Diagnostic Strategies and Newer Management Techniques in Obstructive Sleep Apnea-Hypopnea Syndrome

by Naresh Dewan, M.D., Professor of Medicine

The spectrum of sleep disordered breathing (SDB) includes habitual snoring, hypopnea, respiratory effort-related arousals (RERAs) and obstructive apneas. Habitual snoring is the most common symptom in SDB. Snoring in an individual patient that is accompanied by snorting or gasping for breath during sleep with frequent nocturnal awakenings in conjunction with excessive daytime sleepiness is highly predictive of SDB.

The American Academy of Sleep Medicine recommends that an overnight-attended polysomnography be performed in all patients suspected to have sleep apnea. An overnight polysomnography study, demonstrating five or more obstructed events in conjunction with clinical features, is essential to make the diagnosis of obstructive sleep apnea-hypopnea syndrome (OSAHS). A split-night study may be performed in an individual patient in whom the diagnosis of sleep apnea can be established in the early part of the study and the second half of the study can be utilized for titration of nasal CPAP. Unattended home study, including an overnight trend oximetry with auto-titrating CPAP, are only acceptable if the clinical presentation is highly suggestive of sleep apnea and access to a sleep laboratory is not readily available.

The goals of treatment for OSAHS include reduction or elimination of excessive daytime sleepiness, improvement in neurocognitive impairment, reduction in cardiovascular consequences and relief of snoring. Management options for OSAHS include behavioral treatment, pharmacological treatment, use of nasal CPAP or bilevel pressure therapy, oral appliances and surgical treatment.

Behavioral treatment emphasizes weight loss, avoidance of narcotics, sedatives, alcohol and supine position. The role of pharmacotherapy in OSAHS is limited and not well-established.

Nasal CPAP is considered as an effective first-line therapy for mild, moderate and severe OSAHS. Nasal CPAP acts as a "pneumatic splint" that prevents collapse of the upper airways. The use of nasal CPAP has been demonstrated to eliminate or reduce apneas, hypopneas, RERAs, daytime sleepiness, improve oxygen saturation, blood pressure control, quality of life, cognitive function, steering performance and reduce health care utilization. The overall success rate with nasal CPAP ranges between 65% to 75%. Objective compliance for regular use of nasal CPAP generally tends to be lower than self-reported use. The use of proper fitting masks and headgear, heated humidification, perceived benefit by the patient and education with intensive support are associated with improved compliance. Bi-level ventilation and auto-titrating CPAP devices are other options that may improve compliance in select patients.

Oral appliance therapy in OSAHS is generally indicated for mild OSA or simple snoring. Oral appliances enlarge the upper airway space by advancing the position of the tongue and/or mandible. There are two types of oral appliances: (1) tongue retaining devices that hold the tongue forward, and (2) mandibular advancing devices.
From the Chair

Eugene Rich, M.D.

A few months ago, I reported that we were in the midst of a process to define goals for Creighton Internal Medicine to undertake over the next five years. From meetings I had with the faculty, we developed an extensive list of ideas. The Associate Chairs and Division Chiefs helped refine this list into specific goal statements and identified priorities. During the past two years, the Department leadership and faculty participated in the process of finalizing our Department's goals for 2001 through 2005.

Deriving from the mission of Creighton University, the Department is committed to superlative clinical service to all its patients and to the community; to outstanding education for medical students, residents, and other health professionals; and to a tireless search for new knowledge to better serve our patients and students. Accordingly, we have understood our goals primarily in terms of clinical service, education, and research. Our five-year goals for the Department's clinical mission include expanding faculty and programs in critical care/pulmonary medicine, endocrinology; nephrology; hematology/oncology; dermatology; and gastrointestinal medicine. These efforts include a specific emphasis on improved communication with referring physicians, and enhanced patient satisfaction.

"Creighton exists for students and learning..." begins the University mission statement. Our Department's educational goals are a critical part of our five-year plan. These include efforts to improve the educational program for internal medicine residents, including the ABIM pass rate. On this goal, we are pleased to report the 100% ABIM pass rate achieved by CU medicine residency program graduates this year! We hope to continue our success with recruiting excellent medical school scholarship candidates. Accordingly, we have set ourselves ambitious research goals as well. These include recruiting more investigators into the Department, and broadening the subspecialty research expertise into additional divisions. Increasing the involvement of department investigators in interdisciplinary (cross-division and cross-department) scholarship will, we believe, also enhance the success and recognition of all Creighton's investigators. We intend to continue to build on our success with expanding research on pharmacotherapy. We also see several specialty areas ripe for research expansion, including respiratory system disease, cardiovascular disease, and clinical epidemiology. Of course, we also are determined to enhance the research resources, research mentoring, and research faculty development for our next full-time faculty.

