

LUNG VOLUME REDUCTION SURGERY AND THE NATIONAL EMPHYSEMA TREATMENT TRIAL

Emphysema is a chronic lung disease in which the air spaces distal to the terminal bronchioles are permanently enlarged, their walls destroyed and without obvious fibrosis. This condition results in reduced surface area for perfusion and the exchange of gases. Emphysema is most commonly caused by cigarette smoking and, in some cases, by a genetic deficiency of the enzyme alpha-1-antitrypsin, a protective antiprotease. In emphysema, there is a progressive decline in respiratory function



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due to a loss of lung elastic recoil with a decrease of expiratory flow rates; air-trapping and hyperinflation; enlargement of the lungs and thorax; and, impaired diaphragmatic function. These changes produce the major symptom emphysema patients suffer—dyspnea or shortness of breath.

Current treatments for emphysema include bronchodilators to improve air-flow, as well as use of oxygen therapy for patients with chronic hypoxemia. There are also benefits from pulmonary rehabili-

tation and exercise training, which is indicated for patients with functional limitations and continued dyspnea despite traditional medical therapy.

Lung Volume Reduction Surgery (LVRS)

Lung volume reduction surgery is a procedure that may alleviate symptoms of advanced chronic obstructive lung disease due to emphysema. This surgical resection is variably referred to as lung reduction surgery or reduction pneumoplasty in which the most severely emphysematous lung tissue is resected.

LVRS recently has received much attention from supporters and critics alike. First introduced in the 1950s, LVRS was initially abandoned due to a high operative mortality and lack of objective statistics to support its continued use. One of the main limitations of the procedure was the difficulty in suturing the remaining lung in an airtight manner after resection. Today, bovine pericardium is used to buttress the staple line and minimize air leaks. Using this procedure, published reports have indicated benefits in some patients.

LVRS downsizes the lungs by resecting badly diseased emphysematous tissue that is functionally useless. Surgeons—removing approximately 20–30% of each lung—capitalize on the heterogeneity of emphysema in which lesions are usually more severe at the apices and less severe at the lung bases. During the course of

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surgery, one lung is continually ventilated while the lumen of the contralateral lung is clamped. Subsequently, normal areas of lung deflate as blood flows past the alveoli and resorbs oxygen, while emphysematous portions of the lung with less blood flow and reduced surface area remain inflated and are targeted for resection. LVRS is believed to improve function of the lung by restoring pulmonary elastic recoil and correcting over-distention of the thorax and depression of the diaphragm. The result? Some patients experience better respiratory mechanics and relief from severe dyspnea.

The reported benefits of LVRS in some patients include improved airflow, functional capacity and quality of life. It is unclear which patients benefit most from the surgery. As in any major thoracic procedure, there are risks. The duration of the improvement in lung function following resection is not yet completely known, but there is a suggestion that lung function begins to decline two years after LVRS.

Despite optimistic reports, the morbidity, mortality and financial costs associated with LVRS appear to be high, indicating the need for further studies of both short and long term outcomes to truly evaluate the efficacy of LVRS and which patients it benefits the most. The National Emphysema Treatment Trial fills this need.

The National Emphysema Treatment Trial (NETT)

National Jewish Medical and Research Center and the University of Colorado Health Sciences Center (UCHSC) are among 18 centers nationwide selected to evaluate the effects of medical and surgical treatment in patients with emphysema. The National Emphysema Treatment Trial is a randomized, controlled clinical trial, which compares optimal medical therapy to optimal medical therapy plus lung volume reduction surgery. Testing, evaluations, medical treatment, rehabilitation and follow-up visits are conducted at the Emphysema Clinic at National Jewish – the only medical and research center in the

United States devoted entirely to respiratory, allergic and immune system diseases. The surgery is performed at UCHSC.

The National Emphysema Treatment Trial is funded and coordinated by the Health Care Financing Administration (Medicare) and the National Heart, Lung and Blood Institute, and is the first controlled, randomized long-term study of the safety, benefits and post-operative costs of LVRS.

