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Dr. Anthony S. Fauci said his optimism is based in part on animal studies and phase 1 data that demonstrate robust neutralizing antibody responses to a vaccine that are equivalent to, if not greater than, natural infection with the SARS-CoV-2 virus.

Courtesy American College of Chest Physicians

## Fauci: Cautious optimism for COVID-19 vaccine by end of 2020

BY ANDREW D. BOWSER  
*MDedge News*

**FROM CHEST 2020** ■ Anthony S. Fauci, MD, Director of the National Institute of Allergy and Infectious Diseases, addressed the virtual American College of Chest Physicians annual meeting as keynote speaker, and delivered a cautiously optimistic message.

A COVID-19 vaccine could be proven effective within the last months of 2020, with distribution of first doses possible before the end of the year, he told meeting attendees.

“Given the rate of infection that’s going on in this country, and the distribution of the clinical trial sites involving tens of thousands of volun-

teers, we project that we will have an answer as to whether or not we have a safe and effective vaccine by November or December,” Dr. Fauci explained.

If that timing does come to pass, Dr. Fauci said, it is possible that distribution of doses could start at the end of the year, continuing throughout the beginning and middle of 2021.

Although there are no guarantees, Dr. Fauci is “cautiously optimistic” regarding the timeline. He said that his optimism is based in part on animal studies and phase 1 data that demonstrate robust neutralizing antibody responses to a vaccine that are equivalent to, if not greater than, natural infection with the SARS-CoV-19.

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## Burnout and depression: Half of pulmonology trainees report symptoms

BY DOUG BRUNK  
*MDedge News*

**FROM CHEST** ■ Half of fellows training in pulmonary and critical care medicine screened positive for either burnout or depressive symptoms, results from a national survey demonstrated.

“Given the high prevalence of burnout and depressive symptoms among fellows training in pulmonary and critical care medicine, it is crucial for fellowship training programs and academic hospitals to consider policies and programs that can improve this public health crisis,” first author Michelle Sharp, MD, MHS, and colleagues wrote in a study published in the journal *CHEST*.

Dr. Sharp, of the division of pulmonary and critical care medicine at Johns Hopkins University, Baltimore, and colleagues developed a cross-sectional electronic survey to assess burnout and depression symptoms in fellows enrolled in pulmonary and critical care medicine training programs in the United States. Between January and February 2019, a total of 976 fellows received

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# Doctors challenge FDA standards for COVID-19 vaccine

BY KERRY DOOLEY YOUNG

Researchers and several medical groups have pressed for changes to the Food and Drug Administration's current plans for deciding

how to eventually clear vaccines for COVID-19, arguing tougher standards would help bolster confidence in these critical medicines.

The FDA's Vaccines and Related Biological Products Advisory

Committee met for a wide-ranging discussion beginning around 10 am. The FDA did not ask the panel to weigh in on any particular vaccine. Instead, the FDA asked for the panel's feedback on a series of questions,

including considerations for continuing phase 3 trials if a product were to get an interim clearance known as an emergency-use authorization (EUA).

Speakers at the hearing made a

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variety of requests, including asking for data showing COVID-19 vaccines can prevent serious illness and urging transparency about the agency's deliberations for each product to be considered.

FDA staff are closely tracking the crop of experimental vaccines that have made it into advanced stages

of testing, including products from Pfizer, AstraZeneca, Johnson & Johnson, and Moderna.

#### 'Time for a reset'

Among the speakers at the public hearing was Peter Lurie, MD, who served as an FDA associate commissioner from 2014 to 2017. Now the presi-

dent of the Center for Science in the Public Interest, Dr. Lurie was among the speakers who asked the agency to make its independence clear.

President Trump has been making predictions for months about COVID-19 vaccine approvals that have been overly optimistic. In one example, the president, who

was seeking re-election, spoke in September about being able to begin distributing a vaccine in October.

"Until now the process of developing candidate vaccines has been inappropriately politicized with an eye on the election calendar, rather than the deliberate timeframe science requires," Dr. Lurie told the FDA advisory panel. "Now is the time for a reset. This committee has a unique opportunity to set a new tone for vaccine deliberations going forward."

Dr. Lurie asked the panel to press the FDA to commit to hold an advisory committee meeting on requests by drugmakers for EUAs. He also asked the panel to demand that informed consent forms and minutes from institutional review board (IRB) discussions of COVID-19 vaccines trials be made public.

Also among the speakers at the public hearing was Peter Doshi, PhD, an associate professor at the University of Maryland School of Pharmacy, who argued that the current trials won't answer the right questions about the COVID-19 vaccines.

"We could end up with approved vaccines that reduce the risk of mild infection, but do not decrease the risk of hospitalization, ICU use, or death – either at all or by a clinically relevant amount," Dr. Doshi told the panel.

#### Risks of a 'rushed vaccine'

Other complaints about the FDA's approach included criticism of a 2-month follow-up time after vaccination, which was seen as too short. ECRI, a nonprofit organization that seeks to improve the safety, quality, and cost-effectiveness of medicines, has argued that approving a weak COVID-19 vaccine might worsen the pandemic.

In an Oct. 21 statement, ECRI noted the risk of a partially effective vaccine, which could be welcomed as a means of slowing transmission of the virus. But public response and attitudes over the past 9 months in the United States suggest that people would relax their precautions as soon as a vaccine is available.

"Resulting infections may offset the vaccine's impact and end up increasing the mortality and morbidity burden," ECRI said in the brief.

"The risks and consequences of a rushed vaccine could be very severe if the review is anything shy of thorough," ECRI Chief Executive Officer Marcus Schabacker, MD, PhD, said in a statement prepared for the hearing.

*A version of this article first appeared on Medscape.com.*

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Courtesy American College of Chest Physicians

Dr. Ryan C. Maves: "We're lucky to have multiple phase 3 trials using multiple vaccine technologies in different platforms."

## Vaccine distribution plans underway // continued from page 1

### Rapid development gives reason for hope

Ryan C. Maves, MD, FCCP, a critical care and infectious disease specialist at Naval Medical Center San Diego, said there is reason to be hopeful that a vaccine will be available by the end of the calendar year. He cautioned, however, that this timing is based on the assumption that one of the vaccines will be proven safe and effective very soon.

"We're lucky to have multiple phase 3 trials using multiple vaccine technologies in different platforms," Dr. Maves said in a panel discussion following Dr. Fauci's remarks. "I think the odds are very high that one of them will be effective."

*Reaching communities of color will be an important consideration for prioritization given the disproportionate burden of disease on Black and Hispanic individuals, among other such populations.*

"I'm hoping that multiple vaccines will be effective," Dr. Maves added. "Then we'll be in a good position of determining which is the best of several good options, as a society and as a world."

COVID-19 vaccine development over the past year has been remarkably fast, especially given the previous record set by the mumps vaccine, which took about 4 years to go from initial steps to rollout, Dr. Maves noted.

Dr. Fauci said the federal government has taken a "strategic approach" to the COVID-19 vaccine that includes direct involvement in the research and development of six

different vaccine candidates, five of which are now in phase 3 trials.

As part of that strategic approach, the study protocols are harmonized to have a common data and safety monitoring board, common primary and secondary endpoints, and an independent statistical group to determine correlates of protection, Dr. Fauci said.

### Prioritizing COVID-19 vaccine distribution

Who gets COVID-19 vaccine first will be a challenge for governmental organizations as well as bioethicists, who have proposed different strategies for fairly prioritizing different groups for access.

Reaching communities of color will be an important consideration for prioritization, according to Dr. Maves, given the disproportionate burden of disease on Black and Hispanic individuals, among other such populations.

COVID-19-related hospitalization rates have been substantially higher in communities of color, Dr. Fauci said in his keynote address. Age-adjusted hospitalization rates for Hispanic/Latinx and Black populations are 375 and 368 per 100,000, respectively, compared with just 82 per 100,000 for White non-Hispanics, according to data from the Centers for Disease Control and Prevention.

Outreach to those communities should include building trust in those populations that they will benefit from a safe and effective vaccine, and making sure that the vaccine is available to those communities as quickly as possible, Dr. Maves said.

Dr. Fauci and Dr. Maves provided no disclosures related to their presentations.

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David A. Schulman, MD, FCCP, is Editor in Chief of CHEST Physician.

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the survey, which used the Maslach Burnout Index two-item measure to assess burnout and the two-item Primary Care Evaluation of Mental Disorders Procedure to screen for depressive symptoms. For both burnout and depression, the researchers constructed three multivariate logistic regression models to assess individual fellow characteristics, program structure, and institutional policies associated with the symptoms.

Of the 976 surveys sent, 502 completed both outcome measures, for a response rate of 51%. More than half (59%) were male, 57% described themselves as White/non-Hispanic, and 39% reported at least \$200,000 in student loan debt. The researchers found that 50% of respondents screened positive for either burnout or depressive symptoms. Specifically, 41% met criteria for depressive symptoms, 32% were positive for burnout, and 23% were positive for both.

Factors significantly associated with a higher odds of burnout included working more than 70 hours in an average clinical week (adjusted odds ratio, 2.80) and reporting a somewhat negative or very negative impact of the EHR on joy in medicine (aOR, 1.91).

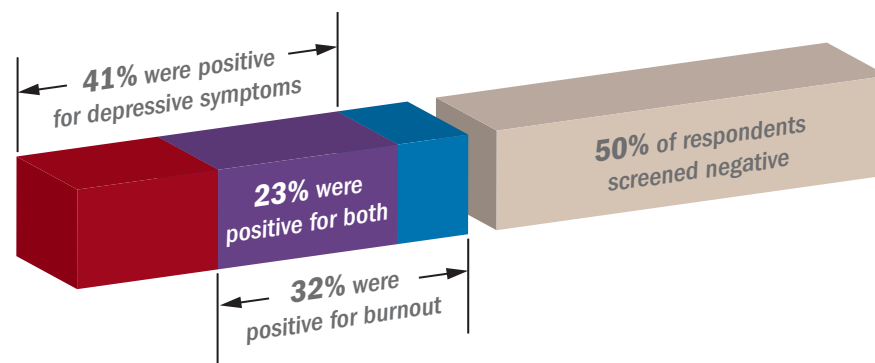
Factors significantly associated with a higher odds of depressive symptoms were financial concern (aOR, 1.13), being located in the Association of American Medical Colleges West region (aOR 3.96), working more than 70 hours in an average clinical week (aOR, 2.24), and spending a moderately high or excessive amount of time at home on the EHR (aOR, 1.71).

Of respondents who reported working in an institution with a coverage system for personal illness or emergency, 29% were uncomfortable accessing the system or felt comfortable only if unable to find their own coverage. In addition, among respondents who indicated that they had access to mental health resources through their place of employment, 15% said they were reluctant to access those resources if needed.

“Our results suggest that further study of systemic solutions at the programmatic and institutional levels rather than at the individual level are needed,” Dr. Sharp and colleagues wrote. “Strategies such as providing an easily accessible coverage system, providing access to mental health resources, addressing work hour burden, reducing the EHR burden, and addressing

## Depression and burnout in pulmonary/critical care fellows

Electronic survey used the Maslach Burnout Index two-item measure and the two-item Primary Care Evaluation of Mental Disorders Procedure.



Note: The survey, conducted in January and February of 2019, received 502 responses.

Source: Dr. Sharp

financial concerns among trainees may help reduce burnout and/or depressive symptoms and should be further studied.”

In an interview, David A. Schulman, MD, FCCP, Editor in Chief



Dr. Sharp

of CHEST Physician, characterized the survey findings as “disheartening” but not surprising. “Burnout and depressive symptoms are a problem because almost everything we do to mitigate them works a little, but nothing works a lot,” said

*“The health care system can be harsh. It will continue to take and take from everyone involved in it until they have nothing left to give. It’s unfortunate, because people are sick, and hospitals can be relatively understaffed, particularly in the context of a major public health emergency.”*

Dr. Schulman, professor of medicine in the division of pulmonary, allergy, critical care, and sleep medicine at Emory University, Atlanta, who was not affiliated with the study. “The limited availability of resources to fight this is a challenge. The thing that seems to correlate best with mitigating burnout and depression rates is just giving people time. In my experience,

most people just want the space and time they need to mitigate burnout in their own way by having schedule flexibility or arranging time to spend with family or involved in other wellness activities.”

*“Strategies such as providing an easily accessible coverage system, providing access to mental health resources, addressing work hour burden, reducing the EHR burden, and addressing financial concerns among trainees may help reduce burnout and/or depressive symptoms and should be further studied.”*

Dr. Schulman, who served as training program director of pulmonary and critical care medicine fellows at Emory for 14 years until stepping down from that role in September 2020, said that nurturing a culture where trainees and sea-



Dr. Schulman

soned colleagues are comfortable talking about burnout and depressive symptoms is one way to foster change. “It’s weird to say that we should try to normalize burnout, but I don’t think the health care system is changing anytime soon. The health care system can be harsh. It will continue to take and take from everyone involved in it until they have nothing left to give. It’s unfor-

tunate, because people are sick, and hospitals can be relatively understaffed, particularly in the context of a major public health emergency. What we really need to do is try to normalize this by saying to trainees: ‘Hey. Everybody is under the gun. We’re going to share in this workload together because we can’t abandon our patients. We will do our best to make sure that the workload is shared amongst everybody.’”

He emphasized that most trainees recognize the importance of the work they do, “and they don’t shirk from it. But I think that drive sometimes gets in the way of self-care. I do think there needs to be a happy medium, where we definitely want you to work, because that’s how you learn and the system needs you, but we also recognize that there’s a need for you to take care of yourself.”

Dr. Schulman recommended that such discussions take place not remotely on Zoom calls and the like but rather in person with small groups of trainees and seasoned clinicians, “where people are more comfortable candidly discussing how they’re feeling. I don’t think grand rounds on burnout or depression are particularly effective. It needs to be interactive, and we need to listen as much as we’re talking.”

Although the survey by Dr. Sharp and colleagues was completed prior to the COVID-19 pandemic, Dr. Schulman has a hunch that the current driver of burnout and depression has more to do with trainees feeling a sense of physical isolation than with being overwhelmed by their workload. “I don’t think that’s unique to medicine,” he said. “When people get home from work, they can’t go out with friends or out to dinner, or travel, whatever they do to decompress. I think that’s a major driver for the current phenomenon, and I don’t think that’s unique to medicine. The psychological ramifications of isolation due to the coronavirus may eventually outpace the physical ramifications of all the illness that we have seen. Depression and burnout may not be as obviously damaging to people, but I think they’re affecting many more people than the virus itself.”

The survey was supported by the Association of Pulmonary and Critical Care Medicine Program Directors.

