Frontline Medical News

Critically ill patients who received transfusions of the freshest-available red cells had a mortality rate similar to that of patients who received standard-issue, oldest-available red cells, according to results from a large randomized trial.

In some earlier studies, transfusion of older red cells was linked to increased mortality for critically ill, surgical, and trauma patients. But the new results provide “strong evidence” that transfusing very fresh red cells rather than older red cells “provides no clinically meaningful benefits” in the critically ill population, reported D. James Cooper, MD, of Monash University, Melbourne, and his colleagues.

“Our results support the current international usual practice of transfusing patients with the oldest red cells available,” the researchers wrote in the report on the trial, known as TRANSFUSE (Standard Issue Transfusion versus Fresher Red-Cell Use in Intensive Care).

Red cells are stored up to 42 days and can undergo biochemical, structural, or metabolic changes during

that time that “may cause harm,” the researchers wrote. However, blood banks typically issue the oldest compatible red cell units available to them, and it’s uncertain whether doing so increases mortality.

To see if the age of red cells impacted mortality, Dr. Cooper and his colleagues at 59 centers in five countries randomized 4,994 critically ill adults to receive the freshest-available or standard oldest-available red cells (N Engl J Med. 2017;377:1858-67).

At 90 days after transfusion, mortality was 24.8% in the group of patients receiving the freshest-available red cells, and 24.1% for the oldest-available group, or an absolute risk difference of just 0.7 percentage points (95% confidence interval, -1.7 to 3.1; $P = .57$).

“Among the many secondary outcomes tested, we noted a nominal difference in febrile nonhemolytic transfusion reactions that was small, and we are not sure of its clinical significance,” the researchers wrote.

The average duration of red cell storage was 11.8 days versus 22.4 days for the freshest-available and oldest-available groups, respectively.

The TRANSFUSE trial is not the first to suggest that age of red blood



HEMERA/THINKSTOCK

cells does not make a difference in mortality after transfusion. There were two earlier trials, ABLE (Age of Blood Evaluation) and INFORM (Informing Fresh versus Old Red Cell Management) that came to similar conclusions. However, the ABLE trial had a small sample size, and INFORM had “limited outcome data” including a low mortality rate “suggesting low illness severity,” the researchers noted.

“The lower in-hospital mortality in the ICU subgroup in the

INFORM trial (13.0%) than that observed in our trial at 90 days (24.5%) is consistent with lower illness severity in the INFORM patients,” they wrote.

The study was funded by organizations including the Australian National Health and Medical Research Council. Dr. Cooper reported receiving consulting fees from Eustralis Pharmaceuticals that were paid to Monash University. No other potential conflicts of interest were reported.

Alarm reductions don't improve ICU response times

BY MITCHEL L. ZOLER

Frontline Medical News

AT CHEST 2017 ■ TORONTO – It will take more than a reduction in alarms to address the issue of alarm fatigue in the ICU; a change in the ICU staff culture is needed, suggests new research.

“It may take years to recondition clinicians [to realize] that alarms are actionable and must get a response,” Afua Kunadu, MD, said during her presentation on the study at the CHEST annual meeting. Results from prior studies had suggested that as many as 99% of clinical alarms do not result in clinical intervention, noted Dr. Kunadu, an internal medicine physician at Harlem Hospital Center in New York.

A program run at Dr. Kunadu’s hospital showed that cutting back in alarm number alone did not lead to better response times to alarms. Counterintuitively, response times worsened as the total number of alarms fell. “This was a big surprise,” Dr. Kunadu said. Dealing with this issue will “require a shift of focus from alarm fatigue to response time. Even though we made the alarms more actionable, the conditioning remained” that most alarms are not actionable.

She described the program, which started in the 20-bed adult ICU of Harlem Hospital Center,



Dr. Afua Kunadu

“It may take years to recondition clinicians [to realize] that alarms are actionable and must get a response.”

following a 2014 National Patient Safety Goal issued by The Joint Commission to improve the safety of clinical alarm systems by reducing unneeded alarms and alarm fatigue. The Harlem Hospital task force that ran the program began

with an audit of alarms that went off in the ICU and used the results to identify the three most common alarms: bedside cardiac monitors, infusion pumps, and mechanical ventilators. The task force arranged to reset the default settings on these devices to decrease alarm frequency and boost the clinical importance of each alarm that still sounded. Concurrently, they ran educational sessions about the new alarm thresholds, the anticipated drop in alarm number, and the increased urgency to respond to the remaining alarms very quickly for the ICU staff.

The raised thresholds effectively cut the number of alarms. The average number of alarms per patient per hour fell from 4.5 at baseline during September 2016 to about 2 after 1 month, during December 2016. Then the rate further declined to reach a steady nadir that stayed at about 1.3 alarms per patient per hour 4 months into the program.

But timely responses, measured as the percentage of alarm responses occurring within 60 seconds after the alarm went off, fell from 60% at 1 month into the program down to 12% after 4 months, Dr. Kunadu reported.

She had no disclosures.

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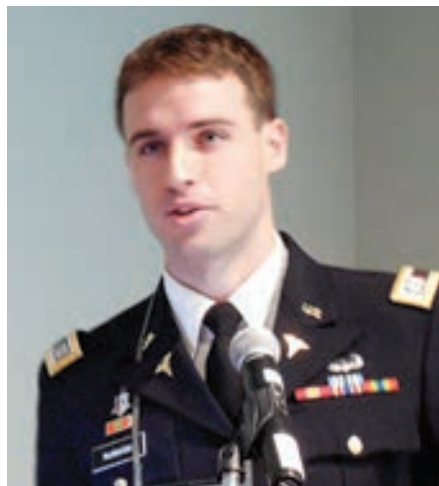
On Twitter @mitchelzoler

Acute kidney injury linked with doubled inpatient VTEs

BY MITCHEL L. ZOLER

Frontline Medical News

AT CHEST 2017 ■ TORONTO – Hospitalized patients with acute kidney injury had more than double the inpatient rate of venous thromboembolism than did patients without acute kidney injury in a prospective, observational study of more than 6,000 hospitalized U.S. soldiers.



MITCHEL L. ZOLER/FRONTLINE MEDICAL NEWS

Dr. Michael McMahon

“I think this should lower our threshold for investigating [possible cases of] venous thromboembolism in patients with acute kidney injury,” Michael McMahon, MD, said at the CHEST annual meeting. Acute kidney injury (AKI) “may require new prophylactic or diagnostic strategies” to prevent in-hospital venous thromboembolism (VTE) or to detect it early, said Dr. McMahon, a pulmonologist and critical care medicine physician at Walter Reed National Military Medical Center in Bethesda, Md.

He offered four possible mechanisms to explain a link between AKI and VTE:

- Patients with AKI are in a hypercoagulable state.
- AKI alters the pharmacodynamics or pharmacokinetics of VTE prophylactic treatments.
- AKI is a marker of an illness that causes VTE.
- VTE leads to an increased rate of AKI rather than the other way around.

Dr. McMahon’s analysis also revealed that two other clinical conditions that are generally believed to raise VTE risk – obesity and impaired overall renal function identified with stagnant measures – did not correspond with a significantly elevated VTE rate in this study.

The data came from 6,552 adults hospitalized for at least 2 days at

Walter Reed between September 2009 and March 2011. The study excluded patients with VTE at the time of admission and also those who had been treated with an anti-

coagulant at the time of admission. The patients averaged 55 years of age and were hospitalized for a median of 4 days. About 22% of patients received VTE prophylaxis

with unfractionated heparin, about 41% received prophylaxis with low-molecular-weight heparin, and about 39% received no VTE prophylaxis (percentages total 102%

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because of rounding).

About 16% of the patients had been diagnosed with AKI at the time of admission, and an additional 8% developed AKI while hospitalized, defined as an increase in serum creatinine during hospitalization of at least 50% above baseline levels or an increase of more than 0.3 mg/dL above the level at time

of admission. During hospitalization, 160 patients (2%) developed a new-onset VTE.

In an analysis that adjusted for baseline differences in type of surgery, body mass index, sex, age, and prior hospitalizations during the prior 90 days, the results showed that patients with preexisting or new-onset AKI had a 2.2-fold

higher rate of VTE, compared with patients without AKI, and this difference was statistically significant, Dr. McMahon reported.

The analysis also showed a significant 62% relatively higher rate of VTE among soldiers hospitalized for a deployment-related event, as well as a significant 63% relatively lower VTE rate among patients

not receiving medical prophylaxis, compared with patients receiving an anticoagulant. Dr. McMahon suggested that this lower rate of VTEs among patients not on prophylaxis reflected success in identifying which patients had an increased risk for VTE and hence received prophylaxis.

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Pulmonary hypertension treatment gets under the skin

BY HEIDI SPLETE

Frontline Medical News

FROM CHEST ■ Pulmonary arterial hypertension (PAH) patients with

moderate, stable disease can benefit from an implantable drug delivery system, based on data from a review of 60 adults with successful implantations. The findings were published

in the December issue of CHEST.

“A fully implanted system offers patients the hope of returning to more normal activities such as bathing, swimming, and reduced

risk of infections from externalized central venous catheter contamination or reduced subcutaneous pain from subcutaneous infusion,” wrote Aaron B. Waxman, MD, PhD, of Brigham and Women’s Hospital, Boston, and his colleagues (Chest. 2017 June 3. doi: 10.1016/j.chest.2017.04.188).

In the DelIVery Trial, clinicians at 10 locations in the United States placed a fully implantable delivery system in adults aged 18 years and older with stable PAH who were

“A fully implanted system offers patients the hope of returning to more normal activities such as bathing, swimming, and reduced risk of infections from externalized central venous catheter contamination or reduced subcutaneous pain from subcutaneous infusion.”

previously receiving treprostinil via an external pump at an average dose of 71 ng/kg per minute.

All 60 patients were successfully implanted with a system consisting of a drug infusion pump placed in an abdominal pocket and an intravascular catheter linking the implanted pump to the superior vena cava.

“The location of the pump pocket was determined in partnership with the patient and was based on consideration of clothing styles, belt line and subcutaneous fat depth,” the researchers noted.

Procedure-related complications deemed clinically significant included one atrial fibrillation, two incidences of pneumothorax, two infections unrelated to catheter placement, and three catheter dislocations (two in the same patient). The most common patient complaints were expected implant site pain in 83% and bruising in 17%.

The findings were limited by the small number of patients, but the researchers identified several factors that contributed to the success of the procedure, including selecting patients who have shown response to treprostinil and are motivated to comply with pump refill visits, performing the procedure at centers with a high volume of PAH patients,

Continued on following page

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Heart transplantation: Preop LVAD erases adverse impact of pulmonary hypertension

BY BRUCE JANCIN

Frontline Medical News

COLORADO SPRINGS – Reconsideration of the role of pulmonary hypertension in heart transplant outcomes is appropriate in the emerging era of the use of left

ventricular assist devices (LVADs) as a bridge to transplant, according to Ann C. Gaffey, MD, of the University of Pennsylvania, Philadelphia.

“Pulmonary hypertension secondary to congestive heart failure more

than likely can be reversed to the values acceptable for heart transplant by the use of an LVAD. For bridge-to-transplant patients, pre-transplant pulmonary hypertension does not affect recipient outcomes post transplantation,” she said at the annual meeting of the Western Thoracic Surgical Association.

Historically, pulmonary hypertension (PH) has been associated with early mortality due to right heart failure and poor transplant survival. An influential report of more than a decade ago by the National Heart, Lung, and Blood Institute Working Group on Cellular and Molecular

Mechanisms of Heart Failure concluded that patients with severe PH as defined by more than 3 Wood units plus poor right ventricular function have a 2-year survival of less than 50% (Circulation. 2006 Oct;114[17]:1883-91).

Vasodilators are prescribed in an effort to reduce PH; however, 40% of patients with PH are unresponsive to the medications and have therefore been excluded from consideration as potential candidates for a donor heart.

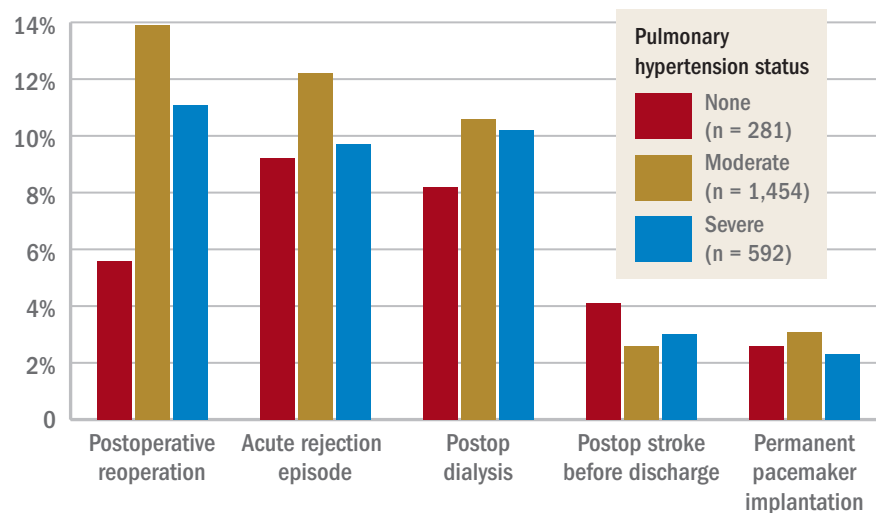
But the growing use of LVADs as a

bridge to transplant has changed all that, Dr. Gaffey said. As supporting evidence, she presented a retrospective analysis of the United Network for Organ Sharing database on adult heart transplants from mid-2004 through the end of 2014.