To ensure the enduring success of Creighton Medicine, we have set some additional goals for Department administration. These include enhancing collaboration with the Omaha VA Medical Center in development of our clinical, education, and research missions. We must also expand space at Creighton for growth of key clinical, research, and educational programs. Over the past five years the Department has shown superb stewardship of Creighton resources, but we must continue to ensure that financial pressures do not crowd out faculty effort in teaching and scholarship, nor jeopardize essential research program infrastructure. Finally, it is our goal over the next five years to increase other sources of revenue (e.g., grants and endowments) to reduce Department dependence on clinical revenue to subsidize teaching and research.

Our faculty and Department leadership have put considerable thought and effort into articulating this vision for our growth during the first decade of the 21st century. These are certainly exciting and ambitious goals. They will challenge us to achieve ever-greater levels of excellence as educators, clinicians, and scholars, true to the best traditions of Creighton Medicine.

Eugene Rich, M.D.
Tenet Professor and Chair
Department of Medicine
Director, Center for Practice Improvement
and Outcomes Research

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After 30 years of outstanding leadership of the Division, Dr. Robert Townley has stepped down as its Chief July 1, 2001. Dr. Townley will remain a valuable faculty member in the Division, focusing his efforts on basic and clinical research in asthma and allergic diseases, as well as patient care and teaching.

The Division has expanded its fellowship program, and now has three first-year fellows: Kevin Boesel, M.D., D. Todd Griffith, M.D., and Henry Lin, M.D., and one second-year fellow, Early Ciesemier, D.O. The program has four training components, including clinical allergy/immunology, basic research, clinical trials research and ancillary electives.

The faculty is actively engaged in research involving new treatments for allergic respiratory disorders. Under the direction of Devendra Agrawal, M.D., Professor of Medicine, investigators are studying new strategies to prevent and reverse the pathophysiologic changes found in a murine model of asthma. Drs. Agrawal and Casale have just submitted a NIH grant examining the effects of FLT-3 Ligand, a newly-described cytokine, on reversing airway remodeling in a mouse model of asthma.

Other novel agents being studied include a humanized monoclonal antibody against IL-4, a critical cytokine for allergic disorders, and ciclesonide, a novel steroid. Ciclesonide represents a new generation of corticosteroids for airway diseases. It is a pure isomer, pro-drug, that is converted to an active drug via esterases in the lungs. This is thought to be important in anti-IgE’s mechanism of action including: decreased serum IgE levels, basophil histamine releasability and expression of the high (FcRII) and low (CD23) affinity IgE receptors on key inflammatory cells. The Allergy/Immunology Division is one of only five centers to study the therapeutic capacity of anti-CD23 for asthma. Dr. Casale is also developing a research program to examine other potential therapeutic areas for use against-anti-CD23.

The Division continues to examine new therapies for allergic respiratory diseases in Phase I through Phase III clinical trials. The Division is integrating its basic and clinical research programs with several new studies. For example, Dr. Casale is studying the onset of action of a humanized monoclonal antibody against IgE to block nasal and skin allergic reactions. At the same time, we are correlating the onset of the clinical responses with key immunologic responses thought to be important in anti-IgE’s mechanism of action including: decreased serum IgE levels, basophil histamine releasability and expression of the high (FcRII) and low (CD23) affinity IgE receptors on key inflammatory cells. The Allergy/Immunology Division is one of only five centers to study the therapeutic capacity of anti-CD23 for asthma.

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Psoriasis, a common skin disorder that affects 1-2% of the population, has always been a challenge to treat, particularly in its most severe forms. Milder psoriasis is effectively treated with a variety of topical corticosteroids. Moderate and severe psoriasis require more aggressive measures. Phototherapy is one option, as are the systemic agents methotrexate, cyclosporin and azathioprine. All of these options can be effective, but are limited by potentially serious side effects. Patients must be carefully selected and monitored through treatment. As a result, research has searched for more safe and equally effective alternatives.

Biologics are a new class of therapy that are being evaluated for certain chronic inflammatory disorders. The most notable of these conditions are psoriasis and rheumatoid arthritis. In Creighton's Division of Dermatology, we have had the opportunity to evaluate two of these biologics. I would like to discuss our experience with these two agents, and two additional agents that are entering into Phase III studies for the treatment of psoriasis.