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**SOURCE:** Sharp M et al. CHEST 2020 Sept 18. doi:10.1016/j.chest.2020.08.2117



# COVID-19 hits medical education: No 'back to normal'

BY DOUG BRUNK

*MDedge News*

The COVID-19 pandemic has thrown a monkey wrench into the medical education landscape across the entire health care spectrum, disrupting the plans of medical students, residents, fellows, and program directors.

As cases of COVID-19 spread across the United States in early 2020, it became clear to training program directors that immediate action was required to meet the needs of medical learners. The challenges were unlike those surrounding the Ebola virus in 2014, “where we could more easily prevent students and trainees from exposure due to the fact that there were simply not significant numbers of cases in the United States,” Tiffany Murano, MD, said at a Society for Critical Care virtual meeting: COVID-19: What’s Next. Dr. Murano is professor of emergency medicine at Rutgers New Jersey Medical School, Newark, and president-elect of the Council of Residency Directors in Emergency Medicine. “COVID was a completely different scenario. We quickly realized that not only was personal protective equipment in short supply, but we also lacked the testing and tracking capabilities for potential exposures. Medical students and other supportive workers who were considered nonessential were removed from the clinical setting. This was after a trial of limiting who the students saw, essentially dampening the risk of exposure. But this proved to be flawed as COVID patients presented with symptoms that were unexpected.”

To complicate matters, she continued, many medical clinics either shut down, had limited access, or converted to telemedicine. Elective surgeries were canceled. This led to an overall pause in clinical medical student rotations and no direct patient care activities. As social distancing mandates were instituted, licensing examination testing centers were closed, and exams and on-campus activities were postponed.

## Limiting trainee exposure

On the graduate medical education front, some training programs attempted to limit exposure of their trainees to persons under investigation for COVID-19. “As the number of COVID cases grew and encompassed most of what we were seeing in the hospital, it was obvious that

residents had to play a vital part in the care of these patients,” said Dr. Murano, who is also a member of the American Council of Graduate Medical Education’s emergency review and recognition committee. “However, there was a consensus among all of the specialties that the procedures that posed the highest risk of exposure would be limited to the most senior or experienced trainees or professionals, and closely supervised by the faculty.”

ACGME activities such as accreditation site visits, clinical environment learning reviews, self-study, and resident and faculty surveys were suspended, postponed, or modified in some way, she said. The ACGME created stages of COVID status to guide sponsoring institutions to suspend learning curricula in order for patients to be cared for. Stage 1 was business as usual, “so there was no significant impact on patient care,” Dr. Murano said. “Stage 2 was increased but manageable clinical demand, while stage 3 was pandemic emergency status, where there were extraordinary circumstances where the clinical demand was so high and strenuous that the routine patient care and education really needed to be reconfigured in order to care for the patients.”

## New requirements to manage training

The ACGME also implemented four requirements to manage training that were consistent among institutions, regardless of their COVID stage status. These included making sure that trainees continued to be held to work-hour limit requirements, ensuring adequate resources for training, ensuring that all residents had the appropriate level of supervision at all times, and allowing fellows to function in the core specialty in which they completed their residency training. “This was only possible if the fellows were ABMS [American Board of Medical Specialties] or AOA [American Osteopathic Association] board-eligible, or certified in their core specialty,” Dr. Murano said. “The fellows had to be appointed to the medical staff at the sponsoring institution, and their time spent on the core specialty service would be

limited to 20% of their annual education time in any academic year.”

Mindful that there may have been trainees who required a 2-week quarantine period following exposure or potential exposure to COVID-19, some specialty boards showed leniency in residency time required to sit for the written exam. Subani Chandra, MD, FCCP, of the division of pulmonary, allergy, and critical care medicine at Columbia University, New York, is the internal medicine residency program director and the associate vice-chair of education for the department of medicine, and she recognized the problem created for medical trainees by the changes necessitated by the pandemic.

“The variability in caseloads and clinical exposure has given thrust to the move toward competency-based assessments rather than number- or time-based criteria for determining proficiency and graduation,” she wrote in an email interview. In addition, she noted the impact on medical meetings and the need to adapt. “Early on, before large regional and national conferences adapted to a virtual format, many were canceled altogether. Students, residents, and fellows expecting to have the opportunity to present their scholarly work were suddenly no longer able to do so. Understanding the importance of scholarly interaction, the virtual format of CHEST 2020 is designed with opportunities to present, interact with experts in the field, ask questions, network, and meet mentors.”

## No return to ‘normal’

By April 2020, cases in the northeast continued to rise, particularly in the New York, New Jersey, and Connecticut region. “These states were essentially shut down in order to contain spread of the virus,” she said. “This was a real turning point because we realized that things were not going to return to ‘normal’ in the foreseeable future.” With the clinical experience essentially halted for medical students during this time, some medical schools allowed their senior students who met requirements to graduate early. “There were a lot of mixed feelings about

this, recognizing that PPE [personal protective equipment] was still in short supply in many areas,” Dr. Murano said. “So, institutions took on these early graduates into roles in which they were not learners in particular, but rather medical workers. They were helping with informatics and technology, telehealth, virtual or telephone call follow-ups, and other tasks like this. There was a movement to virtual learning for the pre-clinical undergraduate learners, so classes were now online, recorded, or livestreamed.”

## Early graduation, the Match, and residencies

On April 3, the ACGME released a statement regarding graduating students early and appointing them early to the clinical learning environment. “They pointed out that institutions that were in emergency pandemic status lacked the ability to offer the comprehensive orientation and training in PPE and direct supervision required for new residents at the start of their residency,” Dr. Murano said. “Their opinion maintained that graduating medical students matriculate in their previously matched program, the National Resident Match Program start date, or other date that would be nationally determined to be the beginning of the 2020-2021 academic year.”

As May 2020 rolled around, the overriding feeling was uncertainty regarding when, if, and how medical schools were going to open in the early summer and fall. “There was also uncertainty about how graduating medical students were going to function in their new role as residents,” she said. “Same for the graduating residents. There were some who had signed contracts for jobs months before, and had them rescinded, and physicians were being furloughed due to financial hardships that institutions faced. There was also postponement of board certification exams, so people were uncertain about when they would become board certified.”

July 2020 ushered in what Dr. Murano characterized as “a whole new level of stress.” For medical students in particular, “we were entering the application season for residency positions,” she said. “Due to travel restrictions placed by various states and institutions, away rotations were limited or nonexistent. Application release dates through the Electronic Residency Application Service



Dr. Murano



Dr. Chandra

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were moved to later in the year. The United States Medical Licensing Examination clinical skills exam was suspended, and there were modifications made for Education Commission for Foreign Medical Graduates requirements. Letters of recommendation were also going to be limited,

so there had to be some degree of leniency within specialties to take a more holistic approach to review of applications for residencies.”

On the graduate medical education front, the ACGME sunsetted the initial stages and created two categories: nonemergency, which was formerly stages 1 and 2, and emergency, which

was formerly stage 3. “All emergency stages are applied for and granted at 1-month intervals,” Dr. Murano said. Board certification exams were modified to accommodate either later exams or online formats, and specialties with oral examinations faced the task of potentially creating virtual oral exams. Despite the challenges, Dr. Chandra

has seen medical training programs respond with new ideas. “The flexibility and agile adaptability of the entire educational enterprise has been remarkable. The inherent uncertainty in a very dynamic and changing learning environment can be challenging. Recognizing this, many programs are creating additional ways to support the mental, emotional, physical, and financial health of students, residents, and fellows and all health care workers. The importance of this innovative response cannot be overstated.”

### New learning formats

The pandemic forced Dr. Murano and other medical educators to consider unorthodox learning formats, and virtual learning took center stage. “Residency programs had shared national livestream conferences and grand rounds, and there were virtual curricula made for medical students as well as virtual simulation,” she said. “Telemedicine and telehealth really became important parts of education as well, as this may have been the only face-to-face contact that students and residents had with patients who had non-COVID-related complaints.”

To level the playing field for medical residents during this unprecedented time, a work group of the Coalition for Physician Accountability developed a set of recommendations that include limiting the number of letters of recommendation accepted, limiting the number of away rotations, and allowing alternative or less conventional letters of recommendation. “Keeping an open mind and taking a more holistic approach to applicants has really been needed during this time,” Dr. Murano said. “Virtual interview days have been agreed upon for all specialties.” Dr. Chandra agreed that virtual interviews are necessary but have inherent limitations. However, “we will all learn a lot, and very likely the future process will blend the benefits of both virtual and in-person interviews.”

### ‘We need to keep moving forward’

Dr. Murano concluded her presentation by noting that the COVID-19 pandemic has created opportunities for growth and innovation in medical education, “so we need to keep moving forward. I’ve heard many say that they can’t wait for things to go back to normal. But I think it’s important to go ahead to new and better ways of learning.”

Dr. Murano and Dr. Chandra reported having no financial disclosures.

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# Avoid these malpractice risks during video visits

BY ALICIA GALLEGOS

During a telemedicine visit with his physician, a 62-year-old obese patient with an ankle injury reported new swelling of his leg. Three weeks had passed since the man visited an emergency department, where he underwent surgery and had a cast applied to the wound. The physician, during the telemedicine visit, advised the patient to elevate his leg and see an orthopedist within 24 hours. A Doppler ultrasound was ordered for 12:30 p.m. that same day.

The patient never made it to the appointment. He became unresponsive and went into full arrest hours later. His death fueled a lawsuit by his family that claimed failure to diagnose and treat deep venous thrombosis. The family contended the providers involved should have referred the patient to care immediately during the video visit.

The case, which comes from the claims database of national medical liability insurer The Doctors Company, illustrates the legal risks that can stem from video visits with patients, says Richard Cahill, JD, vice president and associate general counsel for The Doctors Company.

“By evaluating the patient remotely, the physician failed to appreciate the often subtle nuances of the clinical presentation, which undoubtedly could have been more accurately assessed in the office setting, and would probably have led to more urgent evaluation and intervention, thereby likely preventing the unfortunate and otherwise avoidable result,” said Mr. Cahill.

According to a Harris poll, 42% of Americans reported using video visits during the pandemic, a trend that is likely to continue as practices reopen and virtual care becomes the norm. But as physicians conduct more video visits, so grows their risk for lawsuits associated with the technology.

## Three problems with not being able to touch the patient

1. The primary challenge with video visits “is the inability to directly observe and lay hands on the patient,” says Jonathan Einbinder, MD, assistant vice president of analytics for CRICO, a medical liability insurer based in Boston.

“While you can see them via video, it can be hard to get a full sense of how sick the patient is and whether other things might be going on than what they are reporting,” said Dr. Einbinder, a practicing internist.

Such incomplete pictures can lead to diagnostic errors and the potential for lawsuits, as demonstrated by a recent CRICO analysis. Of 106 telemedicine-related claims from 2014 to 2018, 66% were diagnosis related, according to the analysis of claims from CRICO’s national database. Twelve percent of the telemedicine-related claims were associated with surgical treatment, 11% were related to medical treatment, and 5% were associated with medication issues. “Because a ‘typical’ exam can’t be done, there is the potential to miss things,” said David L. Feldman, MD, chief medical officer for The Doctors Company Group. “A subtlety, perhaps a lump that can’t be seen but only felt, and only by an experienced examiner,

for example, may be missed.”

2. Documentation dangers also loom, said William Sullivan, DO, JD, an emergency physician and an attorney who specializes in health care. The legal risk lies in documenting a video visit in the same way the doctor would document an in-person visit, he explained.

“Investigation into a potential lawsuit begins when there is some type of bad outcome related to medical care,” Dr. Sullivan explained. “To determine whether the lawsuit has merit, patients/attorneys review the medical records to retrospectively determine the potential cause of the bad outcome. If the documentation reflects an examination that could not have been performed, a lawyer might be more likely to pursue a case, and it would be more difficult to defend the care provided.”

3. Poorly executed informed consent can also give rise to a lawsuit. This includes informed consent regarding the use of telehealth as the accepted modality for the visit rather than traditional on-site evaluations, as well as preprocedure informed consent. “Inadequate and/or poorly documented informed consent can result in a claim for medical battery,” Mr. Cahill said.

## Waivers may be weak protection

Since the pandemic started, a number of states have enacted emergency malpractice protections to shield health professionals from lawsuits. Some protections, such as those in Massachusetts, offer immunity to health professionals who provide general care to patients during the COVID-19 emergency, in addition to treatment of COVID-19 patients. Other protections, like those in Connecticut, apply specifically to care provided in support of the state’s pandemic response.

Whether that immunity applies both to in-person visits and video visits during the pandemic is not certain, said J. Richard Moore, JD, a medical liability defense attorney based in Indianapolis. Indiana’s immunity statute for example, does not make a specific provision for telehealth, he said.

“My best prediction is that, if considered by the courts, the immunity would be applied to telehealth services, so long as they are being provided ‘in response to the emergency,’ which is the scope of the immunity,” he said. “I would not consider telehealth physicians to be either more or less protected than in-person providers.”

Regulatory scrutiny for telehealth providers has also been relaxed in response to COVID-19, but experts warn not to rely on the temporary shields for ultimate protection.

In March, the U.S. Department of Health & Human Services’ Office of Civil Rights (OCR) eased enforcement actions for noncompliance with Health Insurance Portability and Accountability Act requirements in connection with the good faith provision of telehealth during the COVID-19 health crisis. Under the notice, health providers can use popular applications such as Apple FaceTime, Facebook Messenger, Zoom, or Google Hangouts, to offer telehealth care without risk that OCR will impose fines or penalties for HIPAA violations.

But once the current health care emergency is

## VIEW ON THE NEWS

**Michael E. Nelson, MD, FCCP, comments:** This is extremely important information to understand, especially since telehealth visits have increased exponentially during the public health emergency (PHE). However, when the PHE is no longer in force, many of the protections will lapse as well. In addition, a knowledge of the type of visits (video/audio, e-visit, audio only, etc.) that are reimbursed during and after the PHE will be important as well. Finally, this article provides useful suggestions about how to avoid litigation related to telehealth visits.



mitigated, the waivers will likely be withdrawn, and enforcement actions will probably resume, Mr. Cahill said.

“It is recommended that, to avoid potential problems going forward, practitioners use due diligence and undertake best efforts to obey existing privacy and security requirements, including the use of technology that satisfies compliance regulations, despite the waiver by OCR,” he said.

In addition, a majority of states have relaxed state-specific rules for practicing telehealth and loosened licensure requirements during the pandemic. At least 47 states have issued waivers to alter in-state licensure requirements for telemedicine in response to COVID-19, according to the Federation of State Medical Boards. Most of the waivers allow physicians licensed in other states to provide care in states where they do not hold licenses, and some enable doctors to treat patients without first having had an in-person evaluation.