Patients—who meet a specific set of criteria—are being enrolled in NETT to determine who will benefit most from LVRS. All patients receive optimal treatment including pulmonary rehabilitation, medications, self-management information and exercise training and are then randomized to receive either continuing medical treatment or continuing medical treatment and LVRS. Follow-up visits are required at 6, 12, 18, 24, 36 and 48 months. The first patient was enrolled at National Jewish Medical and Research Center in October 1997.

The following is a partial list of *inclusion* criteria for NETT:

- History and physical examination consistent with emphysema
- Non-smoker for four months prior to initial interview with continued non-smoking for duration of screening
- Post-bronchodilator Total Lung Capacity >110% predicted
- Post-bronchodilator Residual Volume > 150% predicted
- Diffusing capacity < 70% predicted
- High resolution chest CT scan evidence of moderate to severe bilateral, heterogeneous or homogeneous emphysema

The following is a partial list of *exclusion* criteria for NETT:

- Body mass index > 31.1 kg/m² (males) or 32.3 kg/m² (females)
- Unplanned weight loss > 10% of usual weight in prior 90 days

- Pulmonary hypertension (mean PPA greater than or equal to 35 mmHg or peak systolic PPA greater than or equal to 45 mmHg)
- Clinically significant bronchiectasis, i.e., recurrent pulmonary infections with sputum > 3 tablespoons per day
- Previous laser or lung volume reduction surgery
- Previous coronary artery bypass surgery
- Congestive heart failure within six months of interview and ejection fraction < 45%
- Myocardial infarction within six months of interview and ejection fraction < 45%
- Oxygen requirement exceeding 6 L/min to keep saturation > 90% during exercise
- Any disease or condition which may interfere with completion of tests, therapy or follow-up testing

To refer a patient or to obtain more information on the National Emphysema Treatment Trial or lung volume reduction surgery, contact National Jewish Medical and Research Center, 1400 Jackson Street, Denver, Colorado, 80206, 1-800-NJC-9555.

Medical information on potential NETT patients is requested from the referring physician and includes spirometry, chest x-ray, EKG and

medical history. Candidates are then required to complete extensive additional testing.

Other NETT clinical centers include Baylor College of Medicine, Brigham and Women's Hospital, Cedars-Sinai Medical Center, Cleveland Clinic Foundation, Columbia University, Duke University Medical Center, Mayo Clinic, Ohio State University, Saint Louis University, Temple University, University of California/San Diego Medical Center, University of Maryland at Baltimore, University of Michigan, University of Pennsylvania Medical Center, University of Pittsburgh, University of Washington and Washington University.

References

Cooper JD, Lefrak SS. Is Volume Reduction Surgery Appropriate in the Treatment of Emphysema? Yes. *Am J Respir Crit Care Med* Vol 153:1201-1204, 1996.

Make BJ, Fein AM. Is Volume Reduction Surgery Appropriate in the Treatment of Emphysema? No. *Am J Respir Crit Care Med* Vol 153:1205-1207, 1996.

Fein AM, Branman SS, Casaburi, R, Irvin CG, Make BJ, Rodarte JR, Solway J. Lung Volume Reduction Surgery. *Am J Respir Crit Care Med* Vol 154:1151-1152, 1996.

Outcomes Prove Asthma Treatment Programs Improve Disease Management and Control Costs

Assess the High Cost of Asthma

Nearly one in every 15 Americans has asthma and almost 12 percent of all children have the disease. The annual cost of treating asthma in America is more than \$9 billion a year. But only four percent of all asthma patients account for more than 50 percent of the total cost. Many of these expenses are preventable with appropriate care and monitoring. Now is the time to control the costs of this chronic disease.