Our Division had the opportunity to test alefacept (Amevive), a fusion protein which acts to block the activation of T lymphocytes. It is administered once weekly (similar to methotrexate). In our study, it was given by intramuscular injection, but in other studies has been given by IV push. Psoriasis improvement is measured by what is known as a PASI index, a clinical measure of psoriasis regression. In Phase III data, which included data from our study, the percentage of patients with >75% improvement in PASI scores measured about 30%. Other information derived from the studies indicate that several months of remission after this pulse treatment can be expected. However in certain patients, lasting T cell depletion was observed.

We also had the chance to assess efalizumab (Xanelim). It is a monoclonal antibody to CD11a. Like Amevive, it acts to inhibit T lymphocytes. Xanelim offers the advantage of subcutaneous injection. The key to this mode of administration is that it would allow patients to self-medicate at home with the required weekly injections. Similar to Amevive, PASI scores with >75% improvement measured around 30% in Phase III trials.

Assumptions regarding biologics

<table>
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<th>Product</th>
<th>Mode of administration</th>
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<th>Percentage of patients with PASI &gt;75% improvement (Phase III data)</th>
<th>Other Information</th>
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<td>Amevive (Biogen)</td>
<td>IV push or IM Weekly</td>
<td>Fusion protein; CD 2</td>
<td>20 - 30%</td>
<td>May result in several months of remission after pulse administration; can cause T cell depletion.</td>
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<td>Remicade (Centocor)</td>
<td>IV fusion over two hours, every six weeks</td>
<td>Anti-TNF Mab</td>
<td>40 - 50%</td>
<td>Patient is asymptomatic; treatment may be permanently discontinued.</td>
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<td>Enbrel (Immunex/Wyeth)</td>
<td>SC administration twice per week</td>
<td>TNP receptor fusion protein</td>
<td>40 - 50%</td>
<td>Potential to diminish cell-mediated immunity.</td>
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<td>Xanelim (OKMA/Genzyme)</td>
<td>SC administration weekly</td>
<td>Anti-CD11a Mab</td>
<td>25 - 30%</td>
<td>Potential for psoriasis to rebound within 2-4 weeks of cessation of therapy.</td>
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One of the potential concerns with Xanelim is the possibility of psoriasis rebound within 2-4 weeks of cessation of therapy. We derived a few important conclusions from the use of these drugs. Both medications offer an alternative to other systemic agents with efficacy rate in the same "ballpark," acitretin, methotrexate and azathioprine. The real potential advantage is drug safety. None of the patients we enrolled had any serious adverse side effects and while those drugs are not without adverse reactions, the overall safety profile is impressive.

Two other biologics, infliximab (Remicade) and etanercept (Enbrel), being tested for psoriasis, have already achieved FDA approval for the treatment of rheumatoid arthritis. Methotrexate, an immune modulator that treats psoriasis and rheumatoid arthritis very well has been used for years, so it is not surprising that medicines effective for rheumatoid arthritis would also benefit psoriasis. Let us discuss each drug separately.

Remicade is delivered by IV infusion over two hours every six weeks. It is a monoclonal antibody with anti-tumor necrosis factor activity. PASI score improvements >75% occurred in 40-50% of patients tested in Phase III studies. This represents a better clinical response than Amevive or Xanelim. One potential disadvantage is that it is recommended that Remicade be taken concurrently with methotrexate to avoid decreased efficacy from antibody formation. This use of methotrexate may account for better response and also be carefully selected and monitored through treatment. As a result, research has searched for more safe and equally effective alternatives.

We also had the chance to assess efalizumab (Xanelim). It is a monoclonal antibody to CD11a. Like Amevive, it acts to inhibit T lymphocytes. Xanelim offers the advantage of subcutaneous injection. The key to this mode of administration is that it would allow patients to self-medicate at home with the required weekly injections. Similar to Amevive, PASI scores with >75% improvement measured around 30% in Phase III trials.

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Who have been your most influential teachers? First, my parents, who gave me their faith, and my paternal grand-mother, who encouraged me to go into medicine after the death of my aunt from asthma; then, my professors of philosophy and history at Creighton, who helped me "to see the big picture;" then, my colleagues who are continually "opening new doors" of knowledge in the exciting field of immunology and medicine.

Why did you choose to work at Creighton University? Creighton undergraduate and medical school provided me with a sense of values and an education, for which I am forever grateful. After completing Internal Medicine residency, Allergy fellowship in Boston, and four years on the faculty at the University of Colorado and National Jewish Hospital, I returned to Creighton. With an N.I.H. grant and encouragement from the Chairman of Medicine, Robert Heaney, M.D., I was given the opportunity to begin the long-term goal of studying the risk factors and mechanisms of airway hyper-responsiveness in asthma.