But at least for now, these are temporary changes, reminds Amy Lerman, JD, a health care attorney based in Washington, who specializes in telehealth and corporate compliance. Given the current pandemic environment, a significant concern is that physicians new to the telemedicine space are reacting only to the most recent rules established in the context of the pandemic, Ms. Lerman said.

“As previously noted, the recent developments are temporary in nature – states and various federal agencies have been pretty clear in setting this temporal boundary,” she said. “It is not advisable for providers to build telepractice models around temporary sets of rules. “Furthermore, the recent developments are not necessarily comprehensive relative to all of the state-specific and other requirements that telemedicine providers are otherwise expected to follow, so relying only on the most recent guidance may cause providers to create telepractice models that have key gaps with respect to regulatory compliance.”

*A version of this article originally appeared on Medscape.com.*

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# Optimal sedation strategies for patients with COVID-19 treated in ICU: A work in progress

BY DOUG BRUNK

*MDedge News*

According to the best available evidence, analgosedation remains the focus for managing COVID-19 ICU patients, according to Steven B. Greenberg, MD, FCCP. “The choice of sedation and analgesia is important,” Dr. Greenberg, vice chair of education in the department of anesthesiology at Evanston Hospital, part of NorthShore University Health System, Chicago, said at a Society for Critical Care virtual meeting, COVID-19: What’s Next.

## Analgesia first

Prior to the current pandemic, the approach to sedation of patients in the ICU was based on the PADIS Guidelines of 2018, which call for an assessment-driven, protocol-based stepwise approach to pain and sedation management in critically ill adults (Crit Care Med. 2018;46:e825-73). “[A strategy for COVID-19 in the ICU] should focus on analgosedation defined as analgesia-first sedation rather than jumping to sedation first,” Dr. Greenberg said. “We know that pain management should be a priority of sedation, because pain may increase the risk of delirium, anxiety, and endocrine suppression, and may increase the risk of release of endogenous catecholamines, ischemia, and hypermetabolic states.”

Fentanyl appears to be the most common opioid analgesic used for patients in the ICU, “but fentanyl is a very lipophilic drug and has a long context-sensitive half-life,” he said. “There are components to fentanyl that allow it to become a very long-acting drug upon days and days of infusion. Another opioid used is remifentanyl, which is typically short-acting because it is broken down in the blood by esterases, but may cause rigidity at higher doses. Dilaudid seems to be the least affected by organ dysfunction. In our very critically ill, prolonged mechanically ventilated COVID-19 patients, we’ve been using methadone for its NMDA [N-methyl-D-aspartate] antagonistic effect and its opioid-sparing effects.”

As for nonopioid analgesics, Dr. Greenberg said that clinicians have shied away from using NSAIDs because of their side effects. “Tramadol indirectly inhibits reuptake of

norepinephrine and serotonin, and ketamine is being used a lot more because of its NMDA antagonist effect,” he said. “Lidocaine and gabapentin have also been used.”

## ICU delirium: Risk factors, prevention

Delirium in COVID-19 patients treated in the ICU is of particular concern. According to a systematic review of 33 studies, 11 risk factors for delirium in the ICU were age, dementia, hypertension, emergency surgery, trauma, APACHE score of II, need for mechanical ventilation, metabolic acidosis,



Dr. Greenberg

delirium on prior day, coma, and dexmedetomidine use (Crit Care Med. 2015;43:40-7). Risk factors for ICU delirium among COVID-19 patients, however, “are far different,” Dr. Greenberg said. “Why? First and foremost, we are restricting visitation of family,” he said. “That family connection largely can be lost. Second, there are limitations of nonpharmacologic interventions. There is less mobility and physical therapy employed because of the risk of health care workers’ exposure to the virus. There’s also uncertainty about the global pandemic. Anxiety and depression come with that, as well as disruptions to spiritual and religious services.”

## No ideal sedative agent

The 2018 PADIS Guidelines on the use of ICU sedation suggested strong evidence for modifiable risk factors producing delirium in the context of benzodiazepines and blood transfusion. They recommend a light level of sedation and the use of propofol or dexmedetomidine over benzodiazepines. They also recommend routine delirium testing such as using the CAM-ICU or Intensive Care Delirium Screening Checklist (ICDSC) and nonpharmacologic therapies such as reorientation, cognitive stimulation, sleep improvement, and mobilization.

Several sedation-related factors may be related to an increased risk of delirium. “The type, dose, duration, and mode of delivery are very important,” Dr. Greenberg said. “The ideal sedative agent has a rapid, pre-

## VIEW ON THE NEWS

**Mangala Narasimhan, DO, FCCP, comments:**

The recommendations regarding sedation highlight a struggle that ICU providers have been dealing with during the COVID-19 epidemic. There have been unique challenges with COVID-19 and intubated patients. We have seen severe ventilator dyssynchrony and prolonged duration of mechanical ventilation. I think we can all agree that these patients have extremely high metabolic rates, have required high levels of sedation, have an increased need for neuromuscular blockade, and have high levels of delirium for extended periods of time. The recommendations provided here are reasonable. Strategies to prevent delirium should be employed, pain management should be prioritized, and analgesics can help reduce the need for opioids. Alternatives to sedation are useful in this patient population and are well tolerated. Drug shortages have provided additional challenges to these strategies and have required us to think about the use of alternative agents. The recommendations echo the experience we have had with large numbers of intubated COVID-19 patients.



dictable onset; is short-acting; has anxiolytic, amnestic, and analgesic properties; is soluble; has a high therapeutic index; and no toxicity. The ideal sedative is also easy to administer, contains no active metabolites, has minimal actions with other drugs, is reversible, and is cost effective. The problem is, there really is no ideal sedative agent. There is inadequate knowledge about the drugs [used to treat COVID-19 in the ICU] available to us, the dosage, and importantly, the pharmacokinetics and dynamics of these medications.”

## Choosing the right drug

The keys to success for sedation of ICU patients are choosing the right drug at the right dose for the right duration and the right mode of delivery, and applying them to the right population. However, as noted in a recent study, the pandemic poses unique challenges to clinicians in how they care for critically ill COVID-19 patients who require sedation (Anesth Analg. 2020 Apr 22. doi: 10.1213/ANE.0000000000004887). Dr. Greenberg said, “We’ve used alternate providers who are not necessarily familiar with the sedation and analgesic protocols and how to use these specific medications. Drug shortages have been on the rise, so there’s a need to understand alternative agents that can be used.”

COVID-19 patients face the potential risk for an increase in drug-drug interactions and side effects due to the polypharmacy that is

often required to provide adequate sedation during mechanical ventilation. He noted that these patients may have “unusually high” analgesia and sedation requirements, particularly when they’re mechanically ventilated. “A potential strategy for COVID-19 ICU patient sedation should be analgesia first, as indicated in the 2018 PADIS Guidelines,” Dr. Greenberg advised. “We should also apply nonpharmacologic measures to reduce delirium. In nonintubated patients, we should use light to moderate sedation, targeting a RASS of -2 to +1, using hydromorphone or fentanyl boluses for analgesia and midazolam boluses or dexmedetomidine for sedation.”

For intubated patients, he continued, target a RASS of -3 to -4, or -4 to -5 in those who require neuromuscular blockade. “Use propofol first then intermittent boluses of benzodiazepines,” said Dr. Greenberg, editor-in-chief of the Anesthesia Patient Safety Foundation newsletter. “For heavy sedation, use midazolam and supplement with ketamine and other analgesics and sedatives such as barbiturates, methadone, and even inhalation anesthetics in some cases.”

Dr. Greenberg concluded his presentation by stating that more studies are required “to delineate the best analgesia/sedation strategies and monitoring modalities for COVID-19 ICU patients.”

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# Bronchoscopy in COVID-19 patients: Worth the risk?

BY DOUG BRUNK

*MDedge News*

**FROM CHEST\*** ■ Bronchoscopy with intermittent apnea can be conducted safely for both patients with severe COVID-19 and health care workers, a recent study has found. In addition, the high rate of superinfection in these patients indicates that bronchoalveolar lavage (BAL) should be sent to the lab if there is any suspicion for secondary pneumonia.

Those are two key findings from a single-center retrospective study led by Stephanie H. Chang, MD, that was published in the journal *CHEST*.

“While there is a risk of aerosolization and transmission of COVID-19 with bronchoscopy, this can be mitigated with bronchoscopy under intermittent apnea and appropriate PPE [personal protective equipment] in a negative-pressure room, with no significant adverse patient outcomes and a 0% rate of transmission to health care workers,” Dr. Chang, a thoracic surgeon in the department of cardiothoracic surgery at New York University Langone Health, said in an interview. “In appropriate clinical scenarios that will significantly impact patient care, bronchoscopy can be and should be safely performed in patients with COVID-19.”

Although a recent statement from the American Association for Bronchoscopy & Interventional Pulmonology indicates that bronchoscopy is relatively contraindicated in patients with suspected and confirmed COVID-19 infections, it does support use of the procedure in a subset of such patients (*J Bronchology Interv Pulmonol*. 2020 Oct;27(4):e52-4). It reads: “The only role for bronchoscopy would be when less invasive testing to confirm COVID-19 are inconclusive, suspicion for an alternative diagnosis that would impact clinical management is suspected, or an urgent lifesaving intervention.”

For the current study, Dr. Chang and colleagues retrospectively studied the records of 412 patients with confirmed COVID-19 who were admitted to NYU Langone Health’s Manhattan campus between March 13 and April 24, 2020. Of these, 321 required intubation and 107 (33%) underwent bronchoscopy, with a total of 241 bronchoscopies being performed.

Primary outcomes of interest were patient and health care provider

safety, defined as freedom from periprocedural complications and COVID-19 transmission, respectively. Secondary outcomes included secondary infection with bacterial or fungal pneumonia.

The bronchoscopy team included six cardiothoracic surgeons and four cardiothoracic surgery residents. Each procedure was performed by a sole bronchoscopist in a negative-pressure room, with a bedside nurse immediately available outside

of the room. The bronchoscopist wore full PPE, which consisted of hair cover, a fitted N95 mask, a face shield, gown, and gloves. Each patient was preoxygenated for 2 minutes with a fraction of inspired oxygen at 1.0 in order to maximize apneic time. For patients who were not on sedation and/or neuromuscular blockade, periprocedural anesthesia with propofol and rocuronium was employed to decrease the risk of spontaneous breathing leading to aerosolization.

The bronchoscope used was the disposable Ambu aScope and a corresponding monitor. The device was used to clear all secretions, clot, or mucus plugs, and to collect BAL samples. If oxygen saturation decreased below 90%, the bronchoscopist interrupted the procedure and reconnected the patient to the ventilator. After an additional period of preoxygenation, bronchoscopy was then completed.

The mean age of the 107 patients was 62 years, and 81% were male. Dr. Chang and colleagues reported that, of the 241 bronchoscopies performed, no periprocedural complication of severe hypoxia requiring bag-valve ventilation, pneumothorax, or intraprocedural arrhythmias occurred, and that three patients required endotracheal tube advancement or replacement for dislodgment during the procedure.

About half of patients (51%) received a BAL, and 35 (65%) had a positive culture. Among 23 patients who had a negative tracheal culture, 8 patients had a positive BAL, which indicated a 35% diagnostic yield for patients with negative tracheal aspirates. In addition, three patients had differing cultures between the BAL and tracheal aspirate. One was

growing *Pseudomonas* and *Klebsiella* in the tracheal aspirate with *Enterococcus* in the BAL, while the other two patients were growing an extra pathogen (*Escherichia coli* or *Serratia*) in the BAL.

“The most surprising data was the 65% rate of secondary infection with

*“The most surprising data was the 65% rate of secondary infection with BAL, which is significantly higher than the rate in standard patients with acute respiratory distress syndrome.”*



Dr. Chang

BAL, which is significantly higher than the rate in standard patients with acute respiratory distress syndrome,” Dr. Chang said. “Additionally, the high rate of bronchoscopy (33% in intubated patients) is also significantly higher than that of standard viral ARDS patients. This increased rate of superimposed infection and need for bronchoscopy may be due to the abnormally thick secretions seen in patients with COVID-19.”

Of the 10 cardiothoracic surgery team members, 1 resident was COVID-19 positive by reverse tran-

scriptase polymerase chain reaction (rtPCR) prior to performing any bronchoscopies. The remaining nine team members tested negative for COVID-19 via nasal pharyngeal swab for rtPCR assay, with at least one negative test performed 2 weeks after the last bronchoscopy performed during the study period.

“The use of apnea was well tolerated by the patients and likely contributed to the lack of transmission of COVID-19 to the health care providers,” Dr. Chang said. “Additionally, this work demonstrates a higher rate of superinfection with bacterial or fungal pneumonia, compared to other reports. It is also the only one that describes the false negative rate for negative tracheal aspirates, which is the current recommended diagnostic test for secondary pneumonia in patients with COVID-19.” She acknowledged certain limitation of the study, including its retrospective design. “Thus, the clinical impact of bronchoscopy on patient outcomes cannot be accurately assessed.”

The authors reported having no financial disclosures.

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**SOURCE:** Chang SH et al. *CHEST*. 2020 Oct 8. doi: 10.1016/j.chest.2020.09.263.

## VIEW ON THE NEWS

**Daniel Ouellette, MD, FCCP, comments:** Safety and efficacy must always be considered when evaluating critically ill patients for interventions. The research letter by Dr. Chang and co-workers presents retrospective, uncontrolled data concerning the performance of bronchoscopy in critically ill COVID-19 patients.

They report that bronchoscopy was performed by their team in a cohort of patients without infection of team members and with potentially useful results. While interesting, this report raises more questions than it answers. Importantly, specimens obtained by bronchoscopy that indicate the presence of bacterial or fungal organisms should not always be considered to be synonymous with infection or pneumonia. We do not know if the results obtained by bronchoscopy led to changes in management, nor do we know if such management changes led to changes in important outcomes. The concept of using bronchoscopy for secretion control is controversial and has not been convincingly shown to improve patient outcomes. The ventilator strategies adopted by the Chang team during bronchoscopy could be postulated to pose risk for patients; larger studies with appropriate control subjects would be needed to confirm safety. Recent *CHEST* guidelines suggest a much more limited role for bronchoscopy in seriously ill COVID-19 patients, and this may be the most prudent recommendation for the present. As I often tell my residents during rounds regarding interventions, safety, and efficacy: “Just because you can do something doesn’t mean that you should do it.” Bronchoscopy in critically ill COVID-19 patients should be performed very selectively.



# Link between vitamin D and ICU outcomes unclear

BY INGRID HEIN

**FROM CHEST 2020** ■ We can “stop putting money on vitamin D” to help patients who require critical care, said Todd Rice, MD, FCCP.