The review turned up 3,951 heart transplant recipients who had been bridged to transplant with an LVAD. Dr. Gaffey and her coinvestigators divided them into three groups: 281 patients without pretransplant PH; 1,454 with moderate PH as defined by 1-3 Wood units; and 592 with severe PH and more than 3 Wood units.

“Pulmonary hypertension secondary to congestive heart failure more than likely can be reversed to the values acceptable for heart transplant by the use of an LVAD.”

In-hospital outcomes after LVAD bridge to transplant



Notes: No significant between-group differences were found. Based on data from the United Network for Organ Sharing for heart transplants from mid-2004 through the end of 2014.

Source: Dr. Gaffey

The three groups didn't differ in terms of age, sex, wait-list time, or the prevalence of diabetes or renal, liver, or cerebrovascular disease. Nor did their donors differ in age, sex, left ventricular function, or allograft ischemic time.

Key in-hospital outcomes were similar between the groups with no, mild, and severe PH.

Moreover, there was no between-group difference in the rate of rejection at 1 year. Five-year survival rates were closely similar in the three groups, in the mid-70% range.

Audience member Nahush A. Mokadam, MD, rose to praise Dr. Gaffey's report.

“This is a great and important study. I think as a group we have been too conservative with pulmonary hypertension, so thank you for shining a good light on it,” said Dr. Mokadam of the University of Washington, Seattle.

Dr. Gaffey reported having no financial conflicts regarding the study, which was conducted free of commercial support.

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VIEW ON THE NEWS

Implant may improve quality of life for stable PAH patients

The development of an implantable therapy for pulmonary hypertension could expand the use of treprostinil, a demonstrated effective treatment for PAH that has been limited in its use because of a range of side effects when given intravenously, orally, subcutaneously, or by inhalation, Joel A. Wirth, MD, and Harold I. Palevsky, MD, FCCP, wrote in an editorial.

The use of an intravenous pump and catheter infusion system for stable PAH patients could help them return more quickly to normal activities and curb the risk of catheter-related infections, they said. “Having the potential to remove some of the burden and risk incumbent with an external delivery system may reduce several of the overall barriers to continuous intravenous

prostanoid acceptance by both patients and providers,” they noted (Chest. 2017 Dec 6. doi: 10.1016/j.chest.2017.07.006).

Clinicians must be educated to perform the implant procedure itself, and care centers must be trained in identifying patient management issues and refilling the pump reservoir as needed, Dr. Wirth and Dr. Palevsky emphasized. Patients must be educated in what to expect, including how to monitor the pump and track the need for refills, they said. Although the pump is not appropriate for patients with severe PAH, “a planned staged approach of transitioning PAH patients from IV therapy to a less complex system could lend itself to employing prostanoid use earlier and for less severely affected PAH patients,” they said.

Dr. Wirth is affiliated with Tufts University, Boston. Dr. Palevsky is affiliated with the University of Pennsylvania, Philadelphia. Both Dr. Wirth and Dr. Palevsky disclosed serving as consultants and as principal investigators for United Therapeutics.

Continued from previous page

keeping the procedure consistent for each patient, and using the same implant team in each case. “The implant procedure was successfully performed with a low complication rate by clinicians with a diverse range of specialty training,” the researchers added.

Patients reported satisfaction with the implant system at 6 weeks and 6 months, and said they spent an average of 75% less time managing their delivery system, according to previously published data on the patients' perspective (CHEST 2016;150[1]:27-34).

Medtronic sponsored the study. The lead author, Dr. Waxman, reported not having any financial conflicts to disclose; several coauthors reported relationships with companies including Medtronic, Actelion, Bayer, Gilead, Merck, and United Therapeutics.

Tuberculosis transmission stemmed

BY ELI ZIMMERMAN

Frontline Medical News

SAN DIEGO – Using an on-site multidisciplinary team to approach patients who are unwilling to receive tuberculosis treatment can improve patient cooperation, according to a case study presented at ID Week 2017, an infectious disease meeting.

Such public health interventions may be able to improve disease control and interrupt the transmission cycle among patients who are not adhering to treatment, according to Aisha Haynie, MD, MPA.

The first patient Dr. Haynie and her colleagues interacted with as a team was a young female adult diagnosed with active TB, who had been going back and forth from the hospital over the course of 10 months, according to Dr. Haynie.

“We started the patient on treatment and she actually decided to move into a motel,” said Dr. Haynie. “After that, she moved back into the family home and said she wasn’t having any contact [with residents], which we didn’t really believe.”

While the patient did reluctantly give Dr. Haynie and her team a list of five family members to test, the patient told Dr. Haynie that she and her team were not allowed into the patient’s home.

When the five members were tested, the new patients showed similar signs of reluctance and mistrust of the health system.

“The family members came to our clinic and two of them were TB positive,” recounted Dr. Haynie. “So they came back, but while they were sitting in the waiting room, they signed papers and they left.”

Despite continuous attempts to reach the family and address the growing concern from health professionals of the danger of TB transmission to other members of the family, the patients continued not to adhere to procedures beyond pharmaceutical intervention.

In an attempt to directly contact the patient’s family, Dr. Haynie led a team consisting of a local health authority physician, a TB nurse practitioner, a TB contact analyst, a nurse case manager, a county attorney, and an interpreter for unscheduled visits to family members individually.

“We had specific requests [including] keeping appointments, getting labs, and we added a deadline,” said Dr. Haynie, chief of disease control and medical epidemiology for Harris County (Tex.) Public Health & Environmental Services. “By the next Friday [we told them that] we were filing court papers with or without the information and we [would] be contacting child protective services as well.”

Following the intervention, the patient and her family adhered to testing procedures. This revealed an infant with active TB and 8 other family members with TB infection. Isolation breaches were also discovered. Most importantly, the TB

transmission cycle was interrupted, according to Dr. Haynie.

A key aspect of the team’s successful approach was to address cultural and economic barriers that hindered successful interaction with the family and to correct TB misconceptions in order for a trusting relationship to develop.

The investigators developed this intervention in Harris County, which at 4.3 million residents is the 3rd most populous U.S. county and has reported a TB rate of 7.6 cases per 100,000, or approximately double that of the U.S. average, according to Dr. Haynie. Of those cases in Harris County, 73% are foreign-born, compared with the average rate of 59% in Texas.

Dr. Haynie and fellow investigators asserted that part of the reason patients were so reluctant to receive treatment from the Harris County Public Health department was a combination of mistrust in the system and a number of false ideas patients have regarding TB, a sign of further educational tools being needed.

Since the first use of the intervention, Dr. Haynie and her team have implemented this approach with other non-adherent patients with relative success.

“This is something that we now do and we have not been back to court [to enforce compliance] since,” said Dr. Haynie.

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ARDS incidence is declining; is it a preventable syndrome?

BY DEBRA L. BECK

Frontline Medical News

AT CHEST 2017 ■ TORONTO – The incidence of acute respiratory distress syndrome (ARDS) is on the decline, according to a retrospective, population-based cohort study conducted at the Mayo Clinic in Rochester, Minn.

“This is very promising data in combating this syndrome,” said Augustin Joseph of the Mayo Clinic, and “it suggests that ARDS may in part be a completely preventable disease.”

This study was inspired by a previous effort by Guangxi Li et al. who conducted a population-based cohort study on trends in ARDS using data from the Olmsted County (Minn.) Epidemiology Project from 2001 to 2008 (*Am J Respir Crit Care Med.* 2011;183:59-66). At that time, a steady and significant decline in ARDS incidence was noted, attributable to a reduced incidence of hospital-acquired ARDS. “We attributed this to improvements in hospital practices and management of ARDS and all the research that’s been done

over the past 2 decades,” Mr. Joseph said at the CHEST annual meeting.

To see if ARDS incidence has continued to decline, Mr. Joseph’s group studied all patients admitted during 2009-2014 to the Mayo Clinic’s ICU, the only facility in the county that cares for ARDS patients. From 82,388 ICU admissions, they identified 505 patients with ARDS according to the Berlin definition of ARDS developed in 2012.

The number of annual cases dropped from 108 in 2009 to 59 in 2014, and the incidence steadily declined from 74.5 cases per 100,000 in 2009 to 39.3 per 100,000 in 2014.

Median age was 67 years in 2009 and 62 years in 2014. Hospital mortality ranged from 15% to 26% during the study period, while hospital length of stay ranged from 8 to 15 days, with no clear decline in either.

While the earlier study used the American-European Consensus Conference (AECC) definition of ARDS, Mr. Joseph and his colleagues diagnosed ARDS according to the Berlin definition.

RA ups risk of hospitalizations from COPD

BY ANDREW D. BOWSER

Frontline Medical News

Individuals with rheumatoid arthritis (RA) had an increased risk of hospitalizations from chronic obstructive pulmonary disease (COPD) when compared with the general population in a Canadian retrospective, population-based cohort study.

The risk of COPD hospitalizations was 47% higher in individuals with RA. “This finding emphasizes the need to control inflammation in rheumatoid arthritis, not only to prevent joint damage, but also to prevent complications of systemic inflammation, including the development of comorbidities such as cardiovascular diseases and COPD,” wrote Diane Lacaille, MD, of the University of British Columbia, Vancouver, and her coauthors (*Arthritis Care Res.* 2017 Oct 19. doi: 10.1002/acr.23410).

Several previous studies have suggested a link between COPD

and inflammation, Dr. Lacaille and her colleagues said. Accordingly, they sought to evaluate the risk of COPD hospitalizations in a cohort of 24,625 individuals with RA as compared with 25,396 general population controls randomly selected and matched based on age, sex, and index year. Most subjects in the analysis were female, and the mean age at onset of RA was 57.2 years.

The investigators reported an increased incidence of COPD in individuals with RA, compared with controls, based on an incident rate ratio (IRR) of 1.58 (95% confidence interval, 1.34-1.87) that dropped to 1.47 (95% CI, 1.24-1.74) after adjustment for potential confounders, including comorbidities and health services usage at baseline. The overall incidence rate for COPD was 2.07 per 1,000 patient-years for RA patients and 1.31 per 1,000 patient-years for controls.

When the model was stratified based on sex, COPD hospitalization

risk was significantly increased in women (adjusted hazard ratio [HR], 1.61; 95% CI, 1.30-1.98), but not in men (adjusted HR, 1.25; 95% CI, 0.95-1.66), they said.

Data were not available on smoking, the main COPD risk factor, for the patients in this study; however, the increased risk of COPD hospitalizations in the RA group remained significant after modeling for smoking, according to the investigators.

Combined, these results have “notable implications for the clinical care of RA and COPD,” Dr. Lacaille and her coinvestigators said.

Both clinicians and people living with RA “should be aware of the increased risk of developing COPD and be vigilant in watching for early symptoms of COPD, so that appropriate diagnostic tests can be administered at the onset of early symptoms,” they wrote. “Early detection of COPD is essential so that effective treatments can be initiated before irreversible damage to the lungs occurs, to improve

long-term outcomes.”

These findings strengthen the conclusions of two previous cross-sectional studies showing an association between RA and COPD prevalence, according to the investigators. In one study, RA patients in Israel who were receiving disease-modifying antirheumatic drugs had double the prevalence of COPD, compared with general population controls, according to authors of that study (*Immunol Res.* 2013;56[2-3]:261-6). Similarly, U.K. investigators compared 421 RA patients against controls and reported a twofold increase in obstructive pattern on screening spirometry in the RA group (*Ann Rheum Dis.* 2013;72:1517-23).

The current study from Dr. Lacaille and her coinvestigators was supported by funding from the Canadian Institute for Health Research. The authors reported that they had no financial disclosures, conflicts of interest, or benefits from commercial sources.

Omalizumab helps asthma COPD overlap patients

BY DEBRA L. BECK

Frontline Medical News

AT CHEST 2017 ■ TORONTO – Omalizumab (Xolair, Genentech) decreased asthma exacerbations and improved symptom control to a similar extent in patients with asthma chronic obstructive pulmonary disease (ACO) overlap as seen in patients with asthma but no COPD, in a study presented at the CHEST annual meeting.

While patients with COPD typically experience annual declines in lung function, at least some of the ACO patients in this study, which included one of the largest observational cohorts to date of patients with ACO, showed preserved lung function after 48 weeks of omalizumab treatment.