Which research event has had the most effect on your work? An experiment that failed. I was attempting to induce asthma in a monkey after infusing the monkey with serum from an allergic asthmatic. While nebulizing an allergen to the monkey, the monkey failed to wheeze or react. However, I did wheeze for the first time in my life. That experience led me to compare lower airway responses to allergens, basophil/ eosinophil in asthmatics with a person like myself with allergic rhinitis.

What are your greatest dreams? First, to find the cause of airway hyper-responsiveness, which is now part of the definition of asthma. Second, to develop a vaccine that will prevent asthma and the epidemic of asthma.

What is your greatest regret? An unrealized dream to reach out to the global community by setting up a program of International Health.


How do you relax? Jogging, hiking, reading history, and immunology.

What advice would you offer new medical graduates? Think big, think globally and be forever grateful for the opportunity to practice and teach medicine.

What are your most interesting travels? Cuba and Kosovo, where I learned to appreciate freedom; Gambia, where I witnessed extreme poverty and tropical diseases; many trips to Japan, where I experienced an enduring collegiality over a 30-year span; and finally, Bangkok Thailand; Istanbul Turkey; and Latin America, to collaborate in vaccine and allergy research.
Division News
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Endocrinology
submitted by Karla Malekzer
OPERATIONS MANAGER

Clinical trials
Joan Lappe, Ph.D., R.N., Associate Professor of Nursing and of Medicine, is conducting a study to establish a normative database of bone density in children. The Osteoporosis Research Center will be recruiting 368 healthy children between the ages of 6-16, inclusive, to follow for four years. For more information, please contact Gena Lipszyczuk, M.S.N., at 402-280-4174.

Robert Recker, M.D., Professor of Medicine and Director of the Osteoporosis Research Center, is conducting a study to compare the effects of treatment with raloxifene and alendronate in preventing fractures in postmenopausal women with osteoporosis. Study participants will be randomly assigned to either raloxifene or alendronate. All participants will be provided with calcium and vitamin D. Each participant will be on study for five years. For more information, please contact Jennifer Cavalleri, R.S.N., at 402-280-4230.

Hematology/Oncology
submitted by Thomas Casale, M.D.

Clinical trials
James Mattioli, M.D., Professor of Medicine, is the Principal Investigator of five new trials which compliment the already existing studies we have open:

- SELECT-Prostate cancer prevention trial using supplements Vitamin E and Selenium. For more information, please contact Penny Anzures at 402-280-5274.
- STAR-Breast cancer prevention trial using Tamofoxen and Raloxifene. For more information, please contact Penny Anzures at 402-280-5274.
- Phase II clinical trial evaluating three schedules of ALIMTA plus gemcitabine as frontline chemotherapy for patients with locally advanced or metastatic non-small cell lung cancer. For more information, please contact LuAnn Miller at 402-280-4381.
- Phase II trial of neoadjuvant chemotherapy prior to surgery for patients with advanced non-squamous non-small cell cancer. For more information, please contact LuAnn Miller at 402-280-4381.
- Randomized Phase II trial of paclitaxel plus carboplatin with or without bevacizumab in patients with advanced nonsquamous non-small cell cancer. For more information, please contact LuAnn Miller at 402-280-4381.

Gastroenterology
submitted by Mary Ann Seemanstad
COORDINATOR, ACAD. AFFAIRS, DEPARTMENT OF MEDICINE

New faculty
Safak Reka, M.D. joined the Division on December 3rd as an Assistant Professor of Medicine. She comes to Creighton from the State University of New York Health Science Center in Brooklyn, NY. Dr. Reka is a native of Turkey where she received her medical degree with a residency and fellowship training in gastroenterology. She was also a faculty member at Ege University in Izmir, Turkey. She come to the United States and completed an Internal Medicine Residency and a Gastroenterology Fellowship before becoming an Assistant Professor of Medicine at SUNY-Health Center in Brooklyn. Dr. Reka is certified in Internal Medicine and in Gastroenterology.

General Internal Medicine
submitted by Wendy Taylor
SPECIALIST, CENTER FOR PRACTICE IMPROVEMENT & OUTCOMES RESEARCH

Meetings attended
Bruce Houghton, M.D., Assistant Professor of Medicine, and Henry Sakowski, M.D., Assistant Professor of Medicine participated in a Workshop, "Strange Bedfellows: An Evidence-Based Approach to Teaching Complimentary and Alternative Medicine" at Meeting in Tucson, AZ. November 8-20, 2001. They made the same presentation at the 18th Annual Midwest Regional SGIM in Chicago on September 7-8, 2001. They made the same presentation at the 2001 CDIM National Meeting in Tucson, AZ, October 18-20.


