Notes from the Chair  
by Catherine Foss, BS, RRT, RPFT

Happy New Year! I am excited to be serving as your new section chair in this 2000 millennium year. But before I get started on the job, I’d like to thank Carl Mottram, our outgoing chair, for the mentoring he has provided me during this time of transition. Thanks also to both Vickie Ganey and Mary Kay Collins for all the work they put into preparing the Bulletins for all of us over the past couple of years. I am pleased to announce that Pauline Wulbrecht, from Scott and White Hospital in Temple, TX, and Joyce Canterbury, from National Jewish Center in Denver, CO, have volunteered to be the Bulletin editors for the next year. I would also like to express my appreciation to all the practitioners who participated in the section meeting at the AARC’s International Congress in Las Vegas in December. This meeting is the one time of the year when section members can get together to discuss important current issues. For those members who were unable to attend, we will be publishing a copy of the meeting minutes in the next issue of the Bulletin.

I’d like remind everyone, however, that as a section member, you have other opportunities (besides the annual section meeting) to voice your thoughts and opinions. First and foremost, you can sign up and utilize the section listserve on the AARC web site (www.aarc.org). Once you have subscribed, you can then post questions or air concerns. Your message goes out to all of the other members who have subscribed. You can express your concerns or ask questions, then receive feedback or answers from other diagnostic practitioners. The listserve provides a great forum in which timely, thought-provoking issues can be raised. (For more information on how to sign up, see following article.)

Another way you can communicate with your colleagues in the section is through the Resource Panel of Experts also located in the Diagnostics Specialty Section area of the web site. This list gives you the names and contact information for people with expertise in a variety of diagnostic specialty areas. These practitioners have volunteered to take and answer questions in their areas of expertise. If you would like to volunteer to be a part of this expert panel, please fill out the form that appears on page 7 or contact me at cfoss@umich.edu.

Lastly, as we enter this new millennium, I challenge all of you to recruit new members for the AARC and our section. Promote membership to fellow practitioners. The AARC Board of Directors voted last year to add a member to the Board from each specialty section with at least 1000 active members. Our section currently falls below that mark. If we increase our membership, we will have a louder and more effective voice within the AARC and the medical field.

I am looking forward to serving as your Diagnostic Section chair over the next two years. Please feel free to contact me if you have questions, concerns, or thoughts to share.

How (and Why) to Sign Up for the Section Listserve

What if you, as an individual member of the Diagnostics Section, could quickly and easily tap into the expertise of other members of the Diagnostics Section whenever you had a question or concern regarding your diagnostics practice? Wouldn’t that be great?

A few years ago, that would’ve been a pipe dream. But today it is a reality. Every member of the Diagnostics Section is eligible to sign up for the Diagnostics Section listserve on the AARC web site (www.aarc.org). Once you have subscribed, you can then post questions or air concerns. Your message goes out to all of the other members who have signed up, and any or all of them can respond to you (via email) with feedback.

The listserve, however, can only be effective if all — or at least most — of us subscribe to it. But so far, very few of our members have taken advantage of this important communication tool. We currently have 800 members in our section, but only 60 are signed up for the listserve.

Please note that there is no extra charge to subscribe to this service — as a section member, you all have to do to begin sending and receiving messages to and from the group is sign up. To subscribe, just click on the Diagnostic Specialty Section area of the AARC web site and follow the directions to subscribe to the listserve.
OSHA Revises Bloodborne Pathogens Compliance Directive

In an effort to help minimize serious health risks faced by workers exposed to blood and other potentially infectious materials, the Occupational Safety and Health Administration (OSHA) has revised its bloodborne pathogens compliance directive. The directive guides OSHA’s compliance officers in enforcing the standard that covers occupational exposure to bloodborne pathogens and is expected to ensure that consistent inspection procedures are followed. It updates an earlier directive issued in 1992 and reflects the availability of improved devices, better treatment following exposure, and OSHA policy interpretations.

“We must do everything we can to protect workers who may be at risk of exposure to bloodborne diseases,” says Secretary of Labor Alexis M. Herman. “This directive doesn’t place new requirements on employers, but it does recognize and emphasize the advances made in medical technology. And it reminds employers that they must use readily-available technology in their safety and health programs.”