“Results from vitamin D trials have not been uniformly one way, but they have been pretty uniformly disappointing,” Dr. Rice, from Vanderbilt University Medical Center, Nashville, Tenn., reported at the American College of Chest Physicians virtual annual meeting.

Low levels of vitamin D in critically ill COVID-19 patients have been reported in numerous recent studies, and researchers are looking for ways to boost those levels and improve outcomes.

We are seeing “the exact same story” in the critically ill COVID-19 population as we see in the general ICU population, said Dr. Rice. “The whole scenario is repeating itself. I’m pessimistic.”

Still, vitamin D levels can be elevated, so in theory, “the concept makes sense,” he said. There is evidence that, “when given enterally, the levels rise nicely” and vitamin D is absorbed reasonably well.” But is that enough?

When patients are admitted to the ICU, some biomarkers in the body are too high and others are too low. Vitamin D is often too low. So far, though, “supplementing vitamin D in the ICU has not significantly improved outcomes,” said Dr. Rice.

In the Vitamin D to Improve Outcomes by Leveraging Early Treatment (VIOLET) trial, Dr. Rice and colleagues found no statistical benefit when a 540,000-IU boost of vitamin D was administered to 2,624 critically ill patients, as reported by this news organization.

“Early administration of high-dose enteral vitamin D<sub>3</sub> did not provide an advantage over placebo with respect to 90-day mortality or other nonfatal outcomes among critically ill, vitamin D-deficient patients,” the researchers write

in their recent report.

In fact, VIOLET ended before enrollment had reached the planned 3,000-patient cohort because the statistical analysis clearly did not show benefit. Those enrolled were in the ICU because of, among other things, pneumonia, sepsis, the need for mechanical ventilation or vasopressors, and risk for acute respiratory distress syndrome.



Dr. Rice

*When patients are admitted to the ICU, some biomarkers in the body are too high and others are too low. Vitamin D is often too low. So far, though, “supplementing vitamin D in the ICU has not significantly improved outcomes,” said Dr. Rice.*

“It doesn’t look like vitamin D is going to be the answer to our critical care problems,” Dr. Rice said in an interview.

## Maintenance dose needed?

One theory suggests that VIOLET might have failed because a maintenance dose is needed after the initial boost of vitamin D.

In the ongoing VITDALIZE trial, critically ill patients with severe vitamin D deficiency (12 ng/mL or less at admission) receive an initial 540,000-IU dose followed by 4,000 IU per day.

The highly anticipated VITDALIZE results are expected in the middle of next year, Dr. Rice reported, so “let’s wait to see.”

“Vitamin D may not have an acute effect,” he theorized. “We can raise your levels, but that doesn’t give you all the benefits of having a sufficient level for a long period of time.”

Another theory suggests that a low level of vitamin D is simply a signal of the severity of disease, not a direct influence on disease pathology.

Some observational data have shown an association between low levels of vitamin D and outcomes in COVID-19 patients (Nutrients. 2020 May 9;12[5]:1359; medRxiv. 2020 Apr 24.

doi: 10.1101/2020.04.24.20075838; JAMA Netw Open. 2020;3[9]:e2019722; FEBS J. 2020 Jul 23;10.1111/febs.15495; Clin Endocrinol [Oxf]. 2020 Jul 3;10.1111/cen.14276), but some have shown no association (medRxiv. 2020 Jun 26. doi: 10.1101/2020.06.26.20140921; J Public Health [Oxf]. 2020 Aug 18;42[3]:451-60).

Dr. Rice conducted a search of Clinicaltrials.gov immediately before his presentation, and he found 41 ongoing interventional studies – “not observational studies” – looking at COVID-19 and vitamin D.

“They’re recruiting, they’re enrolling; hopefully we’ll have data soon,” he said.

Researchers have checked a lot of boxes with a resounding yes on the vitamin D question, so there’s reason to think an association does exist for ICU patients, whether or not they have COVID-19.

“Is there a theoretical benefit of vitamin D in the ICU?” Dr. Rice asked. “Yes. Is vitamin D deficient in patients in the ICU? Yes. Is that deficiency associated with poor outcomes? Yes. Can it be replaced safely? Yes.”

However, “we’re not really sure that it improves outcomes,” he said.

## A chronic issue?

“Do you think it’s really an issue of the patients being critically ill with vitamin D,” or is it “a chronic issue of having low vitamin D?” asked session moderator Antine Stenbit, MD, PhD, from the University of California, San Diego.

“We don’t know for sure,” Dr. Rice said. Vitamin D might not have a lot of acute effects; it might have effects that are chronic, that work with levels over a period of time, he explained.

“It’s not clear we can correct that with a single dose or with a few days of giving a level that is adequate,” he acknowledged.

Dr. Rice is an investigator in the PETAL network. Dr. Stenbit disclosed no relevant financial relationships.

*A version of this article originally appeared on Medscape.com.*

# Nerve damage linked to prone positioning in COVID-19

BY BATYA SWIFT YASGUR, MA, LSW

**A**mong COVID-19 patients who undergo mechanical ventilation, lying in the prone position has been associated with lasting nerve damage. A new case series describes peripheral nerve injuries associated with this type of positioning and suggests ways to minimize the potential damage.

“Physicians should remain aware of increased susceptibility to peripheral nerve damage in patients with severe COVID-19 after prone positioning, since it is surprisingly

common among these patients, and should refine standard protocols accordingly to reduce that risk,” said senior author Colin Franz, MD, PhD, director of the Electrodiagnostic Laboratory, Shirley Ryan AbilityLab, Chicago.

The article was published online Sept. 4 in the British Journal of Anaesthesiology (2020 Sep 4. doi: 10.1016/j.bja.2020.08.045).

## Unique type of nerve injury

Many patients who are admitted to the intensive care unit with COVID-19 undergo invasive mechanical ventilation because of acute re-

spiratory distress syndrome (ARDS). Clinical guidelines recommend that such patients lie in the prone position 12-16 hours per day.

“Prone positioning for up to 16 hours is a therapy we use for patients with more severe forms of ARDS, and high-level evidence points to mortality benefit in patients with moderate to severe ARDS if [mechanical] ventilation occurs,” said study coauthor James McCauley Walter, MD, of the pulmonary division at Northwestern University, Chicago.

With a “significant number of COVID-19 patients flooding the

ICU, we quickly started to prone a lot of them, but if you are in a specific position for multiple hours a day, coupled with the neurotoxic effects of the SARS-CoV-2 virus itself, you may be exposed to a unique type of nerve injury,” he said.

Dr. Walter said that the “incidence of asymmetric neuropathies seems out of proportion to what has been reported in non-COVID-19 settings, which is what caught our attention.”

Many of these patients are discharged to rehabilitation hospitals, and “what we noticed, which was

*Continued on page 25*

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Continued from page 21

unique about COVID-19 patients coming to our rehab hospital, was that, compared with other patients who had been critically ill with a long hospital stay, there was a significantly higher percentage of COVID-19 patients who had peripheral nerve damage,” Dr. Franz said.

The authors described 12 of these patients who were admitted between April 24 and June 30, 2020 (mean age, 60.3 years; range, 23-80 years). The sample included White, Black, and Hispanic individuals. Eleven of the 12 post-COVID-19 patients with peripheral nerve damage had experienced prone positioning during acute management.

The average number of days patients received mechanical ventilation was 33.6 (range, 12-62 days). The average number of proning sessions was 4.5 (range, 1-16) with an average of 81.2 hours (range, 16-252 hours) spent prone.

#### A major contributor

Dr. Franz suggested that prone positioning is likely not the only cause of peripheral nerve damage but “may play a big role in these patients who are vulnerable because of viral infection and the critical illness that causes damage and nerve injuries.

“The first component of lifesaving care for the critically ill in the ICU is intravenous fluids, mechanical ventilation, steroids, and antibiotics for infection,” said Dr. Walter. “We are trying to come up with ways to place patients in prone position in safer ways, to pay attention to pressure points and areas of injury that we have seen and try to offload them, to see if we can decrease the rate of these injuries,” he added.

The researchers’ article includes a heat map diagram as a “template for where to focus the most efforts, in terms of decreasing pressure,” Dr. Walter said. “The nerves are accepting too much force for gravely ill COVID-19 patients to handle, so we suggest using the template to determine where extra padding might be needed, or a protocol that might include changes in positioning”.

Dr. Franz described the interventions used for COVID-19 patients with prone positioning-related peripheral nerve damage. “The first step is trying to address the problems one by one, either trying to solve them through exercise or teaching new skills, new ways to compensate, beginning with basic activities, such as getting out of bed and self-care,” he said.

Long-term recovery of nerve injuries depends on how severe the

injuries are. Some nerves can slowly regenerate – possibly at the rate of 1 inch per month – which can be a long process, taking between a year and 18 months.

Dr. Franz said that therapies for this condition are “extrapolated from clinical trial work” on promoting nerve regeneration after

surgery using electrical stimulation to enable nerves to regrow at a faster rate.

“Regeneration is not only slow, but it may not happen completely, leaving the patient with permanent nerve damage – in fact, based on our experience and what has been reported, the percentage of patients

with full recovery is only 10%,” he said.

The study received no funding. Dr. Franz, Dr. Walter, study coauthors, and Dr. Chung report no relevant financial relationships.

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# Vaping cessation: COVID-19 crisis may reverse progress

BY NEIL OSTERWEIL

*MDedge News*

It's an electronic cigarette maker's dream, but a public health nightmare: The confluence of social isolation and anxiety resulting from the COVID-19 pandemic has the potential to make recent progress against e-cigarette use among teens go up in smoke.

"Stress and worsening mental health issues are well-known predisposing factors for smoking, both in quantity and frequency and in relapse," said Mary Cataletto, MD, FCCP, clinical professor of pediatrics at New York University Winthrop Hospital, Mineola, during a webinar on e-cigarettes and vaping with asthma in the time of COVID-19, hosted by the Allergy & Asthma Network.

Prior to the pandemic, public health experts appeared to be making inroads into curbing e-cigarette use, according to results of the 2020 National Youth Tobacco Survey, a cross-sectional school-based survey of students from grades 6 to 12.

"In 2020, approximately 1 in 5 high school students and 1 in 20

middle school students currently used e-cigarettes. By comparison, in 2019, 27.5% of high school students (4.11 million) and 10.5% of middle school students (1.24 million) reported current e-cigarette use," wrote Brian A. King, PhD, MPH, and colleagues, in an article reporting those results (MMWR Morb Mortal Wkly Rep 2020;69:1310-12.).



Dr. Cataletto

"We definitely believe that there was a real decline that occurred up until March. Those data from the National Youth Tobacco Survey were collected prior to youth leaving school settings and prior to the implementation of social distancing and other measures," said Dr. King, deputy director for research translation in the Office on Smoking and Health within the National Center for Chronic Disease Prevention and Health Promotion at the Centers for Disease Control and Prevention.

and colleagues, in an article reporting those results (MMWR Morb Mortal Wkly Rep 2020;69:1310-12.).

"We definitely believe that there was a real decline that occurred up until March. Those data from the National Youth Tobacco Survey were collected prior to youth leaving school settings and prior to the implementation of social distancing and other measures," said Dr. King, deputy director for research translation in the Office on Smoking and Health within the National Center for Chronic Disease Prevention and Health Promotion at the Centers for Disease Control and Prevention.

"That said, the jury's still out on what's going to happen with youth use during the coming year, particularly during the COVID-19 pandemic" he said in an interview.

## Flavor of the moment

Even though the data through March 2020 showed a distinct decline in e-cigarette use, Dr. King and colleagues found that 3.6 million U.S. adolescents still currently used e-cigarettes in 2020; among current users, more than 80% reported using flavored e-cigarettes.

On Jan. 2, 2020, the FDA reported a finalized enforcement policy directed against "unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint."

That enforcement policy applies only to prefilled cartridge e-cigarette products, such as those made by JUUL, and that, while sales of mint- or fruit-flavored products of this type declined from September 2014 to May 2020, there was an increase in the sale of disposable e-cigarettes with flavors other than menthol or tobacco.

Dr. Cataletto pointed out that this vaping trend has coincided with the

COVID-19 pandemic, noting that, on March 13, 2020, just 2 days after the World Health Organization declared that spread of COVID-19 was officially a pandemic, 16 states closed schools, leaving millions of middle school- and high school-age children at loose ends. She said: "This raised a number of concerns. Would students who used e-cigarettes be at increased risk of COVID-19? Would e-cigarette use increase again due to the social isolation and anxiety as predicted for tobacco smokers?"

"It's possible that use may go down, because youth may have less access to their typical social sources or other manners in which they obtain the product," Dr. King said. "Alternatively, youth may have more disposable time on their hands and may be open to other sources of access to these products, and so use could increase."


There is evidence to suggest that the latter scenario may be true, according to investigators who surveyed more than 1,000 Canadian adolescents about alcohol use, binge drinking, cannabis use, and vaping in the 3 weeks directly before and after social distancing measures took effect.

*Continued on following page*

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# MIS-C cardiac evaluation requires more than EF

BY RICHARD MARK KIRKNER

*MDedge News*

**P**atients with multisystem inflammatory syndrome caused by COVID-19 typically seem to avoid coronary artery dilation early on, but they may be prone to cardiac injury and dysfunction longer term that requires a more discerning diagnostic approach to sort out.

The findings were revealed in a study of 28 children with COVID-19–related multisystem inflammatory syndrome (MIS-C) at Children’s Hospital of Philadelphia. The study reported that cardiac injury and dysfunction are common in these patients – even those who have preserved ejection fraction – and that diastolic dysfunction is persistent. For comparison, the study also included 20 healthy controls and 20 patients with classic Kawasaki disease (KD).



Dr. Matsubara

The study analyzed echocardiography findings in the patients, reporting left ventricular (LV) systolic and diastolic function were worse than in classic KD, which MIS-C mimics. Lead author Daisuke Matsubara, MD, PhD, and colleagues reported that four markers – LV global longitudinal strain, LV circumferential strain rate, right ventricular strain, and left atrial strain – were the strongest predictors of myocardial injury in these patients. After the acute phase, systolic function tended to recover, but diastolic dysfunction persisted.

## ‘Strain’ measurement boosts accuracy

While echocardiography has been reported to be valuable in evaluating coronary artery function in MIS-C patients, Dr. Matsubara of the division of cardiology at CHOP, said in an interview that study is the first to use the newer echocardiography indexes, known as “strain,” to assess heart function.

“Strain is a more sensitive tool than more conventional indexes and can detect subtle decrease in heart function, even when ejection fraction is preserved,” he said. “Numerous publications

have reached conclusions that strain improves the prognostic and diagnostic accuracy of echocardiography in a wide variety of cardiac pathologies causing LV dysfunction.”