“These data deal with a topic that we scratch our heads about all the time – the asthma COPD overlap. ... Few of our therapies for asthma have been studied in this patient population,” said Nicola Hanania, MD, FCCP, of Baylor College of Medicine in Houston. “We believe that about 16% of patients with asthma or COPD have ACO,” he added.

Dr. Hanania presented data from the “real-world” PROSPERO (Prospective Study to Evaluate Predictors of Clinical Effectiveness in Response to Omalizumab), which unlike many asthma studies, did not exclude patients with comorbid COPD. PROSPERO was a prospective, multicenter, observational, 48-week study of patients (n = 806) who were 12 years of age and older who were initiating omalizumab treatment for moderate to severe allergic asthma. Asthma control was assessed monthly using the



Dr. Nicola Hanania

Asthma Control Test (ACT).

Participants were identified as having ACO based on two approaches: a positive medical history of asthma and COPD; or A medical history of asthma (but not COPD), at least a 10-pack per year smoking history, and a forced expiratory volume in 1 second/forced vital capacity (FEV₁/FVC) of less than 0.7. From the 728 study participants included in this secondary analysis, 56 were classified as ACO according to the first definition (ACO cohort A) and 59 according to the second (ACO cohort B). Thirty-seven patients fell into both groups.

“All groups had a reduction in their exacerbation rates through 12 months, and it didn’t differ whether they had ACO in cohort A or cohort B, or no ACO,” Dr. Hanania reported. Specifically, asthma exacerbations numbers were reduced from baseline levels though month 12, from 3 or

more exacerbations in both ACO and non ACO groups to 1.1 or less.

Additionally, all three groups showed clinically meaningful improvements in their ACT scores, with mean improvements of 4.1, 4.7, and 4.4 units for ACO cohort A, ACO cohort B, and non-ACO patients, respectively.

Postbronchodilator FEV₁ at study end was improved by 36 mL in ACO cohort A and by 23 mL in the non-ACO cohort. But a 14 mL reduction in postbronchodilator FEV₁ was noted in ACO cohort B, “a reminder that the cohort B population was those patients with fixed airway obstruction and smoking history,” said Dr. Hanania.

Mean age in the non-ACO population was 50 years, rising to 57.6 years in ACO cohort A and 55 years in ACO cohort B. All three groups had three or more asthma exacerbations in the 12 months before starting omalizumab, and all groups had mean ACT scores of less than 15 at baseline, indicating that they were all symptomatic.

Adverse events were consistent with the known safety profile of omalizumab.

“The significance of this study [is that] it’s one of the largest ACO cohorts that we know of and I think it encourages all of us to look at or re-visit both COPD therapies and asthma therapies in populations [not included] in clinical trials because in real life, these are the patients we see ... and we don’t have evidence,” Dr. Hanania said.

Dr. Hanania reported receiving research support from Roche/Genentech, among other companies. Three of the investigators are employees of Genentech, the study’s sponsor.

Tezacaftor-ivacaftor combo shows promise in CF

BY BIANCA NOGRADY

Frontline Medical News

A new drug that targets the cystic fibrosis transmembrane conductance regulator protein could significantly improve lung function and other symptoms in patients with cystic fibrosis.

In a phase 3 double-blind, placebo-controlled crossover trial, researchers examined the effects of tezacaftor – a cystic fibrosis transmembrane conductance regulator (CFTR) corrector – in combination with the CFTR potentiator ivacaftor, compared with ivacaftor alone or placebo.

According to a paper published in the *New England Journal of Medicine*, the 248 cystic fibrosis patients enrolled in the study were heterozygous for the CFTR Phe508del mutation, which can be associated with more severe disease, and a second CFTR mutation that is called a “residual function” mutation. Approximately 5% of the patients with cystic fibrosis exhibit residual CFTR activity in epithelial cells, for example. Patients with one residual function mutation and a second CFTR mutation have a reduced life expectancy but the symptoms have a slower progression.

“The addition of the CFTR corrector tezacaftor was hypothesized to enhance clinical benefit in patients with these mutations by increasing overall CFTR function,” wrote Dr. Steven M. Rowe of the division of pulmonary, allergy, and critical care medicine at the University of Alabama at Birmingham and his coauthors. “This combination treatment is particularly important for restoring activity to those carrying two copies of the Phe508del CFTR mutation, as shown for the approved corrector-potentiator combination

lumacaftor-ivacaftor, and may provide benefit to patients with other CFTR mutations.”

After two 8-week treatment periods in which patients were randomized to two of the three regimens, separated by an 8-week washout period, researchers saw significant improvements in predicted forced expiratory volume in 1 second (FEV₁), both with tezacaftor-ivacaftor and ivacaftor alone, compared with placebo (*N Engl J Med*. 2017 Nov 23;377:2024-35. doi: 10.1056/NEJMoa1709847).

From baseline to the average of week 4 and 8, the combination of tezacaftor-ivacaftor was associated with a 6.8-percentage-point absolute change, and there was a 4.7-percentage-point improvement with ivacaftor alone, compared with placebo. The difference between the tezacaftor-ivacaftor combination and ivacaftor monotherapy was also statistically significant in favor of the combination treatment.

Researchers also saw significant improvements in the secondary endpoint of absolute change in the Cystic Fibrosis Questionnaire–Revised score; the combination treatment was associated with an 11.1 point improvement compared with placebo, and monotherapy achieved a 9.7-point improvement. In the combination therapy group, 65% of patients achieved a clinically important difference of 4 points or greater, compared with 58% of patients in the monotherapy group and 33% of patients in the placebo group.

“These findings confirm the benefits of potentiator therapy in patients with residual CFTR function mutations and the added benefit conferred by corrector-potentiator combination therapy in this population,” the authors wrote.

The investigators also saw a lower rate of pulmonary exacerbations in the combined therapy group,

Susan Millard, MD, FCCP, comments: This NEJM article came out with a companion article reporting phase 3 tezacaftor-ivacaftor results in homozygous CFTR Phe508del patients. Tezacaftor is a CFTR corrector developed by a company that has another corrector on the market, called lumacaftor. Lumacaftor is formulated with ivacaftor and available in the United States for patients age 6 and above who have two copies of Phe508del. It is exciting that another combination therapy has been developed that appears to be very effective and can be used for a second group of patients. This era of personalized medicine is extremely exciting, and we look forward to future therapies for all CFTR mutations.



but this did not reach statistical significance.

The rate of adverse events was similar across all three groups. Most were considered mild or moderate in severity and were largely clinical manifestations of cystic fibrosis.

Vertex Pharmaceuticals, which manufactures tezacaftor and ivacaftor, funded the study. Twelve of the 13 authors reported receiving various kinds of support from Vertex, including personal fees, grant support, and nonfinancial support. Several authors reported ties to other industry sources.

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Expanded testing improves respiratory pathogen detection

BY ELI ZIMMERMAN

Frontline Medical News

SAN DIEGO – Systematic testing of acute respiratory illness patients can increase the likelihood of finding relevant pathogens, according to a study presented at an annual scientific meeting on infectious diseases.

Currently, hospitals conduct either nonroutine assessments or rely heavily on clinical laboratory testing among severe acute respiratory illness patients, which can lead to missing clinically key viruses.

“Detections of some potentially relevant viruses, such as air influenza viruses and human metapneumovirus were often not detected in hospital testing,” said presenter Andrea Steffens, an epidemiologist at the Centers for Disease Control and Prevention.

Systematic testing expands on tests ordered and carried out at hospitals, expanding on them by testing for influenza, respiratory syncytial



This negative-stained transmission electron micrograph (TEM) depicts the ultrastructural details of an influenza virus particle, or “virion.”

virus (RSV), human metapneumovirus, rhinovirus and enterovirus, adenovirus, coronavirus, and parainfluenza viruses 1-4. To test the efficacy of systematic testing, investigators studied 2,216 severe acute respiratory illness patients hospitalized in one of three hospitals in Minnesota during September 2015-August 2016. Patients were

predominantly younger than 5 years old (57%) and had one or more chronic medical condition (63%).

Detection of at least one virus increased from 1,062 patients (48%) to 1,600 patients (72%) when comparing clinically ordered tests against expanded, systematic RT-PCR testing conducted through the Minnesota Health Department (MDH).

By patient age, viral detection increased by 27%, 24%, 18%, and 21% for patients aged younger than 5 years, 5-17 years, 18-64 years, and 65 years and older, respectively. Except for influenza viruses and RSV, the proportions of viruses identified, regardless of age, were all lower in hospital testing, compared with MDH testing.

“RSV targeting was almost systematic among children less than 5 years, but [accounted for] only 28% of RSV detection,” said Dr. Steffens in her presentation. “A smaller proportion of other respiratory viruses, including the human metapneumovirus,

were detected at the hospital, and this was especially true for adults.”

Patients with rhinovirus and enterovirus saw a difference between hospital and expanded testing, increasing from a little over 300 patients detected, to nearly 800 patients.

“Patients admitted to the ICU were less likely to have a pathogen detection than those not admitted to the ICU, and those with one or more chronic medical conditions had lower viral detection than those without,” Dr. Steffens said. “While testing at MDH did increase the percent of patients in each category, trends remained consistent and significant.”

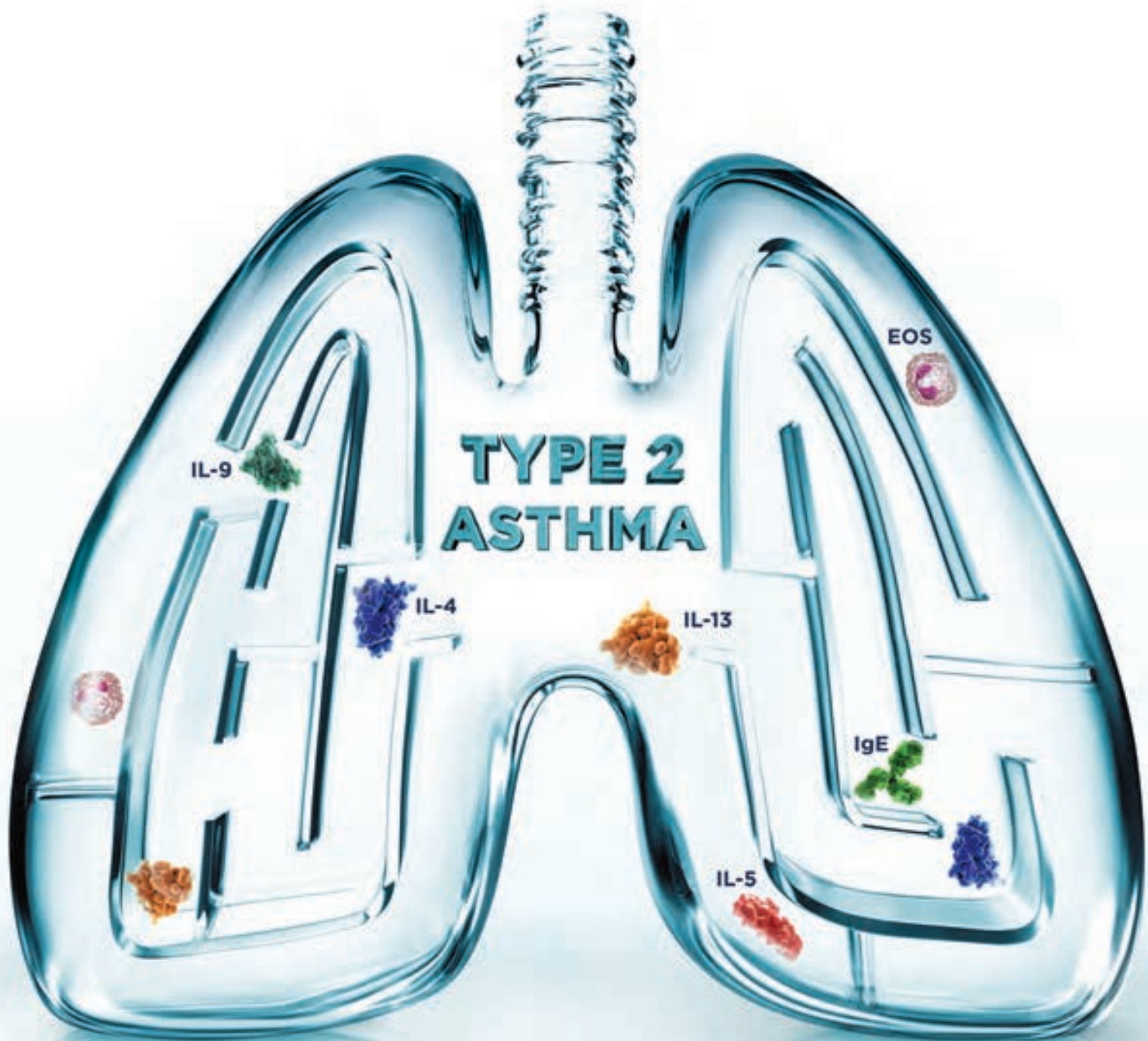
Since testing information was only collected for patients with positive test results at the hospital, investigators were not able to compare testing practices between patients with and without viruses.