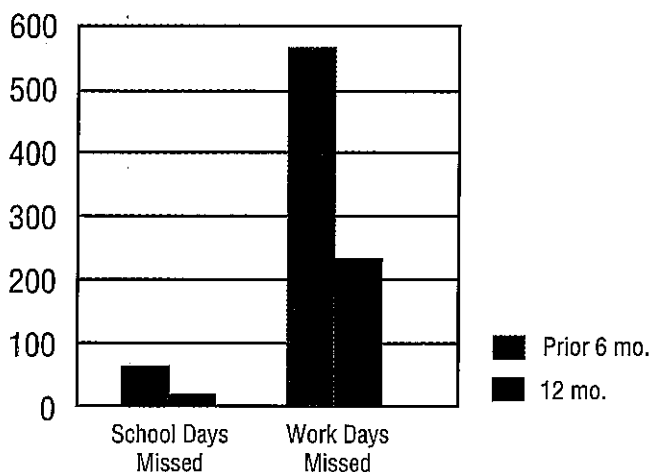
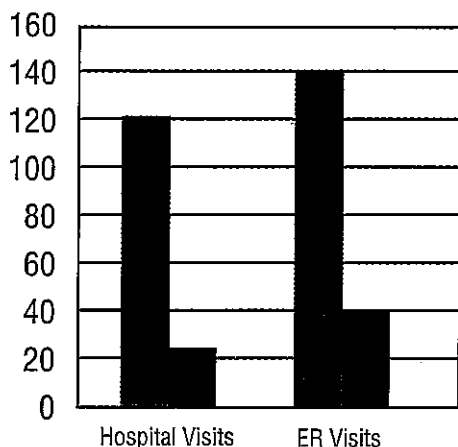
The Leader in Outcomes & Cost Savings

National Jewish Medical and Research Center

is the only facility in the world devoted entirely to treatment and research of chronic respiratory, allergic and immune system diseases. We have also established a track record of demonstrated outcomes for the patient and substantial cost savings for the payor.

In a recent study of moderate to severe asthmatic patients in the 6 months prior to and 12 months after treatment at National Jewish, our data revealed a 77.4 percent decrease in hospitalizations and a 71.8 percent reduction in emergency room visits.

Time Out For Asthma® Outcomes



Graphs represent data collected 6 months before and 12 months after treatment at National Jewish

Proven Value

National Jewish outcomes clearly demonstrate that physicians and payors receive significant value through reduced asthma claims (usually 45-80 percent) and high patient satisfaction through participation in our asthma programs.

Take The Next Step — National Jewish Asthma Treatment Programs

National Jewish's multi-disciplinary treatment

programs provide comprehensive resources for managing moderate to severe asthma patients. We offer unique asthma treatment programs for patients with all types of respiratory and immunological disorders, including *Time Out for Asthma®* and *Disease Specific Case Management*. Both of these programs are proven to achieve high patient satisfaction, improve quality of life indices and reduce utilization of costly medical services.

Time Out For Asthma®: Collaborative Care Management

Time Out For Asthma® provides physicians, payors and patients with a highly effective solution for the high-cost, difficult-to-manage asthma patient. This program offers a multi-day outpatient diagnostic and treatment program without duplicating efforts of the referring physician.

Time Out for Asthma® includes evaluation, observation and therapy tailored to the individual. These needs are defined by the referring physician, payor, patient and National Jewish. From a second opinion to a complex diagnostic work-up, case managers and physicians can confer with nationally recognized specialists and nurses at National Jewish to determine the most appropriate level of care for the patient.

Treatment Tailored To The Individual

With guidance from the referring physician, a program is developed to meet the unique needs of the patient and is consistent with payor requirements. When the patient is discharged, the referring physician receives a discharge summary and information for continued optimal management of the patient. During a multi-day period, the typical patient experiences the following:

- Consultation for Diagnosis
- Objective Measures of Lung Function
- Diagnostic Studies
- Rehabilitation Assessment and Therapy
- Psychosocial and Behavioral Assessment

Nutrition and Speech Counseling
 Pharmacological Therapy
 Environmental Measures
 Patient Education

Disease Specific Case Management: Your Partner In Improving Compliance and Outcomes

A unique program at National Jewish is our *Disease Specific Case Management*. Our program is staffed by expert nurses, trained in respiratory

and immunological disorders. We establish a schedule of proactive calls for maintenance and prevention, as well as a reactive program for early, quick intervention and resolution of exacerbations. *Disease Specific Case Management* also provides post-discharge follow-up for severe, high-cost patients. The Disease Specific Case Manager functions as an extension of the referring physician following a prescribed and individual treatment plan for each patient.

