



Notes from the Chair

by Catherine M. Foss, BS, RRT, RPFT

As a member of the Diagnostic Section, your input is vitally important to the future direction of our group and our ability to achieve the goals set forth by the membership as a whole. Please do not hesitate to contact me with suggestions, comments, or concerns. My contact information appears on page 2.

I want to take this opportunity to encourage all of you to consider writing an article for a future issue of the Bulletin. This publication is designed to represent your needs and interests, and we need direct input from members to make that happen. Here are some article ideas to get you started:

- Present an intriguing case study.
- Share a new program implemented in your department.
- Express concerns about professional matters, such as state licensure.
- Report on research in various areas of diagnostic practice.
- Present results of informal surveys you may have conducted via the section e-mail list, phone, or other venues.

As a section, we also need to put more emphasis on the staff needs of our specialty. Is your facility having difficulty recruiting qualified candidates to apply for open positions? The profession of respiratory care must be proactive in increasing the number of students, including those trained in the diagnostic skills, graduating from RT

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Update on NETT

by Catherine M. Foss, BS, RRT, RPFT

The National Emphysema Treatment Trial (NETT) was recently concluded, and results were presented at the American Thoracic Society (ATS) meeting in Seattle in June, amid great expectation by attendees. Results were also published in the May 22 edition of the *New England Journal of Medicine*.¹ More information concerning the surgical outcomes were released at a surgeon's convention in June, and pulmonary rehabilitation data is on its way as well.

This trial was unique in that it combined the efforts of the National Heart, Lung and Blood Institute (NHLBI), the Centers for Medicare and Medicaid Services (CMS), and the Agency for Healthcare Research and Quality (AHRQ). According to the NHLBI, "This was a multicenter clinical trial designed to determine the role, safety, and effectiveness of bilateral lung volume reduction surgery (LVRS) for the treatment of emphysema. A secondary objective was to develop criteria to identify patients likely to benefit from the procedure."²

The trial began enrolling patients in January of 1998 and was designed to last five years. The final patients were enrolled in July of 2002, and follow-up was completed in December of 2002. Overall, 3,777 people were evaluated for participation in the trial at 17 sites in the United States, and 1,218 individuals were selected.² Respiratory therapists played a crucial role throughout the course of this trial, from the initial diagnostic screenings and numerous follow-up visits in the pulmonary function laboratory, through pulmonary rehabilitation, intensive care and floor care as the LVRS patients moved through the health care continuum of services.

Subjects who qualified after diagnostic screening were sent to pulmonary rehabilitation for six to ten weeks, with optimized medical therapy of their emphysema. The subjects then returned to the lab for repeated diagnostic testing and were randomly assigned to either the medical (610 subjects) or surgical (608 subjects) arm of the study. The surgical arm was then divided into two groups. Some patients had a surgical approach via median sternotomy (359 individuals) while others had VATS, or bilateral video-assisted thorascopy (152 people).

All patients in both arms of the study were brought back for periodic follow up visits, which included diagnostic testing, including pulmonary function, exercise testing, six-minute walk test, radiology studies, and psychosocial and quality of life evaluations.² All patients were required to meet preset criteria based on pulmonary function data and CT scan results. The subjects were also evaluated by, and had to be approved for surgery by, a cardiologist, a pulmonologist, and a thoracic surgeon. Only current nonsmokers qualified for the study, and they must have refrained from smoking for at least four months. They could not have unstable angina, cardiac arrhythmias, an MI within six months, or certain thoracic cardiac surgeries or another disease that was likely to interfere with participation in the trial or reduce survival.²

Approximately 95% of the patients accepted their randomization assignment for the NETT study as directed. As of January 2003, 99% of surviving participants continued to complete low-up clinic visits and telephone contact calls with NETT staff. The average follow-up post-enrollment was just over two years (29 months) for the majority of participants.² Viewed over the course of the 29 months of follow-up, the mortality risk was the same for LVRS and medical arm groups. In May 2001, the study enrollment criteria was revised to exclude a certain subgroup of patients (140) who were found to have a higher mortality risk than the medical group over the short term. This high risk group had an FEV₁ that was 20% or less of predicted values. They also had one of the following abnormalities.²

1. Homogeneous emphysema
2. DLCO 20% or less of predicted

Section Connection

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NOTES FROM THE CHAIR

programs around the country. Consider whether your department can set up a mentoring program or internship to assist respiratory students in gaining interest and involvement in the specialty area of diagnostics.