The revised directive emphasizes the importance of an annual review of the employer’s bloodborne pathogens program and the use of safer medical devices to help reduce needlesticks and other sharps injuries - although OSHA does not advocate the use of one particular medical device over another. The directive also highlights basic work practices, personal protective equipment, and administrative controls.

The emphasis on engineering controls results from OSHA’s request last year for ideas and recommendations on ways to better protect workers from contaminated needles or other sharp objects.

“We received nearly 400 comments from health care facilities, workers, and others,” says OSHA Administrator Charles N. Jeffress. “They told us that safe medical devices already available are effective in controlling hazards and that wider use of such devices would reduce thousands of injuries each year.”

The revised directive also includes detailed instructions to compliance officers on inspections of multi-employer worksites, such as home health services, employment agencies, personnel services, physicians and health care professionals in independent practices, and independent contractors.

Also included in the directive are decontamination requirements, guidelines on hepatitis vaccinations and post exposure treatments, and employee training.

For more information about the revision, visit the OSHA web site at www.osha.gov.

The Combination of Ipratropium and Albuterol Optimizes Pulmonary Function Reversibility Testing in Patients With COPD*

by Paul M. Dorinsky, MD; Colin Reisner, MD, FCCP; Gary T. Ferguson, MD, FCCP; Shailendra S. Menjoge, PhD; Charles W. Serby, MD; and Theodore J. Wittek, Jr., Dr PH

Editor’s Note: The following article is being reprinted with permission from the April 1999 issue of Chest.

Abstract

Study objectives: To determine whether the combination of ipratropium bromide and albuterol results in greater and more consistent pulmonary function test (PFT) response rates than ipratropium bromide or albuterol alone in patients with COPD.

Design: Retrospective review of two recently completed 3-month, randomized, double-blind, parallel, multicenter, phase III trials.

Setting: Outpatient.

“COPD” continued on page 3

Outpatient PPS Information Available

As most of you know, the Health Care Financing Administration is in the process of designing a prospective payment system (PPS) for hospital outpatient departments. The proposed regulations are now available on the AARC web site (www.aarc.org). Please consult the web site for regular updates on the regulations and the ongoing development of the outpatient PPS.
“COPD” continued from page 2

Patients: A total of 1,067 stable patients with COPD.

Interventions: Ipratropium bromide (36 µg qid), albuterol base (180 µg qid), or an equivalent combination of ipratropium bromide and albuterol sulfate (42 µg and 240 µg qid, respectively).

Measurements and results: PFT response rates were analyzed using 12% and 15% increases in FEV₁ compared with baseline values and were measured in the various treatment groups on days 1, 29, 57, and 85 in these trials. Regardless of whether a 12% or a 15% increase in FEV₁ was used to define a positive response, an equivalent combination of ipratropium bromide and albuterol sulfate was superior to the individual agents (p < 0.05; all comparisons within 30 min). In addition, a 15% or more increase in FEV₁ was seen in > 80% of patients who received the combination of ipratropium and albuterol sulfate during the initial PFT and continued to be observed 3 months after initial testing.

Conclusions: Use of a combination of ipratropium bromide and albuterol sulfate is superior to the individual agents in identifying PFT reversibility in patients with COPD.

Introduction

COPD is part of a spectrum of diseases that share in common physiologic evidence of airflow obstruction. Among these diseases, cigarette-induced COPD is the most common; it affects approximately 14 million people in the United States and is responsible for an estimated $6.5 billion in direct and indirect costs per year. Airflow obstruction in COPD occurs largely on a structural basis and is generally considered to be irreversible. However, assessment of responsiveness to bronchodilators in patients with COPD has been problematic both clinically and experimentally. Likewise, there is a poor correlation between current methods of assessing acute pulmonary function reversibility and long-term bronchodilator response. Current American Thoracic Society recommendations for defining a significant bronchodilator response state that FEV₁ should increase by 12% of baseline with an absolute change of 200 mL. Using these criteria, as few as 30% of patients with COPD will demonstrate reversibility during a pulmonary function test (PFT). To the extent that current recommendations for assessing bronchodilator response may result in an underestimation of the true incidence of reversibility in patients with COPD, they may also impact patient care, especially if negative testing results in withholding of therapy.