The presenters reported no relevant financial disclosures.

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Testing for latent tuberculosis infection

BY NEIL SKOLNIK, MD, AND
MATHEW CLARK, MD

Frontline Medical News

While cases of active tuberculosis are relatively rare in the United States, TB is a major cause of morbidity and mortality worldwide. In the United States, there are an estimated 11 million individuals who have latent TB infection (LTBI). Without prophylactic treatment, somewhere between 4%-6% of individuals with LTBI will develop active disease during their lifetimes; roughly half of these cases will occur within a few years of the initial infection. Treatment of LTBI reduces – but does not eliminate – the risk for active disease, decreasing the consequences of active disease for the patient and the risk of transmitting infection to others.

Guidelines from the American Thoracic Society, the Infectious Diseases Society of America, and the Centers for Disease Control and Prevention have been issued with new recommendations for optimal testing strategies for detecting LTBI. The recommended strategies are based on two criteria: the risk of being infected with TB and, in those with LTBI, the risk of progressing to active disease.

Diagnostic tests for LTBI

The tuberculin skin test (TST) has been the standard method of diagnosing LTBI. It involves measuring induration caused by a delayed-type hypersensitivity reaction to *Mycobacterium tuberculosis* (Mtb) 2 or 3 days after injecting the reagent into the skin. The TST can result in false positives when detecting antibodies to BCG and nontuberculous mycobacteria, and false negatives when the patient does not demonstrate a robust immune response. A newer testing method is the

Interferon Gamma Release Assay (IGRA), which involves phlebotomy, followed by a series of laboratory procedures that measure IFN-gamma release by T cells that have been sensitized to Mtb. The sensitivity of IGRA is similar to the TST, but it has better specificity; it is much less likely to react to antigens from BCG or nontuberculous mycobacteria. As detailed below, this guideline suggests a significantly more prominent role for IGRA, compared with previous recommendations.

Recommendation 1. Perform an IGRA, rather than a TST, in individuals 5 years or older who meet the following criteria: 1) are likely to be infected with Mtb; 2) have a low or intermediate risk of disease progression; 3) in whom it has been decided that testing for LTBI is warranted. A TST is an acceptable alternative, particularly if an IGRA is not available, is too costly, or is too burdensome. If an individual either has a history of BCG vaccination or is unlikely to return to have their TST read, then it is strongly recommended to use the IGRA as the test of choice.

Recommendation 2. There are insufficient data to recommend a preference for either a TST or an IGRA as the first-line diagnostic test in individuals 5 years or older who are likely to be infected with Mtb, who have a high risk of progression to active disease, and in whom it has been determined that diagnostic testing for LTBI infection is warranted; either test would be acceptable. In very high-risk patients, consider dual testing, with a positive result from either test (TST or IGRA) being considered positive.

Recommendation 3. Guidelines do not recommend testing for persons



Dr. Skolnik is professor of family and community medicine at Sidney Kimmel Medical College, Thomas Jefferson University, Philadelphia, and associate director of the family medicine residency program at Abington (Pa.) Jefferson Health. Dr. Clark is associate director of the family medicine residency program at Abington (Pa.) Jefferson Health.

at low risk for Mtb infection. However, the authors recognize that testing in such persons may nevertheless be mandated in certain situations (for example in some school or child care settings). In these cases, the authors recommend performing an IGRA instead of a TST, to minimize the chance of a false-positive result, although a TST is an acceptable alternative. Furthermore, if the initial test is positive, they suggest performing a confirmatory test (either an IGRA or TST) and considering the person infected only if both tests are positive.

Recommendation 4. The authors suggest performing a TST rather than an IGRA in healthy children less than 5 years of age for whom it has been decided that diagnostic testing for LTBI is warranted. This recommendation reflects the limited body of evidence regarding IGRA testing in young children and the apparent decreased sensitivity (that is, more false negatives) in this population, compared with TST use.

In the area of serial testing for TB infection, often done in health care and institutional settings, the guideline points out areas of uncertainty with IGRA testing. Specifically, the IGRA test is subject to variability in readings and boosting with antigen exposure that can complicate interpretation of apparent conversion

on repeat testing. One longitudinal study showed conversion rates with IGRA to be six to nine times higher than that seen for the TST, and those conversions were thought to represent false-positive tests. The guideline concludes that, “There is insufficient information available to guide the establishment of definitive criteria for the conversion.” The committee thought that a positive test in a low-risk individual was likely to be a false-positive result and recommended repeat testing. Because of the possibility of boosting with antigen exposure in situations where dual testing is anticipated, it may be preferable to obtain a specimen for IGRA prior to, or concurrently with TST placement.

Bottom line

Current guidelines suggest a more prominent role for IGRA in testing for LTBI, particularly when the likelihood of exposure is low and in situations where a person may have received BCG vaccination, or would be unlikely to return for TST reading.

Reference

Lewisohn DM et al. Official American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children. *Clin Inf Dis*. 2017;64(2):111-5.

FDA approves epinephrine autoinjector for infants

BY CATHERINE COOPER NELLIST

Frontline Medical News

The Food and Drug Administration approved an epinephrine autoinjector constructed specifically to treat life-threatening allergic reactions in infants and small children weighing 16.5-33 pounds.

The Auvi-Q 0.1 mg autoinjector by kaléo was approved after a priority review by the FDA, with features such as “a voice prompt system that guides a user with step-by-step

instructions through the delivery process,” according to a written statement from the company. This autoinjector has a shorter needle length and lower dose of epinephrine than other FDA-approved 0.15-mg and 0.3-mg epinephrine autoinjectors.

In a previous study of 51 infants with a mean weight of 24 pounds who were treated with a 0.15-mg epinephrine autoinjector with a standard 12.7-mm needle length, 43% were at risk of having the needle strike the bone. Unintentional injection of epi-

nephrine into the intraosseous space can cause systemic absorption of the epinephrine and possible cardiac complications (*Ann Allergy Asthma Immunol*. 2017 Jun;118[6]:719-25.e1).

This new autoinjector with a shorter needle length was designed to obviate this problem, according to kaléo’s statement.

The Auvi-Q 0.1 mg autoinjector should be available to patients in the first half of 2018, the company said.

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Sleep apnea treatment may reduce risk of epileptic seizures

BY TED BOSWORTH

Frontline Medical News

WASHINGTON – In patients with epilepsy, treatment of obstructive sleep apnea with continuous positive airway pressure may lead to substantial and sustained reductions in seizure activity, according to data presented at the annual meeting of the American Epilepsy Society.

The reduction in seizure activity with continuous positive airway pressure (cPAP) in patients with epilepsy contributes to other evidence that poor sleep quality is an important but preventable risk factor for seizures, according to Thapanee Somboon, MD, a research fellow at the Sleep Disorders Center at the Cleveland Clinic in Ohio.

“We think many clinicians overlook the relationship of sleep to risk of seizures,” Dr. Somboon said. “All patients with epilepsy should be checked for sleep disorders, including insomnia and sleep apnea, because these are associated with seizures and are easily treated.”

In this study, which was characterized as the largest yet to evaluate the effect of cPAP on seizure activity, all 197 patients had epilepsy but only 122

had obstructive sleep apnea (OSA). Of those with OSA, 73 were treated with cPAP and 49 were not. An additional 75 patients with epilepsy but no OSA were also treated with cPAP. Seizure activity in all groups was evaluated over a period of 1 year.

Treatment success, defined as no seizure activity or at least a 50% reduction from baseline in seizure activity, was achieved in 85% of those with OSA treated with cPAP, 55% of those with OSA that did not receive cPAP, and 65% of those who were treated with cPAP but did not have OSA.

The difference was even greater among those with seizure activity in the 6 months prior to cPAP use. In these, a 50% or greater reduction in seizure activity was achieved in 63% of those with OSA treated with cPAP but in only 14% of those with OSA that did not receive cPAP. In the group without OSA, 44% achieved a 50% or greater reduction in seizure activity from baseline on cPAP.

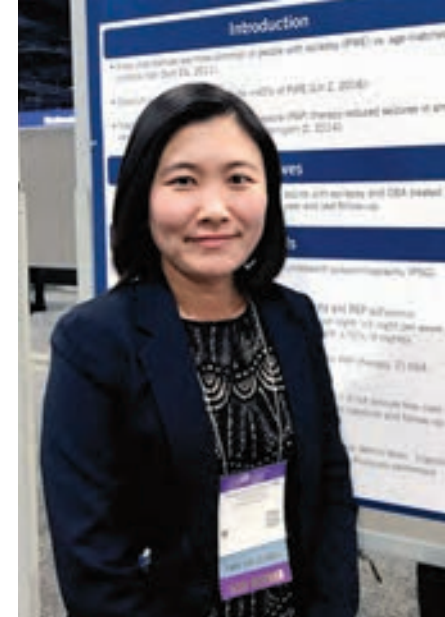
“Epilepsy patients without OSA also appeared to benefit from cPAP, although prospective data are needed to further explore this observation,” Dr. Somboon said.

All patients remained on anti-

epileptic drugs over the course of study, and the drug levels were not different between groups, according to Dr. Somboon. About half of all three groups were seizure free in the 6 months prior to cPAP. Those with OSA who received cPAP had a higher body mass index than did those who were not treated (34.6 vs. 31.1; P less than .001), but they were of similar age (47.6 vs. 47.9 years). Those without OSA who were treated with cPAP had a lower BMI (27.5; P less than .001) and were 10 years younger than were those with OSA (37.7 years; P less than .001). About two-thirds of all three groups had a history of focal seizures.

When expressed as odds ratios (OR), those treated for OSA had almost 10 times the likelihood of treatment success at 1 year (OR, 9.58; P less than .001), although being seizure free in the 6 months prior to cPAP had a 20-fold increased likelihood of treatment success (OR, 20.88; P less than .001).

Sleep disturbances and OSA are more common in patients with epilepsy than age-matched controls, according to Dr. Somboon, who cited published studies substantiating these statements. She noted that there are



The link between sleep and seizure risk is overlooked suspects Dr. Somboon.

also previously published studies associating improved sleep hygiene, including improved sleep hygiene achieved with cPAP, with a reduced risk of seizure activity in epilepsy patients. However, at present there are no guideline recommendations for screening patients with epilepsy for OSA or other causes of impaired sleep, according to Dr. Somboon.

Although Dr. Somboon acknowledged that the data collected in this study cannot provide a definitive link between cPAP treatment, improved sleep, and reduced risk of seizure activity, this study does support these associations in the context of other evidence.

Dr. Somboon reported no financial relationships relevant to the study.

Phrenic-nerve stimulator maintains benefits for 18 months

BY MITCHEL L. ZOLER

Frontline Medical News

AT CHEST 2017 ■ TORONTO – The implanted phrenic-nerve stimulation device that received Food and Drug Administration marketing approval in October 2017 for treating central sleep apnea has now shown safety and efficacy out to 18 months of continuous use in 102 patients.

After 18 months of treatment with the Remede System, patients' outcomes remained stable and patients continued to see the improvements they had experienced after 6 and 12 months of treatment. These improvements included significant average reductions from baseline in apnea-hypopnea index and central apnea index and significant increases in oxygenation and sleep quality, Andrew C. Kao, MD, said at the CHEST annual meeting.

“We were concerned that there would be a degradation of the benefit [over time]. We are very happy that the benefit was sustained,” said Dr. Kao, a heart failure cardiologist at Saint Luke's Health System in Kansas City, Mo.

Dr. Kao's report focused on the 6-, 12-, and 18-month changes relative to baseline for five secondary outcomes: central sleep apnea index, apnea-hypopnea index, arousal index, oxygen

desaturation index, and time spent in REM sleep. For all five of these outcomes, the 102 patients showed an average, statistically significant improvement compared with baseline after 6 months on treatment that persisted virtually unchanged at 12 and 18 months.

For example, average central sleep apnea index fell from 27 events/hour at baseline to 5 per hour at 6, 12, and 18 months. Average apnea-hypopnea index fell from 46 events/hour at baseline to about 25 per hour at 6, 12, and 18 months. The average percentage of sleep spent in REM sleep improved from 12% at baseline to about 15% at 6, 12, and 18 months.

During 18 months of treatment following device implantation, four of the 102 patients had a serious adverse event. One patient required lead repositioning to relieve discomfort and three had an interaction with an implanted cardiac device. The effects resolved in all four patients without long-term impact. An additional 16 patients had discomfort that required an unscheduled medical



DR. KAO

visit, but these were not classified as serious episodes, and in 14 of these patients the discomfort resolved.

The Remede System phrenic-nerve stimulator received FDA marketing approval for moderate to severe central sleep apnea based on 6-month efficacy and 12-month safety data (Lancet. 2016 Sept 3;388[10048]:974-82). The Pivotal Trial of the Remede System enrolled 151 patients with an apnea-hypopnea index of at least 20 events/hour, about half of whom had heart failure. All patients received a device implant: In the initial intervention group of 73 patients, researchers turned on the device 1 month after implantation, and in the 78 patients randomized to the initial control arm, the device remained off for the first 7 months and then went active. The researchers followed up with 46 patients drawn from both the original treatment arm and 56 patients from the original control arm, at which point the patients had been receiving 18 months of treatment.