These are just a few of the issues facing our profession as we move forward. How will you be involved? Can you make a difference? Can you help preserve the future of respiratory care diagnostics? ♦

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UPDATE ON NETT

Even after excluding this high-risk group, the overall mortality for the remaining 1,048 participants was about the same for the LVRS and medical groups throughout follow up. In the three months after randomization, the risk of death for non-high-risk LVRS patients was 5.2%, while the medical arm group had a mortality rate of 1.5%.

The effects of LVRS varied widely among the subjects, but overall, more patients in the surgical group than in the medical group improved in measurable parameters such as function, symptoms, and quality of life. The surgical group (which was not high risk) initially improved post-operatively in terms of pulmonary function, exercise capacity by ergometry, six-minute walk distance, quality of life assessment, and shortness-of-breath scales. After two years of follow up, the test results declined to approximate the pre-LVRS levels. However, those in the medical arm, who received optimal medical therapy and pulmonary rehabilitation but no surgery, saw their test results consistently deteriorate over the two years to levels below that measured at randomization.²

A review of the LVRS results found two characteristics that were most helpful in predicting whether a patient would benefit from the surgery. The first was upper-lobe predominant emphysema. The second predictor was low maximum exercise tolerance despite optimal medical therapy and a pulmonary rehabilitation trial of 6-10 weeks. The cut point found was less than or equal to 25 watts for female patients, and ≤ 40 watts for male patients.² By looking at the radiological distribution of emphysema and the post rehab exercise tolerance, the subjects could be divided into four groups with different risks and benefits for LVRS.^{1,2}

1. Patients with upper-lobe emphysema and low exercise tolerance.
 - LVRS subjects were more likely than medical arm subjects to live longer and function better.
 - Thirty percent of those in the surgical arm group had 10 watt improvement in exercise capacity.
 - The medical arm group had no improvement in exercise capacity.
2. Patients with mostly upper-lobe emphysema with high exercise capacity.
 - No difference in survival between surgical and medical arm subjects.
 - Surgical arm subjects were more likely to function better than those in the medical group.
 - Fifteen percent of LVRS subjects improved more than 10 watts in exercise.
 - Three percent of the medical arm subjects improved exercise tolerance.
3. Patients with non upper-lobe predominant emphysema and low exercise capacity.
 - LVRS and medical arm subjects had similar survival.
 - LVRS and medical arm subjects had similar exercise capacity; however, the surgical group had less shortness of breath.
4. Patients with mostly nonupper-lobe emphysema with high exercise capacity.
 - The surgical group had poor survival compared to the medical arm subjects.
 - Both surgical and medical arm subjects had low functional ability improvement.

Little, if any, difference was found between the two surgical evaluation groups (medi-an sternotomy and VATs) in the following areas:

- The amount of lung removed by gram weight
- Blood loss/transfusion requirements
- Airleak rate and duration.
- Intra-operative complications
- Post-operative complications
- Pulmonary function, exercise test at 6, 12, and 24 months
- Quality of life
- Survival

Areas of variable differences between the surgical groups were:

Median Sternotomy	VATS	
– Operative time	104 min	128 min
– 90-day mortality	4.6	4.0
– 0-1 ICU days	43%	67%
– Any 30 day morbidity	59%	52%
– Atrial arrhythmia	22%	21%
– Pneumonia	22%	15%
– 30-day postop independence	61%	87%

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UPDATE ON NETT

What does the NETT trial mean to pulmonary function labs? At the ATS meeting, it was announced that CMS would be reviewing the results and accepting comments concerning LVRS and pulmonary rehabilitation associated with the surgery for the next 30 days (period to end in June). At that point, the comments would be assembled, and at some point (undefined at the meeting), the government would announce its decision on Medicare coverage for LVRS and the associated pulmonary rehabilitation for emphysema patients. Significant political and patient pressure to expedite this process was expected. As practitioners in the pulmonary function lab, we can expect phone calls from patients wanting evaluations or when this procedure is again approved for selected patients.

Several items of importance were addressed at the meeting. First, pulmonary rehabilitation is under consideration for coverage only for emphysema subjects being covered for LVRS evaluation, not for other pulmonary reasons. Second, pulmonary function labs will be expected to perform evaluations essentially similar to NETT methodologies in order to compare patient status of risk. The NETT used a set of predicted values that might not be commonly used in laboratories across the country, but the government considers it essential to use the same predicted set.