Dr. Matsubara noted that the coronary arteries were mostly unaffected in the acute stage of MIS-C, as only one patient in their MIS-C cohort had coronary artery involvement, which normalized during early follow-up. “On the other hand, 20% of our classic KD patients had coronary abnormalities, including two with aneurysms.”

By using positive troponin I or elevated brain natriuretic peptide (BNP) to assess cardiac injury, they found a “high” (60%) incidence of myocardial injury in their MIS-C cohort. During early follow-up, most of the MIS-C patients showed normalization of systolic function, although diastolic dysfunction persisted.

When compared with the classic KD group, MIS-C patients had higher rates of mitral regurgitation (46% vs. 15%,  $P = .06$ ), more pericardial effusion (32% vs. 15%,  $P = .46$ ), and more pleural effusion (39% vs. 0%,  $P = .004$ ). MIS-C patients with suspected myocardial injury show these findings more frequently than those with actual myocardial injury.

Compared with the healthy controls, the MIS-C patients showed both LV systolic and diastolic dysfunction as well as significantly lower LA strain and peak RV free-wall longitudinal strain.

“In addition to the left ventricle, two other chambers of the heart, the LA and the RV that are often labeled as the ‘forgotten chambers’ of the heart, were also affected by MIS-C,” Dr. Matsubara said. “Both LA and RV strains were markedly reduced in MIS-C patients, compared to normal and KD patients.”

The study also indicates that elevated troponin I levels may not be as dire in children as they are in adults. Dr. Matsubara cited a study of more than 2,700 adult COVID-19 patients that found that even mild increases in troponin I level were associated with increased death during hospitalization (*J Am Coll Cardiol.* 2020;76:533-46).

However, most of the patients in the CHOP

study, even those with elevated troponin I levels, recovered systolic function quickly. “We speculate that the elevation in cardiac troponins may have less dire implications in children, likely due to a more transient type of cardiac injury and less comorbidities in children,” he said. “Clearly further studies are needed before a definitive statement can be made.”

Dr. Matsubara added that recovered COVID-19 patients may be able to participate in sports as some schools reopen. “We are not saying restrict sport participation, but we are merely urging caution.”

## Comprehensive LV evaluation needed

The findings reinforce that myocardial involvement is more frequent and sometimes more severe in MIS-C than previously thought, said Kevin G. Friedman, MD, a pediatrician at Harvard Medical School, Boston, and an attending physician in the department of cardiology at Boston Children’s Hospital. “We are underestimating it by using just traditional measures like ejection fraction. It requires a comprehensive evaluation of left ventricular function; it really affects all aspects of the ventricle, both the systolic function and the diastolic function.”

This study supports that MIS-C patients should have a more detailed analysis than EF on echocardiography, including strain imaging. “Probably these patients should all be followed at centers where they can evaluate a more detailed analysis of the LV and RV function,” he said. Patients with ongoing CA enlargement and LV dysfunction should have follow-up cardiac care indefinitely. Patients who have no cardiac symptoms during the acute phase probably don’t need long-term follow-up.

“We’re just trying to learn more about this disease, and it’s certainly concerning that so many kids are having cardiac involvement,” Dr. Friedman said. “Fortunately they’re getting better; we’re just trying to find out what this means for the long term.”

Dr. Matsubara and Dr. Friedman have no relevant financial disclosures.

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**SOURCE:** Matsubara D et al. *J Am Coll Cardiol.* 2020 Sep 2. doi: 10.1016/j.jacc.2020.08.056.

*Continued from previous page*

The investigators found that the frequency of both alcohol and cannabis use increased during social isolation, and that, although about half of respondents reported solitary substance use, 32% reported using substances with peers via technology, and 24% reported using substances face to face, despite social distancing mandates, reported Tara M. Dumas, PhD, from Huron University College, London, Ont. (*J Adolesc Health.* 2020 Sep;67[3]:354-61).

## E-cigarettes and COVID-19

A recent survey of 4,351 adolescents

and young adults in the United States showed that a COVID-19 diagnosis was five times more likely among those who had ever used e-cigarettes, seven times more likely among conventional cigarette and e-cigarette uses, and nearly seven times more likely among those who had used both within the past 30 days (*J Adolesc Health.* 2020 Oct;67[4]:519-23).

Perhaps not surprisingly, adolescents and young adults with asthma who also vape may be at especially high risk for COVID-19, but the exact effect may be hard to pin down with current levels of evidence.

Dr. King said, “There is an emerging body of science that does indicate that there could be some respiratory risks related to e-cigarette use, particularly among certain populations. ... [But] there’s no conclusive link between e-cigarette use and specific disease outcomes, which typically requires a robust body of different science conducted in multiple settings.”

## An ounce of prevention

“When it comes to cessation, we do know that about 50% of youth who are using tobacco products including e-cigarettes, want to quit, and about the same proportion make an effort

to quit, so there’s certainly a will there, but we don’t clearly have an evidence-based way,” Dr. King said.

Combinations of behavioral interventions including face-to-face consultations and digital or telephone support can be helpful, Dr. Cataletto said, but she said that prevention is the most effective method of reducing e-cigarette use among teens and young adults, including peer support and education efforts.

Dr. Cataletto and Dr. King reported no relevant conflicts of interest. Dr. Cataletto serves on the editorial advisory board for *CHEST Physician.*

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# Insomnia + COPD linked to more outpatient, ED visits

BY CHRISTINE KILGORE

MDedge News

Insomnia is “highly prevalent” in veterans with chronic pulmonary obstructive disease and is significantly associated with greater COPD-related health care utilization, according to an analysis of national Veterans Health Administration data.

“The study highlights the impor-

tance of exploring potential sleep disturbances and disorders in this population and suggests that a targeted treatment for insomnia may help to improve COPD outcomes in veterans with COPD and insomnia,” said Faith Luyster, PhD, assistant professor at the University of Pittsburgh, in an interview after the virtual annual meeting of the Associated Professional Sleep Societies, where she presented the findings.

## VIEW ON THE NEWS

**Octavian C. Ioachimescu, MD, FCCP, comments:** The criteria used to define insomnia – unadjudicated ICD diagnoses as well as sedative-hypnotic prescriptions – may explain part of the reported prevalence of insomnia. Even so, the findings add to existing literature demonstrating that COPD and insomnia are both common disorders among VHA patients, and that their frequent coexistence could have adverse consequences on the overall health, functional status, long-term outcomes, and quality of life of these patients. Questions of causation are yet to be answered. Is it that uncontrolled or severe airflow obstruction causing frequent nocturnal arousals, dyspnea, orthopnea, overuse of inhaled sympathomimetics and heightened anxiety leads to insomnia? Or is it that insomnia – possibly in a cluster with other affective disorders such as depression, anxiety disorders, or PTSD – elicits more frequent or more severe symptoms of shortness of breath in those with smoking-induced airway and parenchymal lung disease, making the latter diagnosis more overt than in others? My bet is on a bidirectional causal relationship.



Dr. Luyster and coinvestigators used an administrative database from the Veterans Affairs Corporate Data Warehouse to identify more than 1.5 million patients with COPD who used VHA services over a 6-year period (fiscal years 2011-2017). Insomnia was defined by ICD-9/10 diagnostic codes and/or a sedative-hypnotic prescription for at least 30 doses during any of these years.

Insomnia with COPD was prevalent in this sample of veterans at 37.3%. Compared with veterans without comorbid insomnia, those who had both COPD and insomnia (575,539 of the total 1,542,642) were older (69 vs. 64 years), more likely to be female (6.3% vs. 3.7%), more likely to be Black (14% vs. 11%), and more likely to be a current smoker (46.1% vs. 35.5%).

Those with both COPD and insomnia were also more likely to have a service-connected disability rating of 50% or greater; use supplemental oxygen; be divorced, widowed, or separated; have a higher body mass index; or have other medical or psychiatric conditions – in particular obstructive sleep apnea (39% vs. 7%), depression (21% vs. 5%), and PTSD (33% vs. 3%).

*P* values were < .001 for all of these demographic and clinical variables, Dr. Luyster reported at the

meeting.

Comorbid insomnia clearly impacted health care utilization, she said. Veterans with insomnia in addition to COPD had more outpatient and ED visits (10.5 vs 6.9, and 1.6 vs. 1.4, respectively) and more hospitalizations (2.2 vs. 1.8) with a primary diagnostic code for COPD or COPD exacerbation (*P* < .001).

A negative binomial regression analysis (*P* < .001) showed that “even after controlling for demographic and other medical conditions, COPD patients with insomnia had greater rates of health care utilization relative to COPD patients without insomnia,” Dr. Luyster said in the interview.

“Regardless of the etiology [of insomnia in veterans with COPD],” Dr. Luyster said, “it’s important that [insomnia] be addressed and treated appropriately, whether that be through pharmacological treatment, or probably more ideally through [cognitive behavioral therapy] for insomnia.”

The study did not control for COPD severity, she said, because of the difficulty of extracting this data from the VA Corporate Data Warehouse. The study was funded by the VA Competitive Career Development Fund.

Dr. Luyster had no disclosures.

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# Obesity-related hypoventilation linked to increased morbidity risk after bariatric surgery

BY CHRISTINE KILGORE

MDedge News

Patients with obesity-associated sleep hypoventilation had a heightened risk of postoperative morbidities after bariatric surgery, according to a retrospective study.

Reena Mehra, MD, director of sleep disorders research for the Sleep Disorders Center at the Cleveland Clinic, led the team and reported the findings at the virtual annual meeting of the Associated Professional Sleep Societies. Her research team examined the outcomes of 1,665 patients who underwent polysomnography prior to bariatric surgery performed at the Cleveland Clinic from 2011 to 2018.

More than two-thirds, 68.5%, had obesity-associated sleep hypoventilation as defined by body mass index (BMI) of  $\geq 30$  kg/m<sup>2</sup> and either polysomnography-based end-tidal CO<sub>2</sub>  $\geq 45$  mm Hg or serum bicarbonate  $\geq 27$  mEq/L.

These patients represent “a subset, if you will, of obesity hypoventilation syndrome – a subset

that we were able to capture from our sleep studies [because] we do CO<sub>2</sub> monitoring during sleep studies uniformly,” Dr. Mehra said in an interview after the meeting.

Pornprapa Chindamporn, MD, a former fellow at the center and first author on the abstract, presented the findings. Patients in the study had a mean age of 45.2  $\pm$  12.0 years and a BMI of 48.7  $\pm$  9.0. Approximately 20% were male and 63.6% were White.

Those with obesity-associated sleep hypoventilation were more likely to be male and have a higher BMI and higher hemoglobin A<sub>1c</sub> than those without the condition. They also had a significantly higher apnea-hypopnea index (17.0 vs. 13.8) in those without the condition, she reported.

A number of outcomes (ICU stay, intubation, tracheostomy, discharge disposition, and 30-day readmission) were compared individually and as a composite outcome between those with and without obesity sleep hypoventilation syndrome (OHS). While some of these postoperative mor-

bidities were more common in patients with the condition, the differences between those with and without OHS were not statistically significant for intubation (1.5% vs. 1.3%, *P* = .81) and 30-day readmission (13.8% vs. 11.3%, *P* = .16).

*More than two-thirds of these patients, 68.5%, had obesity hypoventilation syndrome (OHS) as defined by BMI of  $\geq 30$  kg/m<sup>2</sup> and either polysomnography-based end-tidal CO<sub>2</sub>  $\geq 45$  mm Hg or serum bicarbonate  $\geq 27$  mEq/L.*

However, the composite outcome was significantly higher: 18.9% vs. 14.3% (*P* = .021), including in multivariable analysis that considered age, gender, BMI, Apnea Hypopnea Index, and diabetes.

All-cause mortality was not significantly differ-

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# Screening algorithm safely selects patients for OSA treatment before bariatric surgery

BY CHRISTINE KILGORE  
MDedge News

**A** novel algorithm for selecting patients who require treatment for obstructive sleep apnea (OSA) before undergoing bariatric surgery proved safe in a prospective cohort study of 1,103 patients.

Screening for OSA is recommended before bariatric surgery. OSA has been associated in several meta-analyses with increased risk for postoperative complications – not limited to bariatric surgery – and some studies have suggested that this increased risk may be limited to severe OSA, said Frédéric Series, MD, of Université Laval, Quebec City, at the virtual annual meeting of the Associated Sleep Societies.

The preoperative screening algorithm, which utilizes the results of nocturnal home oximetry and morning capillary gas measurements, effectively stratified patients for the risk of postoperative adverse events and “safely selected patients who don’t need [continuous positive airway pressure] before bariatric surgery,” he said. “The risk of postoperative adverse events following bariatric surgery was not increased

in untreated OSA patients with low or moderate risk of severe OSA and hypoventilation.”

The study also demonstrated, he said, that patients with severe OSA with or without hypoventilation, even when correctly treated, remain at higher risk for complications.

The algorithm utilizes an oxygen desaturation index (ODI) corre-

*The study also demonstrated that patients with severe OSA with or without hypoventilation, even when correctly treated, remain at higher risk for complications.*

sponding to 3% drops in SaO<sub>2</sub> and the percent of the total recording time with an SaO<sub>2</sub> below 90%, as well as capillary gas measurements (PCO<sub>2</sub>). Treatment was initiated for those with severe OSA (ODI ≥ 25/hr, < 10% of recording time with a SaO<sub>2</sub> below 90%) or OSA with hypoventilation (PCO<sub>2</sub> ≥ 45).

“When the ODI was less than 25 per hour, and when the total re-

ording time spent below 90% SaO<sub>2</sub> was less than 10%, with PCO<sub>2</sub> < 45 mmHg, we expected no need for CPAP treatment,” Dr. Series said.

For analysis, the investigators considered part of the untreated group – those with an ODI < 10/hr (no or mild OSA) – as a control group.

Treated patients underwent CPAP/BiPAP for a mean duration of 1.5 months. Good treatment compliance was mandatory for surgery, and treatment was continued immediately after extubation, in the recovery room, in nearly all patients, Dr. Series reported.

The analysis covered 1,103 patients: 447 controls (40.8%), 358 untreated (32.7%), 289 treated for OSA (26.4%) and 9 (0.8%) treated for OSA + hypoventilation. Patients with OSA, particularly those with severe OSA and those with hypoventilation, were older and heavier and significantly more likely to have hypertension and diabetes than controls.

There were no differences between the four groups in 10-day reoperation or 30-day readmission occurrence, and postoperative complications were “particularly infrequent in the control and OSA-un-

treated groups, with no differences between these two groups,” Dr. Series said.