The Remede System pivotal trial was sponsored by Respicardia, which markets the phrenic-nerve stimulator. Dr. Kao's institution, Saint Luke's Health System, received grant support from Respicardia.

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New narcolepsy drug passes phase 3 test

BY JIM KLING

Frontline Medical News

SAN DIEGO – The selective dopamine and norepinephrine reuptake inhibitor solriamfetol is effective in reducing sleepiness in patients with narcolepsy, according to results of a phase 3 study.

At 150-mg and 300-mg doses, the drug had statistically significant effects on objective and subjective measures.

There are wake-promoting drugs available, such as amphetamine-related drugs that are often used off label, but addiction liability is a concern. The nonamphetamine modafinil has been approved by the Food and Drug Administration since 1998.

Jazz Pharmaceuticals is in the process of submitting solriamfetol for FDA evaluation. If approved, the drug will add to the options available for narcolepsy patients. “All of the available drugs have some limitations. Some have more abuse liability than others. Some have more robust wake-promoting properties than others. We haven’t done any head-to-head comparisons, so I can’t tell you how we will stack up,” Philip Jochelson, MD, said in an interview. Dr. Jochelson is vice president of clinical development at Jazz Pharmaceuticals and presented the results of the study at a poster session at the annual meeting of the American Neurological Association.

An earlier study showed the drug had less abuse potential than the schedule IV stimulant phentermine. That’s not surprising given the drug’s mechanism of action, Dr. Jochelson said. Amphetamine-based drugs stimulate dopamine release, which can prompt a dopamine surge that people equate with a high, he said. Solriamfetol also affects dopamine, but it is a reuptake inhibitor, so it doesn’t produce a surge.

If the drug gains approval, it remains to be seen how it will be classified on the Drug Enforcement Agency Controlled Substance scale. “Where it will fall in that spectrum is speculative at this point,” said Dr. Jochelson.

In the current study, 236 adults (aged 18-75 years) with type 1 narcolepsy were randomized to once-daily placebo, 75 mg solriamfetol, 150 mg solriamfetol, or 300 mg solriamfetol; 27.1% of patients in the 300-mg group discontinued,

compared with 7.3% in the 150-mg group, 16.9% in the 75-mg group, and 10.3% in the placebo group. The mean change from baseline on the Maintenance of Wakefulness Test was statistically significant in

the 300-mg group (12.3 minutes vs. 2.1 minutes for placebo, *P* less than .0001) and the 150-mg group (9.8 minutes vs. 2.1 minutes, *P* less than .0001) but not the 75-mg group (4.7 minutes vs. 2.1 minutes).

The drug also outperformed placebo at week 12 on the Epworth Sleepiness Scale. The mean change in the 300-mg group was -6.4 vs. -1.6 for placebo (*P* less than .001), -5.4 in the 150-mg group (*P* less

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“All of the available drugs have some limitations. Some have more abuse liability than others. Some have more robust wake-promoting properties than others. We haven’t done any head-to-head comparisons, so I can’t tell you how we will stack up.”

than .0001), and -3.8 in the 75-mg group (*P* less than .05).

By both Maintenance of Wakefulness Test and Epworth Sleepiness

Scale measures, the 150-mg and 300-mg solriamfetol groups had statistically significant differences as early as week 1.

The drug had some adverse effects, which were expected based on its pharmacologic profile. These included increases in headache (5.1% with placebo, 10.2% with 75 mg, 23.7% with 150 mg, 30.5% with 300 mg), nausea (1.7% for placebo, 5.1% for 75 mg, 10.2% for 150 mg, 16.9% for 300 mg), anxiety (1.7% with placebo, 1.7% with 75 mg, 5.1% with

150 mg, 8.5% with 300 mg), and insomnia (0% for placebo, 3.4% for 75 mg, 0% for 150 mg, 5.1% for 300 mg). Other adverse events occurring in at least 5% of patients were decreased appetite, nasopharyngitis, and dry mouth.

The study was funded by Jazz Pharmaceuticals. Dr. Jochelson is an employee of Jazz.

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Role of Obstructive Sleep Apnea in HTN

BY SUPRIYA SINGH, MD; AND
KANTA VELAMURI, MD

Hearth disease and stroke are leading causes of death and disability. High blood pressure (BP) is a

major risk factor for both.

The 2017 guidelines regarding “Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure” (JNC 7) were

recently published, which is an update incorporating new information from studies regarding BP-related risk of cardiovascular disease (CVD) and strategies to improve HTN (HTN) treatment and control.

Screening for secondary causes of HTN is necessary for new-onset or uncontrolled HTN in adults, including drug-resistant HTN. Screening includes testing for obstructive sleep apnea, which is highly prevalent in this population.

Obstructive sleep apnea is a common chronic condition characterized by recurrent collapse of upper airways during sleep, inducing intermittent episodes of apnea/hypopnea, hypoxemia, and sleep disruption (Pedrosa RP, et al. *Chest*. 2013;144[5]:1487).

It is estimated to affect 17% of US adults but is overwhelmingly under-recognized and untreated (*JAMA*. 2012;307[20]:2169). The prevalence is higher in men than women. The major risk factors for OSA are obesity, male sex, and advancing age. Since these conditions oftentimes predispose to and are concomitant with HTN, it can be challenging to determine the independent effects of OSA on the development of HTN.

The relationship between obstructive sleep apnea (OSA) and HTN has been a point of interest for decades, with untreated OSA being associated with an increased risk for developing new-onset HTN (*JAMA*. 2012;307[20]:2169).

There have been several landmark trials that have sought to determine the extent of a causal relationship between OSAS and HTN. Sleep Heart Health Study (*Sleep*. 2006;29;1009) was one such study, which was limited by the inability to prove that OSA preceded the onset of HTN.

Wisconsin Sleep Cohort (*N Engl J Med*. 2000;342:1378) was another landmark prospective longitudinal study that implicates OSA as a possible causal factor in HTN. The notable limitation of the study was the presence of HTN after initial assessment was found to be dependent upon the severity of OSA at baseline.

While these two cohort studies found an association between OSA and HTN, the Vitoria Sleep Cohort out of Spain (*Am J Respir Crit Care Med*. 2011;184[11]:1299), the third and most recent longitudinal cohort study, looked at younger and thinner patients than the SHHS and the Wisconsin Sleep Cohort, failed to show a significant association between OSA and incident HTN. Methodologic differences may help to explain the disparity in results.

NREM sleep has normal circadian

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Dr. Singh is Director, Sleep Disorder and Research Center, Michael E. DeBakey VA Medical Center; and Dr. Singh is Assistant Professor and Dr. Velamuri is Associate Professor, Pulmonary, Critical Care and Sleep Medicine, Baylor College of Medicine, Houston, Texas.

variation of BP, causing “dipping” of both systolic and diastolic BP at night due to decreased sympathetic and increased parasympathetic activity. REM sleep has predominant sympathetic activity and transient nocturnal BP surges.

OSA results in hypoxemia, which causes nocturnal catecholamine surges, resulting in nocturnal increase in heart rate and BP that is most prominent during post-apneic hyperventilation.

Reduced nocturnal BP (nondipping) or even higher nocturnal BP than daytime BP is an undoubted risk factor for hypertensive patients due to the end-organ damage and subsequent cardiovascular events. With sleep apnea, sleep quality is decreased due to frequent arousal from sleep (*Hypertension*. 2006;47[5]:833).

Sleep duration of less than or equal to 5 hours per night was shown to significantly increase risk for HTN in patients less than or equal to 60 years of age, even after controlling for obesity and diabetes.

Sleep Heart Health Study suggests that sleep duration above or below a median of 7 to 8 hours per night is associated with a higher prevalence of HTN (*Sleep*. 2006;29:1009). Thus, improving duration and quality of sleep in sleep apnea patients may help decrease the risk of developing HTN.

Key question: Will treatment of OSA appreciably alter BP?

Continuous positive airway pressure (CPAP) is an efficacious treatment of choice for OSA. Interventional trials, though limited by issues related to compliance, have shown CPAP to acutely reduce sympathetic drive and BP during sleep. However, this improvement in BP control is not entirely consistent in all patients with the data being less clear-cut regarding nighttime CPAP therapy and impact on daytime BP.

A randomized controlled trial from Barbe et al suggests that normotensive subjects with severe OSA but without demonstrable daytime sleepiness are immune to the BP-re-

ducing effects of CPAP (*Ann Intern Med*. 2001;134:1015); those who were objectively sleepy had a more robust response to the BP lowering effects of CPAP with better cardiovascular outcomes among patients who were adherent to CPAP therapy (≥ 4 hours per night).

Sleep Apnea Cardiovascular Endpoints (SAVE) study looked at CPAP for Prevention of Cardiovascular Events in Obstructive Sleep Apnea (*N Engl J Med*. 2016;375:919). CPAP significantly reduced snoring and daytime sleepiness and improved health-related quality of life and mood, but the risk of serious cardiovascular events was not lower among patients who received treatment with CPAP in addition to usual care compared with usual care alone. This study was not powered to provide definitive answers regarding the effects of CPAP on secondary cardiovascular end points, and the use of PAP was less than 4 hours.

A recent systematic review and meta-analysis looked at “Association of Positive Airway Pressure with Cardiovascular Events and Death in Adults with Sleep Apnea” (*JAMA*. 2017;318(2):156). No significant associations between PAP treatment and a range of cardiovascular events were noted in this meta-analysis.

It is possible that the limited adherence to therapy in many trials was insufficient to drive protection, along with short follow-up duration of most trials that may have given insufficient time for PAP to have affected vascular outcomes.

In a cross-over study of valsartan and CPAP, combining drug treatment with CPAP appeared to have a more synergistic effect in reducing BP than either agent alone (*Am J Respir Crit Care Med*. 2010;182:954).

The beneficial effect of CPAP remains an open question. Considering the multifactorial pathophysiology of OSA-associated HTN, proven therapies, such as BP lowering, lipid lowering, and antiplatelet therapy, along with PAP therapy, should be utilized. This combination strategy is likely to be more effective in improving both nocturnal and daytime BP control in OSA.



2018 Education Calendar



Live Learning Courses

Courses held at the CHEST Innovation, Simulation, and Training Center in Glenview, Illinois.

Mechanical Ventilation: Advanced Critical Care Management

February 15-17 | July 26-28

Comprehensive Bronchoscopy With Endobronchial Ultrasound

March 1-3 | September 20-22

Ultrasonography: Essentials in Critical Care

March 8-10 | September 13-15 | November 29-December 1

Advanced Clinical Training in Pulmonary Function Testing

April 7-8

Bronchoscopy Procedures for the ICU

May 5-6

Advanced Critical Care Echocardiography

June 1-3

Difficult Airway Management

June 8-10 | September 7-9

Lung Cancer: A Multidisciplinary Course for Pulmonologists Covering Current Paradigms for Diagnosis and Management

July 13-15

Bronchoscopy and Pleural Procedures for Pulmonary and Critical Care Medicine Fellows

July 20

Advanced Diagnostic and Therapeutic Bronchoscopy

August 4-5

Cardiopulmonary Exercise Testing (CPET)

August 10-12

Critical Skills for Critical Care: A State-of-the-Art Update and Procedures for ICU Providers

August 24-26

Comprehensive Pleural Procedures

November 3-4

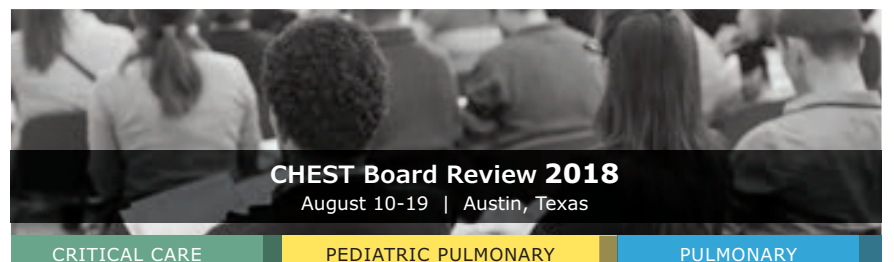
Critical Care Ultrasound: Integration Into Clinical Practice

November 9-11

Venovenous ECMO for Respiratory Failure

December 7-9

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August 10-19 | Austin, Texas

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Calendar subject to change. For most current course list and more information, visit livelearning.chestnet.org.

Yoga benefits lung cancer patients and caregivers

BY ANDREW D. BOWSER

Frontline Medical News

Yoga provides physical and mental benefits for both lung cancer patients and their caregivers, according to results of a randomized study presented at the Palliative and Supportive Care in Oncology Symposium.

“Overall, we are encouraged by the findings,” said lead study author Kathrin Milbury, PhD, of University of Texas MD Anderson Cancer Center, Houston.