Infectious Diseases/VA Hospital
submitted by Marvin Bitter, M.D.
ASSOCIATE PROFESSOR OF MEDICAL MICROBIOLOGY AND IMMUNOLOGY, DEPARTMENT OF MEDICINE

Educational and professional activities
Bioterrorism has affected the activities of many internists. Two members of the Infectious Diseases Division at the VA Medical Center have been especially involved in the response to bioterrorism.

Martha Gentry-Nielsen, Ph.D., Associate Professor of Microbiology and Immunology, spoke on bioterrorism to a group of nurses at the VA Medical Center in Omaha on November 7th. She also lectured nurses and managers at a Saint Joseph Hospital on bioterrorism on November 14th.

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Many therapies have been effective, yet an absolute best treatment eludes us. The basic research that has gone into developing these therapies has increased our understanding of the disease. The biologics are another step in the advance towards that goal of a perfect therapy for the millions that suffer from the "heartbreak of psoriasis." 

Psoriasis Treatments

Residency Program News

Division News

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Dr. Bittner presented a Creighton internal medicine resident teaching conference on histoterrorism on October 25th. He has written an article on the subject for the Omaha Medical Society website (www.omahamedical.com), has served as a resource on histoterrorism for the Creighton University Magazine, and he has been invited to speak to the West Omaha Kiwanis on anthrax on December 19th.

Grant Approval

Gary Gooby, M.D., Associate Professor of Medical Microbiology and of Medicine, has been notified his VA Merit Review Board approval, entitled "Gonococcal Opac: Role in Invasion of Human Fallopian Tube Epithelium," has been approved. The study explores a fundamental question in infectious disease. From time to time, a variety of bacteriologies on mucosal surfaces. Sometimes these bacteria invade the host and cause serious disease. Dr. Gooby is exploring the factors that allow some gonococcal strains to invade the fallopian tube epithelium.

Nephrology

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Pulmonary

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Pat Adams, M.D., Assistant Professor of Medicine, joined the faculty in September. Dr. Adams is a graduate of the Creighton University School of Medicine, where he also completed his medicine residency. His nephrology fellowship was at the University of New Mexico. Dr. Adams' research interest is the management of dialysis access.

Professiona activities

Walter O'Donohue, M.D., Professor of Medicine, was elected to the Board of Regents of the American College of Chest Physicians at the annual meeting in Philadelphia on November 3, 2001. He also served as the Director for a postgraduate course on "CPT Coding in Pulmonary and Critical Care" during the meeting. Dr. O'Donohue presented a medical seminar at the Practice Administration Committee of the American College of Chest Physicians.

De O'Donohue was the recipient of the American Medical Association Award for Excellence in CPT Education and was appointed to the American Association of Medical Colleges (1) Group on Educational Affairs and the Group on Resident Affairs.

Dr. Dewan was elected as the President of the American Association of Chest Physicians of Indian Origin at the annual meeting of the ACCP in Philadelphia on November 9, 2001. He also served as Course Director for a postgraduate symposium on "Sleep Disorders Breathing," at the 2001 Asian-Pacific Congress on Diseases of the Chest, held in Mumbai, India, on November 26th. Dr. Dewan was also invited to speak on Solitary Pulmonary Nodules, COPD Exacerbations and Management of Sleep Apnea at this meeting.
Clinical trials

Effect of 12-week treatment on exercise endurance in patients with chronic obstructive pulmonary disease. For more information, please contact Naresh Dewan, M.D., Principal Investigator, or Study Coordinators: Tony Romero, M.D. at 402-280-5960, or Sharon Kochanowicz, R.N. at 402-280-5972.

Trial evaluating comparative inhalation treatments in patients with chronic obstructive pulmonary disease. For more information, please contact Naresh Dewan, M.D., Principal Investigator, or Study Coordinator: Mike Caldwell at 402-346-8800 Ext 3312.

Rheumatology

submitted by Sharon Kochanowicz, R.N.

Trial assessing the safety and efficacy of COX-2 selective inhibitor as compared to naproxen in patients with primary osteoarthritis. For more information, please contact John Hurley, M.D., Associate Professor of Medicine, Principal Investigator, or Study Coordinator, Sharon Kochanowicz, R.N. at 402-280-5972.

Trial assessing the gastrointestinal safety of COX-2 selective inhibitor as compared to naproxen in patients with osteoarthritis of the knee or hip who are taking low-dose enteric-coated aspirin. For more information, please contact John Hurley, M.D., Principal Investigator, or Study Coordinator, Sharon Kochanowicz, R.N. at 402-280-5972.