Despite remaining uncertainties, recent data obtained in patients with COPD indicates that the long-term (i.e., 3 months) use of a combination of ipratropium and albuterol at recommended doses is superior to either agent alone as assessed by improvements in FEV₁. From these observations, it is reasonable to postulate that the combination of ipratropium and albuterol may also be superior to either agent alone in identifying patients with COPD who have a short-term, clinically significant response to bronchodilators. The purpose of the present study, therefore, was to test the hypothesis that the combination of ipratropium and albuterol would result in greater PFT response rates than albuterol or ipratropium alone in patients with COPD.

Materials and methods

The PFT response rates obtained during two recently completed randomized, multicenter, double-blind, parallel group, phase III clinical trials comparing the safety and efficacy of a combination of ipratropium and albuterol to either ipratropium alone or albuterol alone were reviewed (data on file; Boehringer Ingelheim Pharmaceuticals Inc). Informed consent was obtained from each subject who participated in these trials.

The study groups consisted of outpatients of either sex who were 40 years or older and who had a clinical diagnosis of COPD. Study participants were required to have a smoking history of more than 10 pack-years and to be regularly using at least two bronchodilators for control of their COPD symptoms during the 3-month period immediately preceding enrollment into either trial. Study participants also had to have an FEV₁ of 65% of predicted normal values and an FEV₁/FVC of 70% of FVC. Patients were excluded from participation if they had a history of asthma or allergic rhinitis, atopy, or a total blood eosinophil count > 500/mm³. Patients were also excluded if they required long-term oxygen use or > 10 mg of prednisone per day to manage their COPD symptoms during the month before entering into the study. In addition, patients were excluded if they had a recent history (1 year or less) of myocardial infarction, heart failure (3 years or less), or a cardiac arrhythmia requiring drug therapy.

Protocol: Patients from both trials underwent a medical history and physical examination, laboratory testing, and a 12-lead ECG before enrollment. At this initial screen and a 2-week baseline period, qualified patients (N = 1,067) were randomly assigned to receive two inhalations of ipratropium and albuterol inhalational aerosol (Combivent; Boehringer Ingelheim Pharmaceuticals, Inc; Ridgefield, CT), ipratropium inhalational aerosol (18 µg/inhalation), or albuterol inhalational aerosol (90 µg/inhalation) four times per day for 85 days. The dose selected for the combined ipratropium and albuterol inhalational aerosol was based on the usual recommended doses for each of the individual components (i.e., ipratropium inhalational aerosol, 18 µg/inhalation and albuterol inhalational aerosol, 90 µg/inhalation). These doses are based on mouthpiece delivery and are equivalent to 21 µg and 100 µg delivered from the valve, respectively. The combination delivers 21 µg of ipratropium bromide and 120 µg of albuterol sulfate per actuation from the valve (note that 120 µg of albuterol sulfate is the molar equivalent of 100 µg of albuterol base).

Return visits were scheduled every 2 weeks throughout the 85-day treatment period to assess and record adverse events and concomitant medication use. Likewise, patients in both trials were permitted to take up to two extra doses of investigational drug per day to control exacerbations. Concomitant maintenance doses of theophylline preparations and inhaled steroids were also permitted, but only if the patient’s dosage had been stabilized for at least 1 month before the baseline PFT studies and remained stable throughout the entire study period. Oral corticosteroids were permitted if the patient had been stabilized for at least 1 month on a total daily dose that was the equivalent of 10 mg of prednisone per day or less and the patient remained stable on this dosage throughout the study.

Pulmonary function testing: Pulmonary function testing started at the same time each day (i.e., between 7 and 10 am) and was conducted on treatment days 1, 29, 57, and 85. On these test days, measurements of FEV₁ and FVC were recorded before drug administration and again at 15, 30, 60, and 120 min after drug administration. Spirometric maneuvers were conducted in triplicate and the maneuver with the greatest sum of FEV₁ and FVC was recorded and used in the subsequent analyses. Predicted normal values for men and women for FEV₁ and FVC were derived from published algorithms. Spirometers used in these trials were required to meet American Thoracic Society standards.