“We demonstrated that patients undergoing treatment for lung cancer are not too sick to participate in a behavioral supportive care intervention,” Dr. Milbury said in a press conference. “Both patients and caregivers reported to have enjoyed the experience, and it gave them a

time away from cancer, and [they] learned something new together.”

This study provides preliminary evidence that a yoga program can provide a “buffer” and improve physical function for patients, as well as self-reported improved quality of life for both patients and their caregivers, she added.

All patients in the study had non-small cell lung cancer and were undergoing thoracic radiation therapy, which can cause respiratory toxicities that negatively affect quality of life and physical activity, according to Dr. Milbury and her coinvestigators.

A total of 32 patient-caregiver dyads were randomized to participate in 15 yoga sessions or to be in a “wait-list” control group, and 26 dyads completed all assessments.

Patients who practiced yoga had

significantly better scores on a 6-minute walking test (478 vs. 402 for wait-list enrollees; *P* less than .05), plus better stamina and mental health. Caregivers had improved fatigue and better stamina at work.

Almost all patients (96%) rated the program as “very useful,” investigators reported at the symposium co-sponsored by AAHPM, ASCO, ASTRO, and MASCC.

This study provides additional evidence that yoga and other nonpharmacologic supportive therapies “can be integrated into not only the care of cancer patients, but also the family caregivers who support them,” ac-

ording to Andrew S. Epstein, MD, of Memorial Sloan Kettering Cancer Center, New York.

Next, the researchers plan to conduct a larger, randomized controlled trial with a more stringent comparison group, according to Dr. Milbury.

VIEW ON THE NEWS

M. Patricia Rivera, MD, FCCP,

comments: This is an interesting study further supporting the benefits of yoga and meditation when dealing with a chronic illness such as lung cancer. The benefits included reducing stress and improving quality of life, not only for the patient but also the caregiver.



Defining quality in lung cancer surgery

BY RICHARD MARK KIRKNER

Frontline Medical News

Implementing quality initiatives and creating reporting mechanisms for lung cancer patients can lead to better outcomes, including overall survival. While barriers exist – namely the conflicting perspectives of providers, payers, hospitals, and patients – thoracic oncologic surgeons should seize the opportunity to establish robust quality and value metrics for lung cancer programs, said Whitney S. Brandt, MD, and her coauthors in an expert opinion in the *Journal of Thoracic and Cardiovascular Surgery* (2017;154:1397-403).

Dr. Brandt, a surgeon at Memorial Sloan Kettering Cancer Center in New York, and her coauthors examined the key elements of quality and value initiatives, categorizing them into preoperative, intraoperative, and postoperative components and primarily focusing on early stage lung cancer.

The preoperative evaluation should at least include CT imaging of the tumor and, for smokers, smoking cessation, said Dr. Brandt and her coauthors. All candidates for pulmonary lung resection should have spirometry and diffusion capacity tests; furthermore, both predicted postoperative forced expiratory volume in 1 second and diffusing capacity of the lungs for CO should be calculated. “Patients with a predicted postoperative value less than 40% for either measurement should be considered high risk for lobectomy and should be offered either sublobar resection or nonsurgical therapy,” they recommended.

Dr. Brandt and her colleagues also clarified preoperative management of patients with cardiac disease. Only patients with significant cardiac disease risk factors need to undergo cardiac testing before lung surgery, and patients with stable cardiac disease do not require

revascularization beforehand.

For preoperative staging, the most comprehensive clinical guidelines come from the National Comprehensive Cancer Network, they stated. The guidelines recommend that all patients with a small cell lung cancer or stage II to IV non-small cell lung cancer (NSCLC) receive a brain MRI or – if that’s not available – a head CT with contrast to assess for brain metastasis.

Intraoperative quality measures take into account the surgical approach, including cost, resection and margins, and lymph node evaluation. With regard to surgical approach, trials have shown traditional video-assisted thoracoscopic surgery (VATS) lobectomy results in shorter hospital stays and thereby lower costs, as well as fewer complications and deaths, than thoracotomy, said Dr. Brandt and her coauthors. But that cost advantage has not yet carried over to robotic-assisted VATS. That said, “robotic-assisted VATS remains a relatively new technology, and with time and increased robotic platform competition, costs will likely decrease.”

Dr. Brandt and her coauthors also noted that clinical trials support resection margins of 2 cm in patients having surgery for NSCLC and that adequate lymph node evaluation is a critical component of a lung cancer quality initiative. “Regardless of whether lymph nodes are sampled or dissected, we believe that systematic acquisition of mediastinal nodal tissue based on nodal station(s) is a useful quality metric, and, therefore, we recommend each program adopt a preferred approach and track adherence,” they said.

As for postoperative quality metrics, the most obvious are morbidity and mortality. “A quality program should track 30-day or in-hospital mortality, as well as 90-day mortality, following lung cancer resection.” Such metrics can serve as

VIEW ON THE NEWS

M. Patricia Rivera, MD, FCCP, comments:

Despite advances in diagnostic and therapeutic interventions, overall lung cancer survival remains low, and gains in survival over time have been modest. This is likely explained by advanced disease at the time of diagnosis although an alternative explanation is suboptimal care delivery. Although quality metrics and gaps may be difficult to measure due to challenges in defining quality, a better understanding of gaps in quality of care and disparities in the delivery of care is necessary in order to pursue quality improvement. As the authors point out in this study, in lung cancer surgery, adherence to known quality metrics such as guideline-based preoperative evaluation and systematic acquisition of mediastinal nodes results in improved patient outcomes.

“starting points” for quality improvement initiatives. Length of stay has also emerged as an important metric because it is a surrogate of other metrics, such as patient comorbidities, age, and socioeconomic status. “Length-of-stay metrics likely need to be risk-stratified on the basis of these and other variables to be meaningful to a practicing surgeon,” Dr. Brandt and her coauthors said, adding that “studying the effectiveness of enhanced recovery after surgery programs in thoracic surgical oncology poses an opportunity for a well-designed trial.”

Dr. Brandt and her coauthors reported no financial disclosures. The National Institutes of Health/National Cancer Center provided grant support.

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Ultrathin bronchoscopy plus radial EBUS unreliable

BY MITCHEL L. ZOLER

Frontline Medical News

AT CHEST 2017 ■ TORONTO – Ultrathin bronchoscopy plus radial endobronchial ultrasound is not a great method for determining whether a suspicious lesion is cancerous or benign, suggests new research.

In this study of patients with CT-detected solid lung lesions, the researchers were able to make a diagnosis for only 49% of those whose nodules were evaluated using ultrathin bronchoscopy plus radial endobronchial ultrasound (EBUS). “You have a 50/50 chance” of making a diagnosis using an ultrathin bronchoscope plus radial EBUS, said Nichole T. Tanner, MD, FCCP, at the CHEST annual meeting. “I think you need to be thoughtful about how you use this technology,” said Dr. Tanner, a pulmonologist and critical care medicine physician at the Medical University of South Carolina in Charleston.

“When you do CT-guided biopsies of lung lesions, the [diagnostic] yield is about 94%,” she noted.

The study compared the diagnostic yield of ultrathin bronchoscopy plus radial EBUS with standard bronchoscopy and fluoroscopy in patients with CT-detected solid lung lesions 1.5-5.0 cm in size. It ran at five U.S. centers and randomized 221 patients: 85 evaluable patients were tested using the standard methods and 112 evaluable patients were tested using ultrathin bronchoscopy plus radial EBUS. Patients averaged 65-68 years of age and were divided evenly be-



Dr. Nichole T. Tanner speaks at the CHEST annual meeting.

tween women and men. Their lesions averaged slightly more than 3 cm. The ultrathin device had a 4-mm-wide diameter and had a 2-mm working channel.

The diagnostic yield was 38% among patients who underwent standard bronchoscopy and fluoroscopy and 49% among those biopsied using ultrathin bronchoscopy and radial EBUS, Dr. Tanner reported. The between-group difference in yield fell short of being statistically significant.

Forty-six of the 53 patients who were not diagnosable using standard bronchoscopy and fluoroscopy crossed over to the investigational method, which produced a diagnosis for an additional seven patients (15% of the biopsied crossover patients).

Dr. Tanner disclosed financial relationships with several companies, including having served as a consultant to and received research funding from Olympus, which funded this study.

mzoler@frontlinemedcom.com

MITCHEL L. ZOLER/FROTLINE MEDICAL NEWS

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VIEW ON THE NEWS

M. Patricia Rivera, MD, FCCP, comments: Although bronchoscopic tools are safe and accurate to evaluate both central and peripheral lung lesions, the diagnostic yield of the different available techniques is variable. In this study, a diagnostic yield of only 49% was achieved when ultrathin bronchoscopy with radial EBUS was performed for diagnosis of solid nodules. This yield is not much better than that obtained from conventional bronchoscopy with fluoroscopic guidance and much lower than the diagnostic yield from transthoracic needle biopsy. While there is no doubt that the advances in minimally invasive technologies for diagnosing lung nodules and diagnosing and staging lung cancer have revolutionized clinical practice, pulmonologists and thoracic surgeons need to recognize not only the utility but also the limitations of the available diagnostic procedures (as well as the cost). These technologies are complimentary and multidisciplinary discussions should facilitate selection of the best procedure for each individual case.

This Month in CHEST®

Editor's Picks

BY RICHARD S. IRWIN, MD, MASTER FCCP

Editor in Chief, CHEST

EDITORIAL

Introducing the CHEST Teaching, Education, and Career Hub
Dr. G. T. Bosslet and Dr. M. Miles

TRAINING, EDUCATION, AND CAREER HUB - TEACH

Strategies for Success in Fellowship

Dr. R. W. Ashton, et al.

COMMENTARY

Higher Priced Older Pharmaceuticals: How Should We Respond?

Dr. R. S. Irwin, et al.

GIANTS IN CHEST MEDICINE

Jeffrey M. Drazen, MD, FCCP
Dr. A. S. Slutsky

EVIDENCE-BASED MEDICINE

Classification of Cough as a Symptom in Adults and Management Algorithms: CHEST Guideline and Expert Panel Report

Dr. R. S. Irwin, et al.



ORIGINAL RESEARCH

Three-Hour Bundle Compliance and Outcomes in Patients With Undiagnosed Severe Sepsis

Dr. A. S. Deis, et al.

A Phase II Clinical Trial of Low-Dose Inhaled Carbon Monoxide in Idiopathic Pulmonary Fibrosis

Dr. I. O. Rosas, et al.

New CHEST Physician Leadership for 2018

David A. Schulman, MD, FCCP, is the new Editor in Chief of CHEST Physician. He is a Professor in the

Division of Pulmonary, Allergy, Critical Care and Sleep Medicine at Emory University in Atlanta, where he also directs the pulmonary and critical care fellowship program. He has

served on the CHEST Sleep Network and the Education Committee and currently serves on the Training and Transitions Committee and the Board of Regents. Dr. Schulman's primary area of academic interest is on faculty development in the domains of teaching and assessment. He will serve as the Chair of the CHEST 2018 Scientific Program Committee, where he will focus on crafting novel, interactive programming that will improve attendee en-

gagement and retention.

What are the top three things Dr. Schulman hopes to accomplish as Editor in Chief of *CHEST Physician*?

1 Improve interactivity between CHEST Physician and its readership, to improve our ability to craft the publication that best meets the needs of its readers.

2 Create more opportunities for CHEST Physician to serve as the voice of CHEST members, by increasing space for members and leaders to write for the publication.

3 Build on the incredibly successful work of my predecessor, Dr. Vera DePalo.

Christopher Lettieri, MD, FCCP, is the new Section Editor for Sleep Strategies. He is a Professor of Medicine, Division of Pulmonary and Critical Care Medicine, at the Uniformed Services University of the Health Sciences in Bethesda, Maryland. Dr. Lettieri has previously served as the Chief and Medical



DR. SCHULMAN

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Call for Abstracts & Case Reports

Submit your original investigative research for presentation at next year's annual meeting in San Antonio. Accepted abstracts and case reports (excluding clinical case puzzlers) will appear in an online supplement to the journal *CHEST*®.

Two types of abstracts will be considered:

- Slide presentations
- Poster presentations

Four types of case reports will be considered:

- Fellow case reports
- Medical student/resident case reports
- Global case reports
- Clinical case puzzlers

All submissions are due Friday, March 2.

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March 8-10

Advanced Clinical Training in Pulmonary Function Testing
April 7-8

Bronchoscopy Procedures for the ICU
May 5-6

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DR. LETTIERI

Director of the Sleep Disorders Center at the Walter Reed National Military Medical Center, and as the Program Director for the National Capital Consortium's Sleep Medicine Fellowship training program. He is currently assigned as the Pulmonary and Critical Care Consultant to the Army Surgeon General, and as the Director of Global Health and Senior Clinical Advisor to the Joint Chiefs of Staff. Dr. Lettieri's research interests include enhancing PAP adherence and improving outcomes in sleep disorders related to PTSD and TBI.