National Jewish Disease Specific Case Management Utilization Outcomes

	Hospitalizations	ICU	ER visits	Child Days Missed	Adult Days Missed
6 months before DSCM	73	5	208	197	194
6 months after DSCM	19	3	37	74	42

Data collected prior to enrollment and six months post enrollment, n=78.

Results That Meet Your Needs

National Jewish's asthma treatment programs have an established track record with superior outcomes. Outcome studies demonstrate that it can be the most appropriate referral for severe patients who are unresponsive to conventional treatment as well as moderate patients who are significantly impaired by asthma.

Take time today to learn how National Jewish can become your specialized source for treatment programs for the moderate to severe asthma patient.

National Jewish Physician Line: 1-800-NJC-9555 (1-800-652-9555)

Physicians have easy access to National Jewish through The Physician Line. Consultation is available for respiratory, allergic and immunological diseases.

National Jewish Managed Care Line: 1-800-573-LUNG (1-800-573-5864)

Managed care customers have direct access to National Jewish through The Managed Care Line. Call our nurses to facilitate referrals, discuss cases and request education literature.

Consumer Questions - LUNG LINE: 1-800-222-LUNG (1-800-222-5864)

Consumers and patients who need more information about National Jewish and respiratory health concerns can speak with a National Jewish nurse by calling LUNG LINE.

Managed Care Line, Physician Line and LUNG LINE nurses are available Monday through Friday, 8 a.m. to 5 p.m., Mountain Standard Time.

Internet Access

Access National Jewish through the internet. Visit our home page on the World Wide Web at <http://www.nationaljewish.org>

**For Referrals of Lung Volume Reduction Surgery:
1-800-NJC-9555 (1-800-652-9555)**

Upcoming CME Programs

21st Annual Update on Allergy, Asthma and Clinical Immunology

Keystone Resort, Keystone, CO

February 3 - 7, 1999

For Resort Reservations: 1-800-258-0437

For Conference Information: (303) 398-1000

Fax: (303) 270-2226

*Special Centennial Celebration! There will be
skiing, a gala, family activities, and more!*

Join Us!!!

<http://www.nationaljewish.org/cme/key98.htm>

**For further information on CME programs
at National Jewish, call (303)-398-1000**

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Important Phone Numbers:

Patient referrals/appointments

(303)398-1355 or 1-800-222-5864 x 1355

Fax: (303)398-1183

Home Page on World Wide Web:

<http://www.nationaljewish.org>

Weekly Education Listings

Unless otherwise noted, all sessions are held in Heitler Hall.
For more information call Sandi Rettberg at (303)398-1714
or e-mail rettbergs@njc.org

Monday: Asthma Forum

Tuesday: Pediatric Pulmonary Conference

Research in Progress

Sleep Disorders Conference

Wednesday: Denver Allergy Rounds

Thursday: Pediatric Grand Rounds

Research in Progress

Friday: Topics in Pulmonary Medicine Lecture Series

Pulmonary Research in Progress

Second Opinion Conference

Medical Scientific Update, a publication of the continuing medical education office at National Jewish, provides information to physicians about our clinical and research programs in allergic, respiratory and immune system disorders.

Please send any comments or requests for topics to the Office of Professional Education, National Jewish Medical and Research Center, 1400 Jackson Street, Denver, CO 80206. We'd like to hear from you.

Moving? Please forward change of address form to us to maintain your free subscription to Medical Scientific Update.

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Lung Line® 800-222-LUNG(5864) 355-LUNG (Denver only)

This free information service, staffed by highly qualified registered nurses, answers patients' questions about respiratory, allergic and immunologic diseases. Callers are encouraged to discuss information received with their physicians.

The Physician Line at 1-800-NJC-9555, exclusively for physician use, is a toll free service that connects you with a highly experienced representative who can provide information on National Jewish programs, laboratory tests and referrals.

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