To ensure standardized conditions on all PFT days, theophylline preparations were required to be discontinued 24 h before pulmonary function testing (compliance was assured by measuring theophylline levels before pulmonary function testing and rescheduling patients whose levels exceeded 5.0 µg/mL). Likewise, although long-acting β-agonists were not available at the time of this study, all short-acting bronchodilators and steroids had to be stopped at least 12 h before pulmonary function testing. Finally, the study drug, when applicable, had to be stopped at least 12 h before pulmonary function testing.

Definition of bronchodilator response: The interpretation of bronchodilator response in patients with COPD is controversial. For this reason, PFT data were evaluated on each test day, and a significant bronchodilator response was analyzed as a 12% and a 15% improvement in FEV₁ compared with baseline.

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values. Statistical evaluation: Unless otherwise specified, all data are expressed as the mean ± SD. Response rates of patients who received the combination of ipratropium and albuterol were compared with response rates from each of the other treatment groups using Fisher’s exact test.

Results

Patient demographics

A total of 1,067 patients were enrolled in the two trials with 852 patients completing the entire study. The demographic and baseline characteristics of the 1,067 randomized patients are presented in Table 1. These patients had moderate to severe COPD with baseline values on 3 or more test days. Patients who received ipratropium and albuterol had the highest PFT response rates (p < 0.05 at all time points).

FEV₁ response rate on individual test days

As shown in Table 1, mean baseline values for FEV₁ were comparable among the three groups and remained comparable as well as within 6% of the day 1 baseline values on each of the subsequent PFT days. A clinically significant improvement in FEV₁ occurred on the individual PFT days for the majority of patients from each treatment group, whether improvement was defined as a 12% or a 15% increase in FEV₁ (Table 2 ). The percentage of patients demonstrating a 15% increase in FEV₁ on 3 or more test days if they received the ipratropium plus albuterol combination group continued to demonstrate a 15% increase in FEV₁ compared with baseline values, the combination of ipratropium and albuterol was reproducible throughout a 3-month span. These data suggest that a combination of ipratropium and albuterol at usual doses optimizes the identification of PFT reversibility in a well-defined population of patients with COPD.

The results of this study differ from those previously reported in the literature. Specifically, Anthonisen et al.8 noted that although 70% of their patient population with COPD had at least one test during which FEV₁ increased by 15% after bronchodilator (isoproterenol) administration, only 30% of patients who received the ipratropium plus albuterol combination compared with the single agents, and was most pronounced at the 30-min point.

Discussion

Our study confirms the hypothesis that the combination of ipratropium and albuterol results in greater PFT response rates than ipratropium or albuterol alone in patients with COPD. Specifically, the data demonstrate that whether a significant PFT response is defined as a 12% or a 15% increase in FEV₁ compared with baseline values, the combination of ipratropium plus albuterol is superior to the individual agents. In addition, the superior PFT response rate observed with the combination of ipratropium and albuterol was reproducible throughout a 3-month span. These data suggest that a combination of ipratropium and albuterol at usual doses optimizes the identification of PFT reversibility in a well-defined population of patients with COPD.

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**Table 1. Patient Demographics and Baseline Pulmonary Function**