Angel Coz, MD, FCCP, is the new Section Editor for Critical Care Commentary. He is an Associate Professor of Medicine at the University of Kentucky and the Lexington Veterans Affairs Medical Center. He is the Chair of CHEST's Critical Care NetWork and has served in the Clinical Pulmonary Medicine NetWork Steering Com-

mittee and the Nominating Committee. He has led ICU quality improvement initiatives, including early detection and aggressive management of sepsis. Dr. Coz interests include medical education, sepsis, and ICU quality improvement. He has given multiple talks on sepsis and critical care topics nationally and internationally. He was recently recognized as a Distinguished CHEST Educator. Dr. Coz was very active also in developing the simulation-based difficult airway course for CHEST.



DR. COZ

CHEST extends very special thanks to the following *CHEST Physician* editors for their 3 years of dedicated service in the following roles:

Vera de Palo, MD, FCCP – *Editor in Chief*

Lee Morrow, MD, FCCP – *Section Editor for Critical Care Commentary*

Jeremy Weingarten, MD, FCCP – *Section Editor for Sleep Strategies*

Live Streaming at CHEST 2017

BY KRISTI BRUNO

CHEST Director of Communications, Media, and Marketing

In April 2016, Facebook launched Facebook Live, a tool for live streaming to a Facebook page to share live video with their followers on Facebook. At CHEST 2016, the CHEST New Media team began to experiment with live video with some early success. The CHEST 2017 team made the decision, based on the organization's goal to help educate clinicians to improve patient care, to live stream complete sessions from CHEST 2017. With the help of the CHEST 2017 Education Committee and the Social Media Work Group, more than 25 sessions were selected and live streamed.

CHEST's efforts on Facebook Live resulted in the following:

- Total people reached: 133,737
- Total video views: 34,449
- Total minutes watched: 30,786 (or 513 hours, or 21 days)
- Total interactions: 1,050 (eg, likes, loves, hahas, etc)

- Total shares: 302

The content concept was well received, and comments ranged from followers chiming in with their location, appreciation for live streaming, and even comments from patients.

- "Thank you for sharing this live presentation."
 - "Here from Mexico !!"
 - "Here from Natal/RN, Brazil"
 - "Here from Milan, Italy."
 - "Appreciate this live streaming on important sessions, big service for those who couldn't attend!!"
 - "My brother survived after six days on ECMO. I am so glad to have him."
 - "It's a great chance for physicians working in pulmonology and general practice to get the pearls of guidelines from American College to improve clinical practice. Now distance doesn't matter"
- Plans are underway for live streaming from CHEST 2018 in San Antonio. To view the CHEST 2017 live stream videos, visit CHEST's Facebook page, [facebook.com/acpcchest](https://www.facebook.com/acpcchest).



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Registration opens spring 2018. We hope to see you in San Antonio, October 6 to 10.

Details Coming Soon | chestmeeting.chestnet.org

Winners-All at CHEST 2017

With the great success of CHEST 2017, everyone who shared that event is a winner. But, we would especially like to call out some of the special winners who were recognized during our meeting in Toronto.

CHEST 2017 Awards

- **College Medalist Award**
Sidney Braman, MD, Master FCCP
- **Distinguished Service Award**
Nancy Collop, MD, FCCP
- **Master FCCP**
Suhail Raouf, MD, Master FCCP
- **Master FCCP**
Sidney Braman, MD, Master FCCP
- **Early Career Clinician Educator**
Septimiu Murgu, MD, FCCP
- **Master Clinician Educator**
Stephanie Levine, MD, FCCP
- **Presidential Citation**
Sanjeev Mehta, MD, FCCP
- **Presidential Citation**
Lisa Moores, MD, FCCP
- **Alfred Soffer Award for Editorial Excellence**
Christopher Carroll, MD, FCCP
Deep Ramachandran, MBBS

Honor Lectures

- **Thomas L. Petty, MD, Master FCCP Memorial Lecture**
Personalized Treatment in COPD: A New Era of Treatment Options
Gerard J. Criner, MD, FCCP
- **Presidential Honor Lecture**
Passion, Perseverance, and Quantum Leaps: Major Advances in Lung Cancer Care
M. Patricia Rivera, MD, FCCP
- **Margaret Pfrommer Memorial Lecture in Long-term Mechanical Ventilation**
When Air becomes BREATH...and a LIFE worth living
Audrey King, MA
- **Distinguished Scientist Honor Lecture in Cardiopulmonary Physiology**
Sleep, Death and the Heart
Virend K. Somers, MD, PhD, FCCP
- **Pasquale Ciaglia Memorial Lecture in Interventional Medicine**
Augmented Reality: Getting Real in Procedural Education
Carla R. Lamb, MD, FCCP
- **Roger C. Bone Memorial Lecture in Critical Care**
If You've Seen One ICU You've Seen All ICUs: Evidence-based Recommendations for the Organization of Critical Care
Gordon D. Rubenfeld, MD, MS
- **Edward C. Rosenow III, MD, Master FCCP/Master Teacher**

Honor Lecture

- *"Pills" and the Air Passages*
Atul C. Mehta, MBBS, FCCP
- **Murray Kornfeld Memorial Founders Lecture**
Trying to Change Clinical Practice: The Barcelona Respiratory Research Group
Antonio Torres Marti, MD, PhD, FCCP

CHEST Foundation Grant Awards

- **CHEST Foundation Research Grant in Nontuberculous Mycobacteria**
Keira Cohen, MD
- **CHEST Foundation and the Alpha-1 Foundation Research Grant in Alpha-1 Antitrypsin Deficiency**
Diana Crossley, MBChB
- **CHEST Foundation Research Grant in Asthma**
Drew Harris, MD
- **CHEST Foundation Research Grant in Pulmonary Fibrosis**
Kerri Johannson, MD, MPH
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Kathleen Ramos, MD, MS
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Sandeep Sahay, MD, FCCP
- **CHEST Foundation Research Grant in Lung Cancer**
Kei Suzuki, MD
- **GlaxoSmithKline Distinguished Scholar in Respiratory Health**
Richard Wunderlink, MD, FCCP
- **CHEST Co-Branded Community Service Initiatives**
Sandra Adams, MD, MS, FCCP
Mary Hart, RRT, MS, FCCP
- **GAIN NSCLC Summits Community Service Grant**
J. Scott Ferguson, MD, FCCP
- **CHEST Foundation Community Service Grants Honoring D. Robert McCaffree, MD, Master FCCP**
Negin Hajizadeh, MD, MPH
Adam Silverman, MD

Case Report Poster Winners

- Javier Ramos Rossy, MD
- Bikash Bhattarai, MD
- Nikita Leiter, MD

- Lindsay Boole, MD, MPH
- Muhammad Hammami, MD
- Jonathan Dewald, MD
- Ahmed Mahgoub, MD
- Ali Saeed, MD
- Aditya Kotecha, MD
- David Attalla, MD
- **CHEST Challenge Winners**
San Antonio Military Medical Center
- David Anderson, DO
- Paul Hiles, MD, BSc
- Tyson Sjulín, DO
- **Alfred Soffer Research Award Winners**

- Marcos Restrepo, MD, MSc, FCCP: *Anti-MRSA Coverage Overutilization as Empiric Therapy for Hospitalized Patients With Community-acquired Pneumonia and Health-care Associated Pneumonia*
- Michael Perkins, MD: *Rothman Index Predicts ICU Mortality at 24 hours*

Young Investigator Award Winners

- Adam Przebinda, MD: *Analysis of a Hospital-based Multimodal Quality Improvement Intervention to Improve Recognition and Treatment of Sepsis*
- Roozehra Khan, DO, FCCP: *Growth in Social Media & Live-Tweeting at Major Critical Care Conferences: Twitter Analysis of Past 4 Years*

Top 5 Slide Presentation Winners

- Jonathan Corren, MD: *Dupilumab Improves Asthma Control and Asthma-Related Quality of Life in Uncontrolled Persistent Asthma Patients Across All Baseline Exacerbation Rates*
- Aaron B. Holley, MD, FCCP: *Heparin prophylaxis does not prevent VTE in the presence of acute kidney injury*
- Anil Vachani, MD, FCCP: *A Blood-based Multi-gene Expression Classifier to Distinguish Benign from Malignant Pulmonary Nodules*
- Abhishek Mishra, MD: *Comparison of Catheter directed thrombolysis vs systemic thrombolysis in pulmonary embolism: A propensity score match analysis*
- David E. Ost, MD, MPH, FCCP: *Comparison of Practice Patterns and Outcomes for Recurrent Malignant Pleural Effusions*

Case Report Slide Winners

- Christian Castaneda, MD: *Levofloxacin-Induced Acute Eosinophilic Pneumonitis: A Case Report And Review*
- Lucian Marts, MD: *The Proof Is In The Platelets*
- Fuad Aleskerov, MD: *Disseminated Resistant Nocardiosis In Previously Healthy Male*

- Taylor Myers, MD: *Spontaneous Regression Of Non-Small Cell Lung Cancer*
- Amin Pasha, MD: *Is Fat Always Bad? A Case Study Demonstrating The Lifesaving Effect Of Lipid Emulsion Therapy In Beta Blocker And Calcium Channel Blocker Overdose*
- Anish Geevarghese, MD: *The Use Of Venovenous-ECMO For Refractory Hypoxemia Following Liver Transplantation In A Patient With Hepatopulmonary Syndrome*
- Juilio Huapaya, MD: *Hemophagocytic Lymphohistiocytosis Induced By Histoplasmosis In A Kidney Transplant Patient: Are Steroids Really Necessary?*
- Stephen Doyle, DO, MBA: *Diffuse Pulmonary Nodules: A Rare Infection Causing A Common Problem*
- Catherine Millender, MD: *An Intriguing Case Of Recurrent Bilateral Massive Chylothoraces: Is This Pleural Sarcoidosis?*
- Andrew Lewis, DO: *Transformation Of Benign Metastasizing Leiomyoma (BML) To Leiomyosarcoma*
- Fady Youssef, MD: *Tracheal Leiomyosarcoma Causing Critical Airway Obstruction*
- Kevin Charles, MD: *Pulmonary Metastasis Of Mandibular Ameloblastoma: A Case Report*
- Audra Fuller, MD: *Endobronchial Lipomatous Hamartoma Mimicking Malignancy*
- Lana Alghothani, MD: *Idiopathic Pneumonia Syndrome In Patient With Gray Zone Lymphoma Successfully Treated With Etanercept*
- Aaron Lampkin, MD: *These Aren't The Paraproteins You Have Been Looking For: A Case Of Light Chain Deposition Disease*
- Tyler Church: *His Heart Was Three Sizes Too Smallpox*
- Ki-Yoon Kim, MD: *Coma Secondary To Rickettsia Typhi*
- Nicole Ruopp, MD: *Epoprostenol And Ascites: A High Output State Or Not?*
- Stephanie Guo, MD: *Neuroendocrine Cells And A Spectrum Of Disease*
- Justin Chiam, MBBS: *A Diagnostic Challenge Of Haemoptysis In A TB Endemic Southeast Asian Country*

NetWork Challenge Winners

- **First Round:** *Home-Based Mechanical Ventilation and Neuromuscular Disease NetWork, and Women's Health NetWork*
- **Second Round:** *Home-Based Mechanical Ventilation and Neuromuscular Disease and Practice Operations*
- **Third Round:** *Home-Based Mechanical Ventilation and Neuromuscular Disease and Practice Operations*

Another Small Win to Raise the Tobacco Purchasing Age to 21

BY KIM FRENCH, MHSA, CAPP
CHEST Foundation Trustee

The Elk Grove Village, Illinois, Board of Trustees passed the “Tobacco 21” ordinance that will raise the tobacco purchasing age to 21, which includes nicotine vaping. The policy, which will go into effect January 1, 2018, will protect young people from beginning a lifetime of addiction and, ultimately, save their lives.

Kevin L Kovitz MD, MBA, FCCP, attended the Village Board meeting to advocate for “Tobacco 21.” He is a Sustaining Member of the CHEST Foundation, continually exemplifying what it is to be a lung health champion.

Dr. Kovitz noted, “This poli-

cy will protect our kids from the scourge of Big Tobacco and save funding for health-care costs and, most importantly, will ultimately save lives. The ordinance will protect the most vulnerable parts of our population, our children. Raising the legal age puts tobacco products on par with alcohol and protects young adults from developing a dangerous lifelong habit.”

Five US states have also passed Tobacco 21; they include California, Hawaii, Maine, New Jersey, and Oregon. There are many local ordinances around the country but more are needed.

Advocating for this ordinance demonstrates the effectiveness of grassroots advocacy in our local communities.

Smart Ways to Give More Now

Your gift today truly has an immediate impact that makes a difference now.

We also want you to benefit as much as possible from your generosity.

Gifts of Appreciated Securities, Mutual Funds, and Investments

If you have owned any of these longer than 1 year and they have appreciated in value, they provide a smart option for gifting. You will avoid the capital gains tax, and you also receive a charitable income tax deduction if you itemize your tax return.

