Interventional Pulmonary Research at the University of Vermont Medical Center

C. Matthew Kinsey, M.D.

The clinical practice of interventional pulmonary utilizes advanced technologies for the diagnosis and treatment of airway and pleural disease. One of the new technologies that we are studying at the University of Vermont Medical Center is the use of valves placed in the airway to achieve lung volume reduction for patients with emphysema and shortness of breath. Emphysema is a destructive process in the lung, most commonly associated with cigarette smoking, and results in dilation of the small air sacks in the lung. This causes the lung to become overinflated. The goal of the EMPROVE trial, which stands for Evaluation of the IBV Valve for Emphysema to Improve Lung Function, is to use one-way valves placed in the airway to reduce airflow to areas of the lung that are over-inflated. Reduction in airflow to these areas has been associated with improvements in breathing in prior studies, and this trial hopes to answer that question definitively. These valves are placed using a bronchoscope and thus do not require surgery. They may be removed if needed and are approved for use in Europe for lung volume reduction.

In addition to investigating new technologies, interventional pulmonary techniques may also be used to study tissues directly. Translational research relies on studying tissues or cells to develop or test new therapies for diseases. We recently initiated the MEROPTIC study (Molecular Epigenetic and Radiologic Biomarkers for Thoracic Cancers) for advanced lung cancer. Most research in lung cancer is limited to tissues that have been removed by surgery. However, surgery is only beneficial for the approximately 20% of patients with very early disease. The aim of the MEROPTIC study is to develop treatments for advanced disease, where better therapies are the most needed. To this end, small biopsy tissues (e.g. needle biopsies) from tumors are investigated for susceptibility to drugs that inhibit an enzyme important in cancer called GSTP1, the transcription factor RUNX that drives abnormal production of proteins in cancers. The ultimate goal is to be able to screen an individual person’s tumor against a panel of possible drugs to identify therapies from which that individual might benefit.

We plan to continue to pursue research studies such as these so that we can constantly offer new, safe, and effective therapies for our patients.

The Vermont Lung Center is affiliated with the following:

BECOME A VOLUNTEER FOR RESEARCH!

www.uvm.edu/medicine/
vermontlung.org
Or Call: 802-847-2193
Lung Cancer in the United States  With the decline in smoking over the last 50 years, it often surprises people to hear that lung cancer remains the leading cause of cancer related death in the United States for both women and men. In fact each year more people lose their lives as a result of lung cancer than from the next four most common cancers, breast cancer, prostate cancer, colorectal cancer, and pancreatic cancer combined.

Risks for lung cancer  The most important risk factor for developing lung cancer is a history of tobacco smoking. In 1957, Surgeon General Leroy Burney announced for the first time the official position of the U.S. Public Health Service that there was a causal relationship between cigarette smoking and lung cancer. Over the next 57 years, considerable effort has been spent on smoking prevention and cessation programs. While smoking rates have declined since the 1950s, it is estimated that even today, 94 million Americans are either actively smoking or have smoked in the past and are at increased risk for lung cancer. Around 85% of lung cancers can be linked to cigarette smoking although other exposures including asbestos, radon, diesel fumes, and welding fumes also increase risk for developing the disease. The risk of developing lung cancer increases with age. Those with a first degree family member with lung cancer are at increased risk as are those who have personally had lung cancer in the past.

Prevention and screening  Abstaining from cigarette smoking is the only way to prevent lung cancer. For those who smoke, it is never too late to stop smoking. The risk of developing lung cancer decreases the longer cigarettes are avoided.

Screening refers to detection of cancers in people without symptoms. A yearly low-radiation CT scan of the chest in people at increased risk for lung cancer may catch cancers earlier and reduce number of people dying from the disease. As a result, this type of lung cancer screening has been endorsed by the US Preventive Services Task Force (USPSTF) and the Centers for Medicare & Medicaid Services (CMS) for people meeting the following criteria:

- Age 55-80 years (55-77 for Medicare)
- History of smoking at least 30 pack-years (average of 1 pack per day for 30 years)
- Actively smoking or quit within the last 15 years
- Healthy enough

Lung cancer screening is now being offered at the University of Vermont Medical Center. The screening program is one of only a handful of sites in the United States currently accredited by the American College of Radiology to perform and interpret the results. If you meet the above criteria, speak with your health care provider about lung cancer screening. If you live in Vermont and would like resources to help you quit smoking, call 1-800-QUIT-NOW (784-8669) or visit www.802quits.org.

Please join us for the LUNGFORCE Walk

American Lung Association Burlington    Thursday, June 25, 2015

5 pm – 8 pm          Oakledge Park        Flynn Ave           www.LungForce.org

The Vermont Lung Center is supported in part by the following organizations:
Interested in Being a Volunteer?

Things to Know: The Vermont Lung Center is responsible for making sure you know what is expected of you in regards to the study.

1. Once the study is explained to you, you will be asked to read and sign an “Informed Consent”. This form is designed to explain everything you need to know about the study.

2. Studies may be therapeutic (involving observation of lung function). However, The Vermont Lung Center can make no claims that your involvement in a research study will improve your condition.

3. Compensation may or may not be provided to you for your involvement in a study. If compensation is provided, it is meant to cover your time and expenses incurred—it does not constitute employment. If you are interested in volunteering for a research study, please call us at (802)-847-2193

ASTHMA

APR (Asthma Patient Registry) Volunteers: Asthmatics ages 12+, What: A registry to identify patients especially specific subgroups (e.g., smokers, elderly, and demographics to contact for future studies, and develop future research studies.