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<thead>
<tr>
<th>Patient Demographics and Baseline Pulmonary Function</th>
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<tr>
<td>Ipratropium and Albuterol (n = 358)</td>
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<td>---------------------------------------------</td>
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<tr>
<td>Age, yr</td>
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<tr>
<td>% Male</td>
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<td>Duration of disease, yr</td>
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<td>Baseline FEV₁, L</td>
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<td>Percent of predicted FEV₁-baseline</td>
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* All data expressed as mean (SD).
80% of patients 3 months after initial testing. There are several plausible explanations for these apparent discrepancies. First, as suggested by Dompeling et al., the severity of underlying lung disease as assessed by baseline FEV₁ may affect responsiveness to bronchodilators. Thus, it is possible that the severity of underlying lung disease in the patients with COPD from the current study may have differed substantially from those reported previously and accounted for the differences in FEV₁ response rates. In this context, the FEV₁ for the overall group in the present study was 0.95 ± 0.41 L and the baseline FEV₁ percent predicted was 35.6 ± 13.6%. Although these values for baseline FEV₁ are somewhat lower than those reported by Brand et al. (baseline FEV₁ > 1.2 L) and Dompeling et al. (baseline FEV₁ = 2.44 ± 0.82 L), they are comparable to those reported by Meslier et al (FEV₁ percent predicted = 41.3 ± 16.8%). Hence, although it is intuitive that bronchodilator responsiveness may not be the same at all stages of disease severity in patients with COPD, the values for baseline FEV₁ observed in patients from the present study did not differ sufficiently from those reported in the literature to account for the fact that a significant improvement in FEV₁ occurred in > 80% of the study patients.

It is also arguable that in patients with low baseline FEV₁, variability in the measurement of FEV₁ may have a more confounding effect on the assessment of bronchodilator response in that the absolute change in FEV₁ for any given percentage change from baseline in FEV₁ will be smaller. However, in this large study, variability in mean baseline FEV₁ measurements was small (< 6%) and did not increase during the study. Hence, it is unlikely that differences in the severity of underlying lung disease or variability in mean baseline FEV₁ measurements alone accounts for the higher FEV₁ response rates reported in the present study.

Second, it is possible that differences in study design accounted for the higher FEV₁ response rates observed in patients with COPD from the current study. Along this line, previous studies include medication washout protocols that vary considerably. For example, Meslier et al. required that ß2-agonists be stopped only 8 h before pulmonary function testing, but did not require theophylline be discontinued. By contrast, the medication washout protocol was much more rigorous in the present study and involved not only a 12-h washout period for even short-acting ß-agonists, but also a 24-h, verifiable washout of theophylline preparations. Moreover, patients were required to refrain from caffeine-containing foods and beverages, smoking, strenuous activity, and noxious fumes during the PFT days. Clearly, this rigorous medication washout preparation accounts, in part, for the fact that baseline FEV₁ remained unchanged among the treatment groups on the PFT days throughout these trials, and the fact that the FEV₁ response rates, as assessed by a 15% increase in FEV₁, exceeded 60% on 3 or more test days even for the ß2-agonist-treated patients.

Finally, it is possible that the combined actions of the medications themselves contributed to the improved PFT response rates observed in the study. In this regard, bronchial smooth muscle tone depends on both the innervation of the parasympathetic system and stimulation of ß2-receptors in the lung. Hence, it is logical to postulate that attempts to reduce bronchoconstriction through two distinct mechanisms (anticholinergic and sympathomimetic) may maximize bronchodilator response. That this postulate is true is consistent with the results of recent trials in which the combination of ipratropium and albuterol were more effective than either agent alone in improving pulmonary function in patients with COPD. Hence, the improved FEV₁ response rates observed consistently with time in patients with COPD in the current study were caused, in large part, by the use of a combination medication that counteracts two distinct mechanisms of bronchodilation.
“COPD” continued from page 5

It must be acknowledged that there were small declines (2% to 8%) in the percentage of patients who responded to bronchodilator therapy on test day 4 compared with test day 1 in all groups, and this decline was significant for the ipratropium and albuterol combination group. The precise explanation for these modest declines is unclear, but it may be related to these small fluctuations that occurred in baseline FEV₁ on test days subsequent to test day 1. Likewise, although all patients were required to have a stable respiratory status for 6 weeks before entry into the study, patients in long-term trials can and do develop

top conditions (eg, COPD exacerbations, upper respiratory infections) after entry into the study that can affect lung function and responsiveness to bronchodilators. Finally, although tolerance to a bronchodilator can also lead to a decline in bronchodilator responsiveness, this explanation is unlikely in that there was no evidence of a tolerance effect in the ipratropium and albuterol treatment group as detailed in the published report of the full phase III trial.¹¹

It must also be acknowledged that the definition of airway responsiveness to bronchodilator therapy in patients with COPD is controversial and that regardless of the definition, it may not remain stable with time. It is for this reason that we defined response to bronchodilator therapy using standard PFT criteria (i.e., a 12% or 15% increase in FEV₁), and that the conditions on the PFT day were rigidly adhered to throughout these trials. In this regard, the fact that response rates, albeit highest for the patients treated with ipratropium plus albuterol, were reproducible with time in all treatment groups suggests that differences observed among the groups were caused by the drugs themselves and not by random fluctuations in pulmonary function within treatment groups.