Cardiac arrhythmia (mainly atrial fibrillation) occurred more frequently in the OSA-treated group (2.4%) and the OSA/hypoventilation patients (11%) than in the other groups (0.5%-0.6%).

Respiratory failure occurred in about one-third of patients with hypoventilation, and admission to the ICU was “dramatically higher” in patients with hypoventilation (67%), because of respiratory failure, arrhythmia, or other unstable medical conditions, Dr. Series said.

There were no differences between the groups in the duration of surgery or the amount of anesthetic used, but the length of stay in the recovery room was significantly longer in the OSA-treated and hypoventilation groups. The length of hospital stay was also longer in these groups. Sleeve gastrectomy was the most frequent bariatric surgical procedure across all groups, including 100% of patients with hypoventilation, he noted.

Dr. Series reported that he has no relevant disclosures.

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ent between the groups, likely because of its low overall rate (hazard ratio, 1.39; 95% confidence interval, 0.56-3.42).

“In this largest sample to date of systematically phenotyped obesity-associated sleep hypoventilation in patients undergoing bariatric surgery, we identified increased postoperative morbidity,” said Dr. Chindamporn, now a pulmonologist and sleep specialist practicing in Bangkok.

Dr. Mehra said in the interview that patients considering bariatric surgery are typically assessed for obstructive sleep apnea, but “not so much obesity hypoventilation syndrome or obesity-associated sleep-related hypoventilation syndrome.” The findings “support the notion that we should be closely examining sleep-related hypoventilation in these patients.”

At the Cleveland Clinic, “clinically, we make sure we’re identifying these individuals and communicating the findings to bariatric surgery colleagues and to anesthesia,” said Dr. Mehra, also professor of medicine at Case Western Reserve University, Cleveland.

OHS is defined, according to the 2019 American Thoracic Society clinical practice guideline on evaluation and management of OHS, by the combination of obesity, sleep-disordered breathing, and awake daytime hypercapnia, after ex-

cluding other causes for hypoventilation (Am J Respir Crit Care Med. 2019;200[3]:e6-24).

A European Respiratory Society task force has proposed severity grading for OHS, with early stages defined by sleep-related hypoventilation and the highest grade of severity defined by morbidity-associated daytime hypercapnia (Eur

*Patients considering bariatric surgery are typically assessed for obstructive sleep apnea, but “not so much OHS or obesity-associated sleep-related hypoventilation syndrome.”*

Respir Rev. 2019;28:180097). However, Dr. Mehra said she is “not sure that we know enough [from long-term studies of OHS] to say definitively that there’s such an evolution.”

Certainly, she said, future research on OHS should consider its heterogeneity. It is possible that a subset of patients with OHS, “maybe these individuals with sleep-related hypoventilation,” are most likely to have adverse postsurgical outcomes.

Atul Malhotra, MD, professor of medicine at the University of California, San Diego, who was asked to comment on the study, said that OHS is understudied in general and particularly in the

perioperative setting. “With the obesity pandemic, issues around OHS are likely to be [increasingly] important. And with increasing [use of] bariatric surgery, strategies to minimize risks are clearly needed,” he said, adding that the potential risks of nonbariatric surgery in patients with OHS require further study.

He noted that mortality rates in good hospitals “have become quite low for many elective surgeries, making it hard to show mortality benefit to most interventions.”

The ATS guideline on OHS states that it is the most severe form of obesity-induced respiratory compromise and leads to serious sequelae, including increased rates of mortality, chronic heart failure, pulmonary hypertension, and hospitalization caused by acute-on-chronic hypercapnic respiratory failure.

Dr. Chindamporn said in her presentation that she had no disclosures. Dr. Mehra’s research program is funded by the National Institute of Health, but she has also procured funding from the American College of Chest Physicians, American Heart Association, Clinical Translational Science Collaborative, and Central Society of Clinical Research. Dr. Malhotra disclosed that he is funded by the NIH and has received income from Merck and Livanova related to medical education.

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# E-cigarettes may be linked to sleep deprivation

BY RICHARD FRANKI

MDedge News

Current and former users of e-cigarettes are more likely to report sleep deprivation, compared with those who have never used e-cigarettes, according to the first study to evaluate the association in a large, nationally representative population of young adults.

“The e-cigarette use and sleep deprivation association seems to have a dose-response nature as the point estimate of the association increased with increased exposure to e-cigarette,” Sina Kianersi, DVM, and associates at Indiana University, Bloomington, said in Addictive Behaviors.

Sleep deprivation was 49% more prevalent among everyday users of e-cigarettes, compared with non-users. Prevalence ratios for former users (1.31) and occasional users (1.25) also showed significantly higher sleep deprivation, compared with nonusers, they reported based on a bivariate analysis of data from young adults aged 18-24 years who participated in the 2017 and 2018 Behavioral Risk Factor Surveillance System surveys

After adjustment for multiple confounders, young adults who currently used e-cigarettes every day were 42% more likely to report sleep deprivation than those who never used e-cigarettes, a difference that was statistically significant.

The prevalence of sleep deprivation among those who used e-cigarettes on some days was not significantly higher (prevalence ratio, 1.08), but the ratio between former users and never users was a significant 1.17, the investigators said.

“The nicotine in the inhaled e-cigarette aerosols may have negative effects on sleep architecture and disturb the neurotransmitters that regulate sleep cycle,” they suggested, and since higher doses of nicotine produce greater reductions in sleep duration, “those who use e-cigarette on a daily basis might consume higher doses of nicotine, compared to some days, former, and never users, and therefore get fewer hours of sleep.”

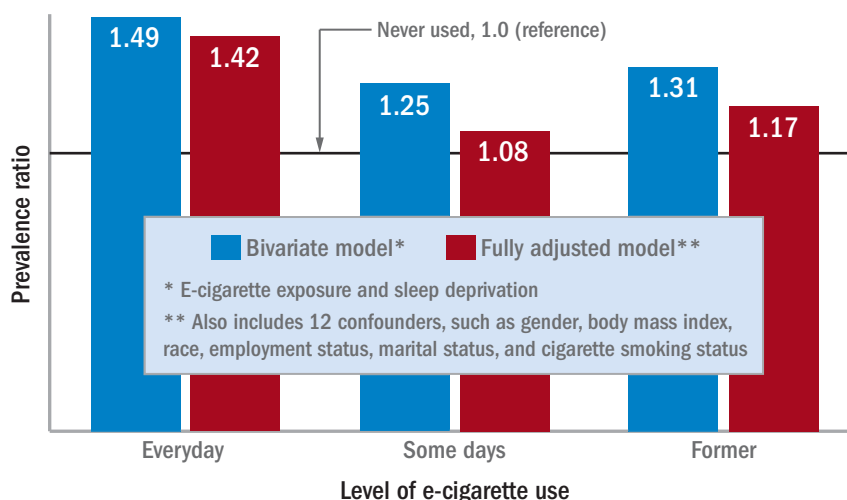
Nicotine withdrawal, on the other hand, has been found to increase sleep duration in a dose-dependent manner, which “could explain the smaller [prevalence ratios] observed for the association between e-cigarette use and sleep deprivation among former and some days e-cigarette users,” Dr. Kianersi and associates added.

The bivariate analysis involved 18,945 survey respondents, of whom 16,427 were included in the fully adjusted model using 12 confounding factors.

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**SOURCE:** Kianersi S et al. Addict Behav. 2020 Sep 6. doi: 10.1016/j.addbeh.2020.106646.

## Sleep deprivation more common in e-cigarette users



Note: Based on data for 18,945 (bivariate) and 16,427 (fully adjusted) young adults who responded to the 2017 and 2018 Behavioral Risk Factor Surveillance System surveys.

Source: Addict Behav. 2020 Sep 6. doi: 10.1016/j.addbeh.2020.106646



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# OSA may affect pain threshold in young adults

BY DOUG BRUNK

*MDedge News*

**S**leep specialists might want to take a closer look at the connections between obstructive sleep apnea, chronic pain, and reported pain intensity in younger patients. Young adults with a diagnosis of obstructive sleep apnea (OSA) are more likely to report moderate to severe pain intensity, compared with their peers who do not have the diagnosis, results from a large cross-sectional analysis showed.

“Because of the high burden of chronic pain conditions in younger adults, this study highlights the need to understand the impact of OSA diagnosis and treatment on pain intensity,” researchers led by Wardah Athar, a graduate student at Yale University, New Haven, Conn., and Lori A. Bastian, MD, MPH, a professor of internal medicine at Yale, wrote in an article published in *Annals of the American Thoracic Society*. “This understanding would then help inform the development of interventions to promote screening for OSA among young adults with chronic pain and pain management among those with diagnosed OSA.”

The study looked at data from young adult veterans, who frequently report significant musculoskeletal pain. “The specific link between



Dr. Lori A. Bastian

OSA and pain remains unclear, but one hypothesis posits that patients with OSA become hyperalgesic because of fragmented sleep, thereby enhancing sensitivity to pain, promoting inflammation, and advancing spontaneous pain. It is also believed that this association may be bidirectional, with an increase in pain and opioid use shown to be associated with sleep-disordered breathing. In addition, OSA is associated with the development and progression of headaches. Most studies examining the association of OSA and pain intensity have includ-



Wardah Athar

ed older (age 50 years and above) patients, so there is a need to understand the relationship between OSA and pain among younger adults and to examine for potential sex differences.”

In an effort to assess whether young adults with diagnosed OSA are more likely to report higher pain intensity, compared with those without OSA, the researchers drew from a sample of 858,226 veterans from Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn who had at least one visit to a VA clinic between 2001 and 2014. They used ICD-9 codes to identify OSA and assessed self-reported responses to pain measures on a 0-10 numeric scale which were recorded in each veteran’s EMR. Next, they averaged pain intensity responses over a 12-month period and categorized them as none (0), mild (1-3), and moderate/severe (4-10). Covariates included age, sex, education, race, mental health diagnoses, headache diagnoses, pain diagnoses, hypertension, diabetes, body mass index, and smoking status. The researchers used multivariate logistic regression models and multiple imputation to generate values for missing variables.

The mean age of the patients was 30 years, 64% were White, 17% were Black, 12% were Hispanic, and remainder were other/unknown race/ethnicity. Ninety percent were male, and 20% had greater than a high school education. Of the 858,226 patients, 91,244 (11%) had a diagnosis of OSA. Compared with patients who had no diagnosis of OSA, the

unadjusted odds of reporting moderate/severe pain was 48% higher among those with OSA (odds ratio, 1.48;  $P < .0001$ ). After the researchers adjusted for all covariates in the model, the association between OSA and moderate/severe pain remained significant though attenuated, with an adjusted odds ratio of 1.09 ( $P < .0001$ ).

Several characteristics were different between those who had a diagnosis of OSA and those who did not, including age (a mean of 36 vs. 26 years, respectively) and having the following diagnoses: pain (36% vs. 16%), headache (28% vs. 14%), diabetes (12% vs. 2%), hypertension (40% vs. 12%), and a body mass index of 30 kg/m<sup>2</sup> or greater (69% vs. 35%). Certain psychiatric disorders were also common among patients with OSA, including major depressive disorder (20% vs. 10%), posttraumatic stress disorder (50% vs. 30%), and substance use disorder (26% vs. 17%). Patients with OSA were also more likely to have been prescribed benzodiazepines or opioids within 90 days of their OSA diagnosis. Although men were more likely to have a diagnosis of OSA, no differences related to sex in the association of OSA and pain were observed in sex-based stratified analyses.

“Based on these results, we suggest more thorough and more frequent pain intensity screening in patients with OSA, particularly in those patients who are younger than 60 years old without significant comorbid illness,” the researchers concluded. “Furthermore, we also recommend increased OSA screening for patients with moderate/severe pain intensity and pain diagnoses.” One tool they recommend is the STOP-Bang (Snoring, Tiredness, Observed Apnea, Blood Pressure, Body Mass Index, Age, Neck Circumference, and Gender) questionnaire, which has been validated in multiple settings (PLoS One. 2015;10:e0143697).

The study was supported by the Health Services Research & Development in the Department of Veterans Affairs of the Veterans Health Administration, the Yale School of Medicine Medical Student Fellowship, and the U.S. National Institutes of Health.

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**SOURCE:** Athar W et al. *Ann Am Thorac Soc*. 2020;17(10):1273-48.

## VIEW ON THE NEWS

**Krishna M. Sundar, MD, FCCP, comments:** One of the problems with sleep apnea studies is that there are always confounding effects, especially from BMI. This is a population that has a significant medical burden of disease, but I think this is a well-done study to look at the relationship between pain and OSA in a younger population. The authors tried to adjust for all these confounders and they still found a significant association. This indicates that sleep affects one’s pain threshold. And sleep apnea, by mechanisms still yet to be defined, also alters that pain threshold. It may also affect the expression of pain or management of pain, making treatment more problematic in this population. A key limitation of the study was the fact it evaluated only one aspect of sleep: OSA. They didn’t look at duration of sleep, comorbid insomnia, or fragmentation of sleep from apnea or from other causes. We have multiple ways of treating sleep apnea. Clearly, we need studies of treating sleep apnea with continuous positive airway pressure and how that affects the occurrence of pain. The relevant practical aspect of this is that there are pain clinics all over the country that should screen for sleep apnea. Along the same lines, sleep practitioners should be aware that pain has an important association with sleep apnea.





# COLCOT: The earlier the better for colchicine post MI

BY PATRICE WENDLING

**T**he earlier the anti-inflammatory drug colchicine is initiated after a myocardial infarction the greater the benefit, a new COLCOT analysis suggests.

The parent trial was conducted in patients with a recent MI because of the intense inflammation present at that time, and added colchicine 0.5 mg daily to standard care within 30 days following MI.

As previously reported, colchicine significantly reduced the risk of the primary end point – a composite of cardiovascular (CV) death, resuscitated cardiac arrest, MI, stroke, or urgent hospitalization for angina requiring revascularization – by 23% compared with placebo.

This new analysis shows the risk

lating for colchicine from COLCOT, LoDoCo, and, most recently, the LoDoCo2 trial, even as another anti-inflammatory drug, methotrexate, flamed out as secondary prevention in the CIRT trial.

The new COLCOT substudy included 4,661 of the 4,745 original patients and examined treatment initiation using three strata: within 0-3 days (n = 1,193), 4-7 days (n = 720), and 8-30 days (n = 2,748). Patients who received treatment within 3 days were slightly younger, were more likely to be smokers, and had a shorter time from MI to randomization (2.1 days vs 5.1 days vs. 20.8 days, respectively).