Third, the exercise testing followed a very specific protocol for all patients, only varying with the workload gradient based on MVV. The important feature that labs would have to gear up for is the fact that the exercise test is performed while breathing 0.30 FIO₂ through a Hans-Rudolph Valve system attached to the exercise pneumotach. The NETT evaluation included spirometry pre- and post-bronchodilator, lung volumes using body plethysmography (TGV and SVC linked), DLCO, MIP/MEP, six-minute walk test for endurance (on oxygen if needed), blood gas on room air, and maximum cardiopulmonary exercise test using enhanced 0.30 oxygen on a cycle ergometer. As many of you surely know, testing severe emphysema patients can be a time-consuming process when the goal is to achieve reproducible, valid data by ATS standards, as the testing procedures must wait for subjects to "catch their breath" between efforts. These patients will greatly stretch the time-productivity standards commonly used to evaluate laboratories.

I encourage you to take the time to read the New England Journal of Medicine articles on NETT and watch the AARC web site for an update on the notice that will be posted in the Federal Register. ♦

REFERENCES

1. National Emphysema Treatment Trial Research Group. A Randomized Trial Comparing Lung-Volume-Reduction Surgery with Medical Therapy for Severe Emphysema. *The New England Journal of Medicine*, 348 (21), pp 2059-2073.
2. National Heart, Lung, and Blood Institute "National Emphysema Treatment Trial (NETT): Evaluation of Lung Volume Reduction surgery for emphysema". <http://www.nhlbi.nih.gov/health/proc/lung/nett/lvrsweb.htm>

FURTHER READING

- National Emphysema Treatment Trial Research Group, Cost Effectiveness of Lung-Volume-Reduction Surgery for Patients with Severe Emphysema Vol. *The New England Journal of Medicine*, 348 (21), 22 May 2003, pp 2092 - 2102.
- Ware, James H. The National Emphysema Treatment Trial - How Strong Is the Evidence? *The New England Journal of Medicine*, 348(21), 22 May 2003 pp 2055 - 2056.

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Resources from the National Lung Health Education Program

One of the AARC's key partners in the fight to improve the outlook for respiratory patients is the National Lung Health Education Program (NLHEP), headed up by Thomas L. Petty, MD, FAARC. Chief among the organization's goals is greater utilization of office-based spirometry in the diagnosis of COPD. As diagnosticians in respiratory medicine, members of our section have a large role to play, not only in promoting the NLHEP objectives, but also in ensuring the validity of spirometry in this setting and working with primary care physicians to offer further testing to their patients who have abnormal results.

How can we take better advantage of this important partnership? One way we can all benefit is by utilizing the resources available on the NLHEP web site. What's on the site? Take a look at the following list, then go directly to www.nlhep.org to download these brochures and reports and put them to work in your labs.

BROCHURES

Two informative brochures are available online to physicians, but AARC members may also receive preprinted copies of up to 200 each - by sending their full name, company, mailing address, phone, e-mail address, and number of copies of brochure they are requesting, along with a brief description of how they are planning to use them to Gretchen Lawrence, RRT at gl-lungs@swbell.net. There is a modest charge to other individuals.

SAVE YOUR BREATH AMERICA!

by Thomas L. Petty, MD, and Dennis E. Doherty, MD
Advice for patients with asthmatic bronchitis, chronic bronchitis or emphysema, and their families.

PREVENT EMPHYSEMA NOW

by Thomas L. Petty, MD, and Dennis E. Doherty, MD
A companion booklet for physicians.

INFORMATION FOR PATIENTS

- The Second Breath of Life
- Test Your Lungs - Know Your Numbers...You May Just Breathe a Little Easier!

PHYSICIANS AND HEALTH PROFESSIONALS

- The Lung Cancer Frontiers web site includes issues of a newsletter dedicated to advancing knowledge about lung cancer and emphasizing early identification and treatment. www.lungcancerfrontiers.org

SLIDE PRESENTATIONS

- NLHEP Physician Slide Presentation I
- NLHEP Physician Slide Presentation II

SERIES OF FRONTLINE BOOKS

- Frontline Treatment of COPD, an electronic book in PDF format
- Frontline Assessment of Common Pulmonary Presentations, by the Snowdrift Pulmonary Conference

COPD

- "The Big Picture: RTs Screen for COPD, Raise Awareness," a reprint of an article by Gretchen Lawrence from *AARC Times*, January 2003
- "COPD Surveillance-United States, 1971-2000," David M. Mannino, MD, David Homa, PhD, Laura Akinbami, MD, Earl Ford, MD, Stephen Red, MD
- "Epidemiology, Prevalence, Morbidity and Mortality, and Disease Heterogeneity," David M. Mannino, MD, FCCP

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