In summary, the data from this study indicate that bronchodilator responsiveness can be demonstrated to occur in the majority of patients with COPD who receive either ipratropium bromide or albuterol alone or the combination of ipratropium and albuterol. However, the data also indicate that the combination of ipratropium and albuterol is superior to either agent alone at standard dosages in identifying bronchodilator responsiveness in patients with COPD. In addition, the reproducibility of responsiveness to bronchodilators in patients with COPD is improved when the PFT is performed using a combination of ipratropium and albuterol. Thus, consideration should be given to assessing bronchodilator response in patients with COPD using a combination of ipratropium and albuterol in place of the current use of a β-agonist for bronchodilator FEV₁. Eur Respir J 5,975-981[Medline]


Table 3. Patients With 12% Improvement in FEV₁: 30 Min After Drug Administration*  

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<tr>
<th>No. of Test Days With Positive Response</th>
<th>Ipratropium and Albuterol (n = 292)</th>
<th>Ipratropium (n = 283)</th>
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<td>All 4 test days</td>
<td>63</td>
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* SEM ≤ 3% for all data points. Pulmonary function tests performed on days 1, 29, 57, and 85.

Ipratropium and albuterol combination significantly better than individual agents (p < 0.05).

Table 4. Patients With 15% Improvement in FEV₁: 30 Min After Drug Administration*  

<table>
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<th>No. of Test Days With Positive Response</th>
<th>Ipratropium and Albuterol (n = 292)</th>
<th>Ipratropium (n = 283)</th>
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<td>0 Test days</td>
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<td>All 4 test days</td>
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Ipratropium and albuterol combination significantly better than individual agents (p < 0.05).
Diagnostics Resource Directory Posted Online

In the last issue of the Bulletin I requested updates for your Resource Directory and announced that an updated version would be printed and mailed with this issue. However, upon examining the current list more closely, I realized that merely “calling for updates” wasn’t sufficient to get the list into prime condition. For example, many people on the list have not given me current contact information including email addresses which for many is a key networking tool.

I have decided to spend some serious time rebuilding your Resource Directory into a tool that will be the most helpful possible. While that process is underway I believe it is best to simply post the current list on your section’s home page on AARC Online. In doing so I can make regular updates and the information you access will be entirely accurate. Until new lists are compiled and printed, I recommend you refer to your section’s home page for current information. If you do not have access to the Internet, you should use your printed list from 1999 keeping in mind that some of the information is no longer accurate.

So now, again, I am calling for your support of the Diagnostics Resource Directory. If you are on the current list, please send me confirmation of your contact information as listed and also give me your email address. If you want to be added to the list, please send me the information requested in the form below. You may complete the following form and mail or fax it to me (11030 Ables Lane, Dallas, TX 75229 / 972/484-2720) or the best option would be to email me (hagen@aarc.org). With your help we will soon have a truly helpful Resource Directory filled with names of people who are dedicated to helping others in their field succeed — and you will have accurate contact information to make it as easy as possible to take advantage of their expertise and advise.

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TOPICS

**Pulmonary Diagnostics**

- Spirometry
- Lung Volumes
- Airway Mechanics
- Diffusing Capacity
- Steady State Diffusing Capacity
- Blood Gas, Electrolyte and Hemoximetry Analysis
- Point of Care Testing
- Bronchoscopy
- Sweat Chloride Testing
- Conscious Sedation
- Cardiopulmonary Exercise Testing
- Airways Challenge Testing
- Pulmonary Mechanics and Occluding Pressures
- Sleep Disorders

**Critical Care Pulmonary Diagnostics**

- High Altitude Simulation
- Ventilatory Drive

**Pediatric and Neonatal Care**

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- Clinical Practice Guidelines