In the subset receiving treatment within 3 days, those assigned to colchicine had the same number of cardiac deaths as those given placebo

(2 vs. 2) but fewer resuscitated cardiac arrests (1 vs. 3), MIs (17 vs. 29), strokes (1 vs. 5), and urgent hospitalizations for angina requiring revascularization (6 vs. 17).

“A larger trial might have allowed for a better assessment of individual endpoints and subgroups,” observed Bouabdallaoui.

“Although there is growing support for colchicine, experts caution that the drug may not be for everyone. In COLCOT, 1 in 10 patients were unable to tolerate the drug, largely because of gastrointestinal (GI) issues.

**Pharmacogenomics substudy**  
A second COLCOT substudy aimed to identify genetic markers predictive of colchicine response and to gain insights into the mechanisms behind this response. It included 767 patients treated with colchicine and another 755 treated with placebo – or about one-third the patients in the original trial.

A genomewide association study did not find a significant association for the primary CV endpoint, although a prespecified subgroup analysis in men identified an interesting region on chromosome 9 (variant: rs10811106), which just missed reaching genomewide sig-

nificance, said Marie-Pierre Dubé, PhD, director of the Université de Montréal Beaulieu-Saucier Pharmacogenomics Centre at the Montreal Heart Institute.

In addition, the genomewide analysis found two significant regions for GI events: one on chromosome 6 (variant: rs6916345) and one on chromosome 10 (variant: rs74795203).

For each of the identified regions, the researchers then tested the effect of the allele in the placebo group and the interaction between the genetic variant and treatment with colchicine. For the chromosome 9 region in males, there was no effect in the placebo group and a significant interaction in the colchicine group.

For the significant GI event findings, there was a small effect for the chromosome 6 region in the placebo group and a very significant interaction with colchicine, Dr. Dubé said. Similarly, there was no effect for the chromosome 10 region in the placebo group and a significant interaction with colchicine.

Additional analyses in stratified patient populations showed that males with the protective allele (CC) for the chromosome 9 region represented 83% of the population. The primary CV endpoint occurred in 3.2% of these men treated with colchicine and 6.3% treated with placebo (HR, 0.46; 95% CI, 0.24-0.86).

For the gastrointestinal events, 25% of patients carried the risk allele (AA) for the chromosome 6 region and 36.9% of these had GI events when treated with colchicine versus 18.6% when treated with placebo (HR, 2.42; 95% CI, 1.57-3.72).

Similarly, 13% of individuals carried one or two copies of the risk allele (AG+GG) for the chromosome 10 region and the risk of GI events in these was nearly four times higher with colchicine (47.1% vs. 18.9%; HR, 3.98; 95% CI 2.24-7.07).

Functional genomic analyses of the identified regions were also performed and showed that the chromosome 9 locus overlaps with the SAXO1 gene, a stabilizer of axonemal microtubules 1.

“The leading variant at this locus (rs10811106 C allele) correlated with the expression of the HAUS6 gene, which is involved in microtubule generation from existing microtubules, and may interact with the effect of colchicine,

**G. Hossein Almassi, MD, FCCP, comments:** This is an interesting

study on an old drug finding new use in patients with myocardial infarction. The pharmacogenomic studies opens new avenues for personalized medicine in cardiac patients.



which is known to inhibit microtubule formation,” observed Dr. Dubé.

Also, the chromosome 6 locus associated with gastrointestinal events was colocalizing with the Crohn’s disease locus, adding further support for this region.

“The results support potential personalized approaches to inflammation reduction for cardiovascular prevention,” Dr. Dubé said.

This is a post hoc subgroup analysis, however, and replication is necessary, ideally in prospective randomized trials, she noted.

The substudy is important because it provides further insights into the link between colchicine and microtubule polymerization, affecting the activation of the inflammasome, session moderator Dr. Imazio said.

“Second, it is important because pharmacogenomics can help us to better understand the optimal responder to colchicine and colchicine resistance,” he said. “So it can be useful for personalized medicine, leading to the proper use of the drug for the proper patient.”

COLCOT was supported by the government of Quebec, the Canadian Institutes of Health Research, and philanthropic foundations. Bouabdallaoui has disclosed no relevant financial relationships. Dr. Dubé reported grants from the government of Quebec; personal fees from DalCor and GlaxoSmithKline; research support from AstraZeneca, Pfizer, Servier, Sanofi; and minor equity interest in DalCor. Dr. Dubé is also coauthor of patents on pharmacogenomics-guided CETP inhibition, and pharmacogenomics markers of response to colchicine.

*A version of this article originally appeared on Medscape.com.*

*Experts caution that colchicine may not be for everyone.*

*In COLCOT, 1 in 10 patients were unable to tolerate the drug, largely because of gastrointestinal issues.*

was reduced by 48% in patients receiving colchicine within 3 days of an MI (4.3% vs. 8.3%; adjusted hazard ratio, 0.52; 95% confidence interval, 0.32-0.84;  $P = .007$ ).

Risk of a secondary efficacy end point – CV death, resuscitated cardiac arrest, MI, or stroke – was reduced by 45% over an average follow-up of 22.7 months (3.3% vs 6.1%; adjusted HR, 0.55; 95% CI, 0.32-0.95;  $P = .031$ ).

“We believe that our results support an early, in-hospital initiation of adjunctive colchicine for post-MI prevention,” Nadia Bouabdallaoui, MD, Montreal Heart Institute, said during an online session devoted to colchicine at the European Society of Cardiology Congress 2020.

Session moderator Massimo Imazio, MD, professor of cardiology at the University of Turin (Italy), said the improved outcomes suggest that earlier treatment is better – a finding that parallels his own experience using colchicine in patients with pericarditis.

“This substudy is very important because this is probably also the year in cardiovascular applications [that] early use of the drug could improve outcomes,” he said.

Positive data have been accumu-



# Outgoing President's final report

BY STEPHANIE M. LEVINE,  
MD, FCCP

**A**s I am writing this report, my presidential year is coming to a close. It was certainly not what I could have anticipated, but an incredible opportunity for my personal and professional growth, and a year in which CHEST adapted and grew, as well. We accomplished a great deal during this unprecedented year, and I will take this opportunity for a year-in-review!

In the winter, as COVID-19 appeared across the globe, we established a COVID-19 Task Force led by then incoming President, Dr. Steve Simpson, with the goal of keeping our members updated on the latest research and clinical management of COVID-19 illness, as well as distilling and delivering the latest COVID-19-related information quickly to those on the front lines. We have held weekly COVID-19 webinars, disseminated infographics, and developed an interactive COVID-19 quiz. CHEST also published several COVID-19-related guideline statements and expert panel reports on bronchoscopy, tracheostomy, lung nodule management, and venous thromboembolism in the setting of COVID-19.

Knowing the stress that our health-care workers were under, we also established a CHEST Wellness Center. This longitudinal, webinar-based curriculum, led by Dr. Alex Niven, had its impetus with COVID-19 but will continue and be extended to general wellness topics.

In March, we joined forces with NAMDRC, under the CHEST umbrella, and a combination of our board members and their former board members now make up our Health Policy and Advocacy Committee (HPAC), led by Drs. Neil Freedman and Jim Lamberti, with CHEST Past-President, Dr. John Studdard, also actively involved. Our HPAC is already focusing on home ventilation and competitive bidding, oxygen prescribing, education and access, pulmonary rehabilitation, and tobacco and vaping. The monthly *Washington Watchline* online publication features the latest on advocacy-related issues of interest to our membership. Last month, the HPAC held a multiorganizational technical expert panel meeting on nocturnal noninvasive ventilation, with plans

to submit a manuscript on outcomes from the meeting to the journal *CHEST*. These activities are an answer to our member's requests and needs in the areas of advocacy.

With the onset of the pandemic, we pivoted the delivery of our signature education to virtual platforms beginning with a successful global congress in Bologna in June with 3,500 registered attendees. This was

*Knowing the stress that our health-care workers were under, we also established a CHEST Wellness Center. This longitudinal, webinar-based curriculum, led by Dr. Alex Niven, had its impetus with COVID-19 but will continue and be extended to general wellness topics.*

a wonderful way to provide education to our global audience. I want to thank co-chairs Dr. Bill Kelly and Dr. Girolamo Pelaia, and Dr. Francesco de Blasio from our Italian Delegation, for their innovative leadership. In August, we held our first virtual board review courses in pulmonary medicine, critical care medicine, and pediatric pulmonary medicine, attended by 775 registered attendees complete with didactic sessions, audience response sessions, SEEK sessions, and live Q&A with the faculty. The on-demand versions of these courses are also available.

The *CHEST* journal, in its second year with Dr. Peter Mazzone at the helm, continues to be a leading source of clinically relevant research and patient management guidance for pulmonary, critical care, and sleep medicine clinicians worldwide. The year 2020 has been a year like no other – submission rates have doubled since the start of the pandemic, with nearly 5,000 manuscript submissions so far, this year. The journal has rapidly built a robust and growing COVID-19 topic collection, with relevant original research, guidelines, commentaries, and more, published online, within days of acceptance. The journal will continue to seek innovative ways to meet the needs of its readers and

contributors during this time when our members and their patients urgently need current and high-quality information.

This year, CHEST hit a publishing milestone, with the publication of *CHEST SEEK™ Critical Care Medicine: 30th Edition* and the SEEK program is celebrating 30 years! Those who registered for CHEST 2020 by October 15 received the access an-



Dr. Levine

nouncement regarding the commemorative 30 Years of SEEK collection in the CHEST SEEK Library.

Our Guidelines Oversight Committee has continued to publish evidence-based guidelines in the areas of cough and cryobiopsy, with a guideline on hypersensitivity pneumonitis and updated guidelines in our core topics of lung cancer and venous thromboembolism in the works.

Under the leadership of Dr. Aneesa Das, the NetWorks Task Force started work to accomplish the goal of increasing member engagement and reach by developing pilot projects focusing on infographics interviews with key opinion leaders and social media communications. Additionally, the Digital Strategy Task Force launched a redesigned website for the CHEST Foundation, which you can see at [chestfoundation.org](http://chestfoundation.org), and look for exciting changes coming to the CHEST website in the very near future.

We have continued our collaborative partnerships with our sister societies. We established the volunteer clinician matching program with the American Thoracic Society (ATS) to send clinicians to areas of need during the pandemic, and partnered on other COVID-19 related activities. We held a virtual fellows' graduation with ATS and the Asso-

ciation of Pulmonary and Critical Care Medicine Program Directors. CHEST leadership attended the Asian Pacific Respiratory Society in Vietnam in November, the Society of Critical Care Medicine, and Forum of International Respiratory Societies in February and the recent virtual meetings of ATS, European Respiratory Society, and the Brazilian Thoracic Society.

The CHEST Foundation has continued on their mission to champion lung health and make a difference through their successful fundraising. This was highlighted with a tremendous foundation gala in San Antonio in December, The Golden Era of Erin Popovich, attended by more than 500 people. Since COVID-19, the foundation held several creative virtual fundraising events ranging from wine tastings to poker night to bingo night to a recent trivia night, as well as actively participating in COVID-19-related campaigns, such as the partnership with ATS for COVID-19 public service announcements directed to those affected by COVID-19, and other fundraising campaigns, such as the Buy-A-Mask, Give-A-Mask campaign. In addition, the foundation has continued with their support for clinical research grants, community service grants, and patient education resources and toolkits. For example, they have developed an oxygen tool kit to provide access and empowerment to patients in need.

Thank you to all our donors for continuing to support these CHEST Foundation initiatives. The foundation couldn't continue to do this amazing work to create an impact and raise awareness for lung health without you.

As the movement to combat racism and racial disparity swept across our nation, we issued a statement of equity in early June. In September, the CHEST Foundation launched the first of a series of listening tours to hear community needs in the areas of trust, access, and equity. Information from these tours will be used to launch a designated fund to have the power to transform these needs into action. CHEST is now actively developing a strategic plan focusing on how CHEST can make an impactful difference in this arena. We want to ensure we take this essential time to listen, reflect, and make appropriate plans for ways we can truly make a difference. Expect more to come on this in the coming year.



The year concluded with CHEST 2020. CHEST 2020 had the highest number of case reports and abstracts ever submitted to a CHEST Annual Meeting, and a total registration of more than 4,000. At CHEST 2020, you had an opportunity to see a reimagined virtual annual meeting with combinations of interactive live and prerecorded didactic sessions, audience response sessions, live Q&A with the faculty, educational games at the CHEST Gaming Hub, CHEST Challenge Championship, networking opportunities, narrated abstracts, case reports, original research presentations, COVID-19 update sessions, industry-sponsored programs, a virtual exhibit hall, and surprises, to deliver the in-person CHEST experience virtually. In addition, this came with the greatest number of CME/MOC credits we have ever offered! And, CHEST 2020 education will continue throughout the year with ongoing postgraduate courses creating the ultimate longitudinal educational experience. While

You will hear more from him, but you are in the hands of a thoughtful and dedicated leader with a long history of CHEST experience, strong expertise in critical care, and a thought leader in the COVID-19 pandemic, including serving on the NIH COVID-19 Treatment Guidelines Panel.

There are so many people to thank! I want to thank my family: my husband and children, and my work family, the faculty and fellows of my division, for their unwavering support. I also want to thank my Co-President lineage group for their counsel and wisdom, several Past Presidents who I have called on over this past year for advice, Drs. John Studdard, Gerard Silvestri, and Darcy Marciniuk among others, the board (who I only saw face-to-face once!); our CHEST leadership and educators; the incredible CHEST staff; the Executive Leadership team; and our superb, hard-working CEO/EVP Bob Musacchio. Last, and most impor-

*Through this year of crisis and change, you all have shown resilience: a resilience molded by being flexible. Not only have you embodied flexibility at your home institutions, you've embodied flexibility in your learning, teaching, and connecting. You've joined us as we've reimagined what learning at CHEST is all about - I sincerely thank you for that!*

nothing can replace the opportunity to connect with our community in person, I hope you found that this year's meeting provided a wealth of learning, connection, and fun.

My sincere thanks to the CHEST 2020 Program Chair, Dr. Victor Test, to the entire Scientific Program Committee, and to our incredible CHEST staff, for the immense amount of hard work over the past year to reimagine CHEST 2020 and make it a reality. Little did Victor know that he would be planning three meetings: a live meeting, a hybrid meeting, and, ultimately, a virtual meeting. Thank you for all you did to make CHEST 2020 a meeting to remember. We plan to continue our efforts to maintain and grow educational innovation year-round through more e-learning, virtual learning, and, hopefully soon, live learning, both locally, nationally, and internationally.