NAC: Effects of BMI On Allergic Responses
Volunteers: Asthmatics and Healthy Controls ages 18–60 yrs / 2 - 3 visits / Compensation: Up to $150

Pfizer: Biomarkers In Uncontrolled Asthma
Volunteers: Asthmatics 15-70 yrs. using Advair or Symbicort / Visits: 2 - 3 / Compensation: up to $250

Interleukin – 6 Receptor Production in Asthma
Volunteers: Asthmatics 18-65 yrs. / Visits: 2 / Compensation: up to $150

UVM MG: Airway Compliance In Relation to BMI In Asthma
Volunteers: Asthmatics and Healthy Subjects 35-55 yrs / Visits: 3 - 4 / Compensation: up to $300

IDIOPATHIC PULMONARY FIBROSIS (IPF) STUDIES

Roche (A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of Lebrikizumab in Subjects with IPF)
Volunteers: Age 40 and over, with IPF – Up to 34 visits over a 2 year period – Compensation for travel over 100 miles

Fibrogen-067 (A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of FG-3019 in Subjects with IPF) Volunteers: Age 40-80 years inclusive with IPF – Up to 38 visits over a 2 year period – Compensation: up to $3,800

BMS (Safety and Efficacy of A Lysophosphatidic Acid Receptor Antagonist in Idiopathic Pulmonary Fibrosis A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study of the Safety and Efficacy of BMS-986020 in Subjects with IPF)
Volunteers: age 40 and over with IPF – 14 visits for a total of 30 weeks – Compensation: $1,025 – 1,275

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

VHIP (The Effect of Pulmonary Rehabilitation on Ventilation Heterogeneity in Patients with COPD)
Volunteers: Patients enrolled in the University of Vermont Medical Center Pulmonary Rehab program – 2 Visits

EMPROVE: A Prospective, Randomized, Controlled, Multicenter Clinical Study to Evaluate the Safety and Effectiveness of the IBV Valve System for the Single Lobe Treatment of Severe Emphysema
Volunteers: Patients diagnosed with Severe Emphysema – Please call Sara Ardren at 802-656-7953 for more information.

ACE (Anxiety and COPD Evaluation)
Volunteers: Patients diagnosed with COPD – 2 Visits – Compensation: up to $100

CYSTIC FIBROSIS

Serial Microbiome – Comparative Evaluation of Bacterial Diversity and Richness in the Cystic Fibrosis Lung In Patients Who Use Cycled Every Other Month Tobramycin Inhalation Powder (TIP, TOBI Podhaler) or continuous Alternating Therapy with Tobramycin Inhalation Powder (TIP, TOBI Podhaler) and Colistimethate (Colistin, Coly-Mycin M)
Volunteers: Age 12 and over, diagnosed with Cystic Fibrosis, - 7 visits over 6 months – compensation: $50 per visit

PULMONARY ARTERIAL HYPERTENSION

DLCO-PAH (Changes in the Diffusion Capacity for Carbon Monoxide (DLCO) in Response to Vasodilator Therapy in Patients with Pulmonary Arterial Hypertension)
Volunteers: Patients with Pulmonary Arterial Hypertension – 3 Visits – Compensation: up to $150
CANCER: WHAT DOES A POSITIVE LUNG CANCER SCREENING MEAN? Garth Garrison, M.D.

Despite the decline in cigarette smoking over the last 50 years, lung cancer remains the most common cause of cancer related death in the United States. In patients who are at significantly increased risk lung cancer, screening with an annual low radiation dose CT (LDCT) of the chest has the potential to decrease the number of people who die from this disease. This test is now recommended by many professional organizations and has been endorsed by the US Preventive Services Task Force (USPSTF) and the Centers for Medicare & Medicaid Services (CMS).

Positive results are common with screening A “positive” study indicates that an abnormality is seen in the lungs that could be cancer. Most often, this abnormality would be a very small nodule (“spot”) within the lung. These nodules are too small (typically under one centimeter) to directly cause symptoms and often people are surprised to hear that a nodule is present. Small non-cancerous nodules are very common, particularly in people who have a history of cigarette smoking. In fact, in the largest study to date, nearly 40 percent of the high risk patients had a positive screening test on at least one of three CT scans. Of these positive studies, only 4 percent were actually diagnosed with lung cancer.

Some nodules have more concerning features. Every case is unique; reviewing the case with a health care provider familiar with lung cancer screening is important. In general, the most important features of nodules that suggest cancer are size and growth. Lung nodules under 4-6mm (about ¼ inch) are unlikely to be cancer and may not require any additional testing outside of the annual CT scan. Nodules that are noted to be “calcified” are typically non-cancerous and may not require further testing. “Non-calcified” nodules greater than 6mm or those showing growth between scans generally require more evaluation.

Further testing may be recommended: Depending on the appearance, size, and growth pattern of the nodule, further testing may be pursued. In many circumstances, the nodule will be followed over time with low-radiation dose CT scans at 3-6 month intervals. If there is no growth for 2 years (longer for some types of nodule) the nodule is unlikely to be cancer. If the nodule has more concerning features, a scan called a PET/CT may be considered. Alternatively, a surgical or non-surgical biopsy may be recommended.

Lung cancer screening at the University of Vermont Medical Center: If you smoke now or have in the past, ask your healthcare provider if lung cancer screening is appropriate for you. Screening tests are currently being performed at the University of Vermont Medical Center. A dedicated Lung Nodule Clinic and the Lung Cancer Multidisciplinary Clinic are available to see people who have had a positive result on a CT screening study.