The Charitable Individual Retirement Plan Option

If you are 70 1/2, you may distribute funds from your IRA directly to the CHEST Foundation.

You will not pay any income taxes, and it will also qualify for your re-



quired minimum withdrawal. You may distribute up to \$100,000 per person per year (\$200,000 if you are married and both own an IRA).

Retirement Plan Beneficiary Designation

You may also designate a charity as a beneficiary of your IRA, 401K, or 403B.

This will avoid any income tax, so 100% will be directed to the charity of your choice.

For more information on these and other ways to support the CHEST Foundation, confidentially and with no obligation, contact Angela Perillo, CHEST Director of Development & Foundation Operations, at aperillo@chestnet.org.

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News From American Association of Critical-Care Nurses (AACN)

AACN has published a new edition of “AACN Scope and Standards for Acute Care Nurse Practitioner Practice” to reflect the specialty’s evolving role and an ever-changing critical care landscape.

First issued in 2006 and previously updated in 2012, the new edition describes and measures the expected level of practice and professional performance for acute care nurse practitioners (ACNPs). The 2017 edition, which came from collaboration from a work group of ACNP subject matter experts convened by AACN collaborated to update the content to reflect current practice incorporates advances in scientific knowledge, clinical practice, technology and other changes in the dynamic healthcare environment. It addresses the full scope of practice for ACNPs, including those whose education and training prepare them to care for children with acute and critical illnesses. It also aligns with the “Consensus Model for APRN Regulation” — also called the LACE Model — developed to create nation-

ally congruence for licensure, accreditation, certification, and education of advanced practice nurses.

“The role of acute care nurse practitioners continues to expand as more hospitals and healthcare organizations discover the value of having ACNPs on staff,” said Linda Bell, AACN clinical practice specialist and editor of the publication. “Patients who used to be hospitalized are now cared for throughout the healthcare system. As a result, the services or care provided by ACNPs and other advanced practice providers are not defined or limited by setting but rather by patient care needs.”

These standards are a valuable resource for acute care pediatric nurse practitioners (CPNP-AC), adult ACNPs (ACNPC-AG or ACNP-BC) and those developing educational programs for advanced nursing practice, job descriptions and credentialing, among other uses.

New edition of ACNP Scope and Standard is available from American Association of Critical-Care Nurses (aacn.org).

Miss Out on CHEST 2017?

If you were unable to attend CHEST 2017 in Toronto, don't worry, you can still gain access to the recorded session content.

CHEST members	\$199
Nonmembers	\$299

The CHEST 2017 recorded sessions include all of the presentations from the top clinicians and researchers in chest medicine featured at this year’s annual meeting. Access includes a 1-year subscription to the mp4 video files from this year’s live sessions, including lectures and slide presentations.

Content will include the latest relevant research and discussions on:

- Chest infections
- Critical care medicine
- Obstructive lung disease
- Lung cancer
- Obstructive sleep apnea
- Pediatric pulmonary medicine

And much more.



Complete Details
chestnet.org/CHEST2017Recordings

Note: CHEST 2017 registrants receive the recorded sessions for free. These free recordings will be available online for the next year. Note, files are not downloadable and must be played from a device with an internet connection. This product is not eligible for CME credit.

CHEST President, Dr. John Studdard on the Search for a New Editor in Chief for *CHEST*[®]

CHEST[®], the flagship peer-reviewed journal of the American College of Chest Physicians (CHEST), is seeking applicants for the next Editor in Chief (EIC). President of CHEST, Dr. John Studdard, has given some insight into the successes of the journal during current EIC, Dr. Richard Irwin's tenure, and what we can expect from the respected individual who will take his place in 2019.

"From my perspective as a community-based physician practicing pulmonary, critical care, and sleep medicine, I believe the responsibility of member-based organizations like CHEST is to ensure that we create meaningful science, create outstanding education, and work to ensure these are disseminated and implemented. One of the most important vehicles that we depend on is our *CHEST*[®] journal.



DR. STUDDARD

as the face of the organization is an incredibly important aspect of what it means to the CHEST organization as a whole."

Dr. Studdard's insights as to some of the successes and the future of *CHEST*[®]:

Question: What is your view on the successes of the journal over Dr. Irwin's tenure?

Answer: A. The journal consistently

CHEST[®] is more than just a medical journal; it is the face and brand of the American College of Chest Physicians. Recognition and awareness of the journal

- ranks as the #1 relevant journal for respiratory clinicians and providers.
- B. The journal's "impact factor" has increased significantly, which supports its efforts to attract the best clinical research and content.
 - C. New sections added provide applicable clinical information, address hot and controversial topics, and underscore the human side of medicine to support the best patient-focused care.
 - D. The continual improvement of our online platform, including development of multimedia content and other innovations that take advantage of the digital evolution of online content delivery.
 - E. Last, but not least, I believe our members who are clinicians consider *CHEST*[®] to be the one

journal to review cover to cover and to be their "go to" journal for relevant clinical insights and information.

Question: What challenges does CHEST expect the next EIC to be facing?

Answer: We clearly practice in an environment where there are constant pulls for the time and attention of clinicians ... a constant influx of information and education in multiple formats and delivery systems. The journal *CHEST*[®] must highlight the information we need most that will impact patient care. Our new EIC, and the team assembled, will need to solicit the best research, continue our digital evolution, and ensure they are delivering this infor-

Continued on following page

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NETWORKS

BP targets questioned, *Candida auris* infections

Cardiovascular Medicine and Surgery

The Holy Grail of Blood Pressure Management?

Blood pressure treatment recommendations have been confusing over the past few years. The Joint National Committee (JNC) 8 stirred up controversy in 2014 because they raised the recommended tolerating systolic blood pressures, in certain people aged 60 and above, up to 150 mm Hg [James, et al. *JAMA*. 2014;311(5):507-520]. The new AHA/ACC hypertension guidelines cosponsored by 11 societies generated controversy because they changed the definition of hypertension (normal <120/80 mm Hg, elevated 120-129/80-89, stage 1 130-139/80-89, or stage 2 >140/90) [Whelton et al. *J Am Coll Cardiol*. 2017 pii:S0735-1097(17)41519-1]. The SPRINT trial [Wright, et al. *N Engl J Med*. 2015;373:2103-2116] largely influenced these recommendations. SPRINT demonstrated a 25% relative risk reduction of heart attack, stroke, cardiovascular death, or decompensated heart failure with more aggressive blood pressure management (BP goal <120/90 vs <140/90).

This new classification would label 46% of Americans, or 103.3 million people, as hypertensive. However, there is uncertainty in how broadly applicable the SPRINT results are, particularly in those under the age of 45. The majority of large clinical trials, including SPRINT, have limited numbers of patients who were less than 50 years old and, therefore, it is unknown if younger patients benefit to the same degree. The absolute improvement is also questionable because as an editorial points out [Welch, "Don't Let New Blood Pressure Guidelines Raise Yours" *NY Times*. Nov. 15, 2017], the primary endpoint in SPRINT only occurred in less than or equal to 8% of patients.

These guidelines reinforce the need to measure ambulatory blood pressures, perform proper in-office blood pressure measurements, and emphasize lifestyle modifications. Whether aggressive blood pressure management is worth the potential risks and the degree to which ideal blood pressure measurement can be applied to real world practices, remains uncertain.

David J. Nagel, MD, PhD
Steering Committee Member

Chest Infections

Candida auris

Invasive fungal infections are frequently managed by ICU physicians and are a leading cause of mortality among critically ill patients. Invasive candidiasis is associated with an attributable mortality rate of up to 49%. Historically, the majority of these infections has been caused by *Candida albicans*, but this may be changing.

The first outbreak of *Candida auris* in the Americas (18 patients) occurred in the ICU of a hospital in Venezuela. Resistance to common azoles was documented, and half of the isolates showed decreased susceptibility to amphotericin B. As of August 2017, a total 153 clinical cases of *C auris* infection have been reported to CDC from 10 US states; most have occurred in New York and New Jersey.

What has been learned from these cases is that close contacts can be colonized, colonization can be persistent (approximately 9 months), the yeast can survive in the hospital environment, bleach or sporicide is needed for elimination, isolation precautions are recommended as for MDRO bacteria, and serial resistance to echinocandins has been observed.

Principal takeaways:

- 1 *Candida auris* isolates are often MDR, with some strains having elevated MICs to drugs in all the three major classes of antifungal medications.
 - 2 The isolates are difficult to identify and require specialized methods, such as MALDI-TOF or molecular identification based on sequencing.
 - 3 Misidentification may lead to inappropriate treatment.
 - 4 *C auris* has the propensity to cause outbreaks in health-care settings, as has been reported in several countries, and resistance may result in treatment failure.
- Richard Winn, MD, MS, FCCP
Immediate Past Chair

References

1. Sarma S. Current perspective on emergence, diagnosis and drug resistance in *Candida auris*. *Infect Drug Resistance*. 2017;10:155-165.
2. Pan American Health Organization/World Health Organization. Epidemiological Alert: *Candida auris* outbreaks in health care services. October 3, Washington, DC: PAHO/WHO; 2016.
3. Centers for Disease Control and Prevention. Global emergence of invasive infections caused by the multidrug-resistant yeast *Candida auris*. CDC; 2016 [updated June 24, 2016]

EIC Search continued from previous page

mation in the way that our members and learners find the most accessible.

Question: Where do "we" want the journal to go?

Answer: Your leadership of the American College of Chest Physicians has great respect for the editorial independence of the journal. The EIC and the Editorial Board that is assembled will lead where the journal goes. As the embodiment of the brand of the CHEST organization, we clearly want to see the journal continue to be the authoritative, respected, trusted, "go to" resource for clinical pulmonary, critical care, and sleep medicine professionals.

CHEST is now accepting applications for the position of Editor in Chief of the *CHEST* journal. For more information visit <http://info.chestnet.org/editor-in-chief>. Applications are due by February 1, 2018.

Congratulations, CHEST!

2017 Accreditation With Commendation

On December 2, CHEST received Accreditation with Commendation from the Accreditation Council for Continuing Medical Education (ACCME). This achievement grants CHEST accreditation through November 2023, and places the organization in the highest tier of continuing medical education (CME) providers.

"It is a true privilege to serve as a member of our outstanding CHEST Education team. We are very proud of our education program and have worked very hard to provide CHEST members and their health-care team with state-of-the-art learning opportunities," said Alex Niven, MD, FCCP, current Chair of CHEST's Education Committee, "ACCME Accreditation with Commendation is an important benchmark of this success, and we look forward to further advancing CHEST's leadership role in medical education through its simulation, active learning, and other innovative

educational offerings."

To receive accreditation from the ACCME, CHEST met all of the requirements of the ACCME, has transitioned clinician knowledge into action, and has enhanced procedural performance to improve patient outcomes. Accreditation with Commendation is "a reward for going above and beyond requirements--having the absolute best practices and for striving to meet the aspirational goals of medical education," said William Kelly, MD, FCCP, previous Chair of CHEST's Education Committee.

In achieving Accreditation with Commendation, CHEST demonstrated compliance with the following:

- Improving the professional practice by consistently integrating CME into CHEST processes.
- Utilization of noneducation strategies such as the CHEST Foundation's grant programs and disease awareness campaigns, to

enhance change as an adjunct to CHEST's activities/educational interventions.

- Identification of factors that effect patient outcomes and are outside of the provider's control.
- Implementation of educational strategies, including the offering of additional training to improve procedural capabilities, so as to remove, overcome, or address barriers to physician change.
- Building of bridges with stakeholders such as The France Foundation, National Comprehensive Cancer Network (NCCN), and the American Society for Clinical Pathology (ASCP), through collaboration and cooperation.
- Participation within an institutional framework for health-care quality improvement.
- Positioned to influence the scope and content of activities/educational interventions.

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¹ Tapson, et al, "Optimum Duration and Dose of r-tPA with the Acoustic Pulse Thrombolysis Procedure for Submassive Pulmonary Embolism: OPTALYSE PE," American Thoracic Society (ATS) Meeting, Washington, DC, May 2017.

² Lin, P., et al., "Comparison of Percutaneous Ultrasound-Accelerated Thrombolysis versus Catheter-Directed Thrombolysis in Patients with Acute Massive Pulmonary Embolism." *Vascular*, Vol. 17, Suppl. 3, 2009, S137-S147.

³ Nykamp M., et al. "Safety and efficacy of ultrasound-accelerated catheter-directed lytic therapy in acute pulmonary embolism with and without hemodynamic instability." *J Vascular Surgery: Venous and Lymphatic Disorders* 2015; 3(5): 251-7.

⁴ Piazza, G., et al., A Prospective, Single-Arm, Multicenter Trial of Ultrasound-Facilitated, Low-Dose Fibrinolysis for Acute Massive and Submassive Pulmonary Embolism: the Seattle II study." *Journal of the American College of Cardiology: Cardiovascular Interventions* 2015; 8: 1382-92.

⁵ Acute efficacy pending long-term data availability for OPTALYSE PE.

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