As my year closes, you are in excellent hands with Dr. Steven Simpson, your 83rd President, who will lead the organization forward.

tantly, I would like to thank our members for being in the trenches this year as we all dealt with COVID-19. You are the heroes! At the beginning of my term last year, I told you that my goal was to be "the welcoming home" for interprofessional health-care team members seeking to obtain the best possible educational experiences and patient outcomes. I had no idea how absolutely needed this would be for our chest medicine family this year. CHEST has always been your connection to relevant clinical information and late-breaking updates in our field - but this year, our CHEST community has been even more than that. Through this year of crisis and change, you all have shown resilience: a resilience molded by being flexible. Not only have you embodied flexibility at your home institutions, you've embodied flexibility in your learning, teaching, and connecting. You've joined us as we've reimagined what learning at CHEST is all about - I sincerely thank you for that!



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### CHAMPIONSHIP FINAL

- Thursday | February 18 | 7:00 PM CT





## SLEEP STRATEGIES

## Sleep-disordered breathing in neuromuscular disease

BY MEREDITH KENDALL GREER, MD; AND NANCY A. COLLOP, MD, MASTER FCCP

**S**leep-disordered breathing (SDB) is a common sleep disturbance in neuromuscular disease (NMD) affecting 36% to 53% of diagnosed adults (Arens R, et al. *Paediatr Respir Rev.* 2010;11[1]:24). Disturbances in sleep may serve as the earliest sign of muscle weakness in these patients, at times being detected before their underlying neuromuscular disease is diagnosed. This is of paramount importance to sleep medicine and pulmonary physicians who may be among the first specialists to evaluate these patients and can play a vital role in the recognition and diagnosis of neuromuscular disease. Herein, we will provide a guide to aid the reader in recognizing the early signs and symptoms of NMD as it pertains to sleep, as earlier diagnosis may lead to improved quality of life or possibly even survival, in some cases.

### Pathophysiology

To begin, it is important to understand the pathophysiology of NMD and how it is altered during the sleep state. Sleep-related physiologic changes in healthy humans include reduction in upper airway muscle tone, blunting of chemoreceptors associated with pharyngeal dilator augmentation, and sleep stage-specific changes in skeletal muscle tone. In patients with NMD, these changes may not be adequately compensated for, leading to sleep-disordered breathing that can present as sleep apnea, hypoventilation, or hypoxia (Govindarajan R, et al. *Sleep Issues in Neuromuscular Disorders: A Clinical Guide.* Springer International Publishing AG, Springer Nature 2018).

### Central respiratory control

The respiratory centers in the pons and medulla are generally spared from the primary effects of most NMD; however, over time, they may be affected secondarily. Similar to obesity hypoventilation syndrome (OHS), untreated chronic sleep-related hypoventilation from NMD can impair the sensitivity of respiratory chemoreceptors leading to worsening hypoventilation.



Dr. Greer

### Upper airway resistance

Pharyngeal muscle tone is key to maintaining a patent airway during sleep. In some NMD, bulbar muscle weakness with pharyngeal dilator muscle hypotonia leads to increased upper airway resistance, especially during REM sleep, which can result in obstructive sleep apnea (OSA). In addition to weakness affecting the upper airway musculature, anatomical changes may also contribute to SDB. In Pompe disease, for example, macroglossia and fibro-fatty replacement of tongue muscles may occur, leading to the development of OSA.

### Diaphragm weakness

In NMD that affects the diaphragm, there is an increased reliance on the skeletal muscles of respiration to maintain adequate ventilation as the underlying disease progresses. Generally, weakness of the diaphragm will cause disturbances in REM sleep first as, during REM, ventilation predominantly depends on the diaphragm and patients lose the assistance of their skeletal muscles. However, over time, the progressive weakening of the diaphragm will progress to involve NREM sleep as well, clinically manifesting with frank sleep apnea, hypoventilation, and, ultimately, chronic hypercapnic respiratory failure.

### Inspiratory muscle weakness

As noted above, there are many other muscles used in inspiration in addition to the diaphragm. Other primary muscles include the intercostal and scalene muscles, and accessory muscles include the



Dr. Collop

sternocleidomastoid, pectoralis, latissimus dorsi, erector spinae, and trapezius muscles. While sleep and breathing problems may begin early in the course of a neuromuscular disease, the complex restrictive lung disease pattern that we see in these patients may not develop until the respiratory muscles of the chest wall are involved. This restriction, which corresponds to lower lung volumes, leads to a fall in the caudal traction force of the airways which can lead to reduction in the pharyngeal airway cross section. Because these issues are worsened in the supine position, their pathophysiologic effects on respiration are most notable during sleep, putting patients at higher risk of OSA.

### Cardiac abnormalities

Lastly, it should be noted that diseases such as the muscular dystrophies, myotonic dystrophy, mitochondriopathies, and nemaline myopathy can be associated with a cardiomyopathy, which can lead to central sleep apnea in the form of Cheyne-Stokes breathing.

### Sleep-disordered breathing in specific NMDs

In amyotrophic lateral sclerosis (ALS), up to 75% of patients may have SDB, the majority of which is central sleep apnea (CSA) and hypoventilation although they still have a higher prevalence of OSA than the general population. Whether the diaphragm or the pharyngeal muscles are predominantly affected may have something to do with the type of apnea a patient experiences; however,

studies have shown that even in bulbar ALS, CSA is most common. It should be noted, that this is not Cheyne-Stokes CSA, but rather lack of chest wall and abdominal movement due to weakness. (David WS, et al. *J Neurol Sci.* 1997;152[suppl 1]:S29-35).

In myasthenia gravis (MG), about 40% to 60% of patients have SDB, and about 30% develop overt respiratory weakness, generally late in the course of their disease. Many of these patients report excessive daytime sleepiness, often attributed to myasthenic fatigue requiring treatment with corticosteroids. It is important to evaluate for sleep apnea, given that if diagnosed and treated, their generalized fatigue may improve and the need for steroids may

*Pharyngeal muscle tone is key to maintaining a patent airway during sleep. In some NMD, bulbar muscle weakness with pharyngeal dilator muscle hypotonia leads to increased upper airway resistance, especially during REM sleep, which can result in obstructive sleep apnea.*

be reduced or eliminated altogether. It is also important to note that the respiratory and sleep issues MG patients face may not correlate with the severity of their overall disease, such that patients well-controlled on medications from a generalized weakness standpoint may still require home noninvasive ventilation (NIV) for chronic respiratory failure due to weakness of the respiratory system muscles.

Duchenne muscular dystrophy (DMD), an X-linked disease associated with dysfunction of dystrophin synthesis, is often diagnosed in early childhood and gradually progresses over years. Their initial sleep and respiratory symptoms can be subtle and may start with increased nighttime awakenings and daytime somnolence. Generally, these patients will develop OSA in the first decade of life and progress to hypoventilation in

*Continued on page 42*



**This advertisement is  
not available for the digital edition.**



Continued from page 40

their second decade and beyond. These patients are especially important to recognize, as studies have shown appropriate NIV therapy may significantly prolong their life (Finder JD, et al; American Thoracic Society. *Am J Respir Crit Care Med.* 2004(Aug 15);170[4]:456-465).

In addition to the well-known motor neuron and neuromuscular diseases mentioned above, neuro-pathic diseases can lead to sleep disturbances, as well. In Charcot-Marie-Tooth (CMT), pharyngeal and laryngeal neuropathy, as well as hypoglossal nerve dysfunction, lead to OSA. Similar to ALS and MG, there is a significant amount of CSA and hypoventilation, likely related to phrenic neuropathy. In contrast to MG, in CMT, the severity of neuro-pathic disease does correlate to the severity of sleep apnea.

### Testing

Testing can range from overnight oximetry to polysomnogram (PSG) with CO<sub>2</sub> monitoring. Generally, all patients with a rapidly progressive neuromuscular disease should get pulmonary function testing (PFT) (upright and supine) to evaluate

forced vital capacity (FVC) every 3 to 6 months to monitor for respiratory failure. Laboratory studies that can be helpful in assessing for SDB are the PaCO<sub>2</sub> (> 45 mm Hg) measured on an arterial blood gas and serum bicarbonate levels (> 27 mmol/L or a base excess >4

*Generally, all patients with a rapidly progressive neuromuscular disease should get pulmonary function testing (upright and supine) to evaluate forced vital capacity every 3 to 6 months to monitor for respiratory failure.*

mmol/L). Patients can qualify for NIV with an overnight SaO<sub>2</sub> less than or equal to 88% for greater than or equal to 5 minutes in a 2-hour recording period, PaCO<sub>2</sub> greater than or equal to 45 mm Hg, FVC < 50% of predicted, or maximal inspiratory pressure (MIP) < 60 cm H<sub>2</sub>O. For ALS specifically, sniff nasal pressure < 40 cm H<sub>2</sub>O and orthopnea are additional criteria that can be used. It is worth noting that a PSG is not required for NIV qualification in neuromuscular respiratory insufficiency. However, PSG is beneficial in

patients with preserved PFTs but suspected of having early nocturnal respiratory impairment.

### Therapy

NIV is the mainstay of therapy for SDB in patients with NMD and has been associated with a slower

in bilevel PAP or more advanced modes such as volume-assured pressure support (VAPS) modality. For patients who are unable to tolerate NIV, particularly those with severe bulbar disease and difficult to manage respiratory secretions, tracheostomy with mechanical ventilation may ultimately be needed. This decision should be made as part of a multidisciplinary shared decision-making conversation with the patient, their family, and their team of providers.

### Summary

Sleep is a particularly vulnerable state for patients with NMD, and in many patients, disturbances in sleep may be the first clue to their ultimate diagnosis. It is important that sleep medicine and pulmonary specialists understand the pathophysiology and management of NMD as they can play a vital role in the interdisciplinary care of these patients.

*Dr. Greer is a sleep medicine fellow, Division of Pulmonary, Allergy, Critical Care, and Sleep Medicine. Dr. Collop is Professor of Medicine and Neurology, Director, Emory Sleep Center; Emory University, Atlanta, Georgia.*



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# Confronting health disparities: A virtual listening tour

BY RUDY ANDERSON

Executive Director, CHEST Foundation

**H**ow do we discuss race and lung health issues that impact our most deserving, underserved communities? Continuously and uncomfortably. As the Executive Director of the CHEST Foundation and as a young Black man, I am hopeful that we, as CHEST, can lead these uncomfortable conversations to better our communities. Our ability to listen and deliver support to our most-deserving communities is critical in how we fulfill our mission. CHEST continues to be a leader in lung health because we choose to give a voice and a platform in support of better lung health – especially to those who are disproportionately affected by lung disease, specifically addressing the quality of care they receive and bringing to light the fact that too often these patients are forgotten by the rest of society.

As cases of COVID-19 and civil unrest continue to swell across our nation, we, the CHEST Foundation, have launched a virtual listening tour. We are taking this pragmatic, and more importantly, passionate approach to addressing health disparities



Mr. Anderson

by identifying and addressing barriers and issues affecting our most deserving and disproportionately underserved communities. By bringing together these communities' patients and caregivers, local leaders, involved businesses, and our CHEST members in a virtual community gathering, we intend to



clearly define the needs of each community, elevate those needs to a national level, and work to collaborate with and support these local communities and leaders to address their most-pressing issues.

Stories are what connect us and move us forward. We are confident that this virtual listening tour will be an opportunity for constituents to tell their own stories and learn from each other, while allowing the CHEST organization, through the CHEST Foundation, to act as the arbiter for pulmonary health and provide a path forward to create equity for those suffering from chronic lung disease.

We need your support to challenge these longstanding disparities in chest medicine. Help us advance these critical conversations and move the needle toward equality by contributing today at [chestfoundation.org/donate](http://chestfoundation.org/donate).

## CHEST and American Thoracic Society respond to proposed fee schedule

**C**HEST and the American Thoracic Society (ATS) submitted joint comments regarding the proposed Medicare Physician Fee Schedule for 2021 to CMS Administrator Seema Verma on topics of direct interest to members. The letter focuses on:

Medicare payment for critical care services: Further to the joint letter from CHEST, ATS, and the Society of Critical Care Medicine to Depart-

*ATS and CHEST voice support for the proposed changes to E/M office visits and the increased reimbursement for the cognitive component of E/M medicine.*

ment of Health and Human Services Secretary Azar (see article in September 2020 *Washington Watchline*), the concerns related to the proposed 8% reduction in reimbursement for critical care services are explained, particularly relating to the role of critical care providers during the pandemic. They call for waiving budget neutrality or utilizing the public health emergency declaration to ensure appropriate patient care.

E/M payment changes: ATS and CHEST voice support for the proposed changes to evaluation and management (E/M) office visits and the in-

creased reimbursement for the cognitive component of E/M medicine. They urge CMS to use its authority to waive the budget neutrality requirements while implementing the E/M changes.

Adoption of RUC-recommended values for pulmonary services: They urge CMS to finalize values for specific pulmonary services while acknowledging thanks for the adoption of the Relative Value Scale Update Committee (RUC)-recommended physician work values for a range of Current Procedural Terminology codes.

Telehealth services: While commending CMS for actions related to telehealth to provide care during the pandemic, they suggest it is now appropriate to sunset the telehealth listing for critical care services as providers have acquired additional experience in treating COVID-19.

GPC1X descriptors and utilization projections: They urge CMS to clarify the descriptors and seek additional comments on primary and ongoing health-care services.

Watch for reports of ongoing efforts from CHEST as the fee schedule process continues. Details of other activities in support of CHEST members appear in the November issue of *Washington Watchline*.

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## This month in the journal *CHEST*<sup>®</sup>

### Editor's picks

BY PETER J. MAZZONE,  
MD, MPH, FCCP

**International Perspective on the New 2019 IDSA/ATS CAP Guideline: A Critical Appraisal by a Global Expert Panel.**  
*By Dr. Mathias Pletz, et al.*

**Development of an Accurate Bedside Swallowing Evaluation Decision Tree Algorithm for Detecting Aspiration in Acute Respiratory Failure Survivors.**  
*By Dr. Marc Moss, et al.*

**How I Do It: Managing Fatigue in Patients With Interstitial Lung Disease.**  
*By Dr. Marlies Wijsenbeek, et al.*

**Life-Threatening and Non-Life-Threatening Complications Associated With Coughing: A Scoping Review.**  
*By Dr. Richard S. Irwin, Master FCCP, et al.*

**Obstructive Sleep Apnea in Professional Transport Operations: Safety, Regulatory, and Economic Impact.**  
*By Dr. Indira Gurubhagavata, et al.*

## In memoriam

CHEST has been informed of the following deaths of CHEST members. We extend our sincere condolences.

**Hassan M. Alkhouli, MD, FCCP (2019)**  
**Doros Michaelides, MD, FCCP (2019)**  
**Clive Kearon, MBBCh, PhD (2020)**  
**Joseph J. Costa, MD (2020)**

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