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JUNE 2004

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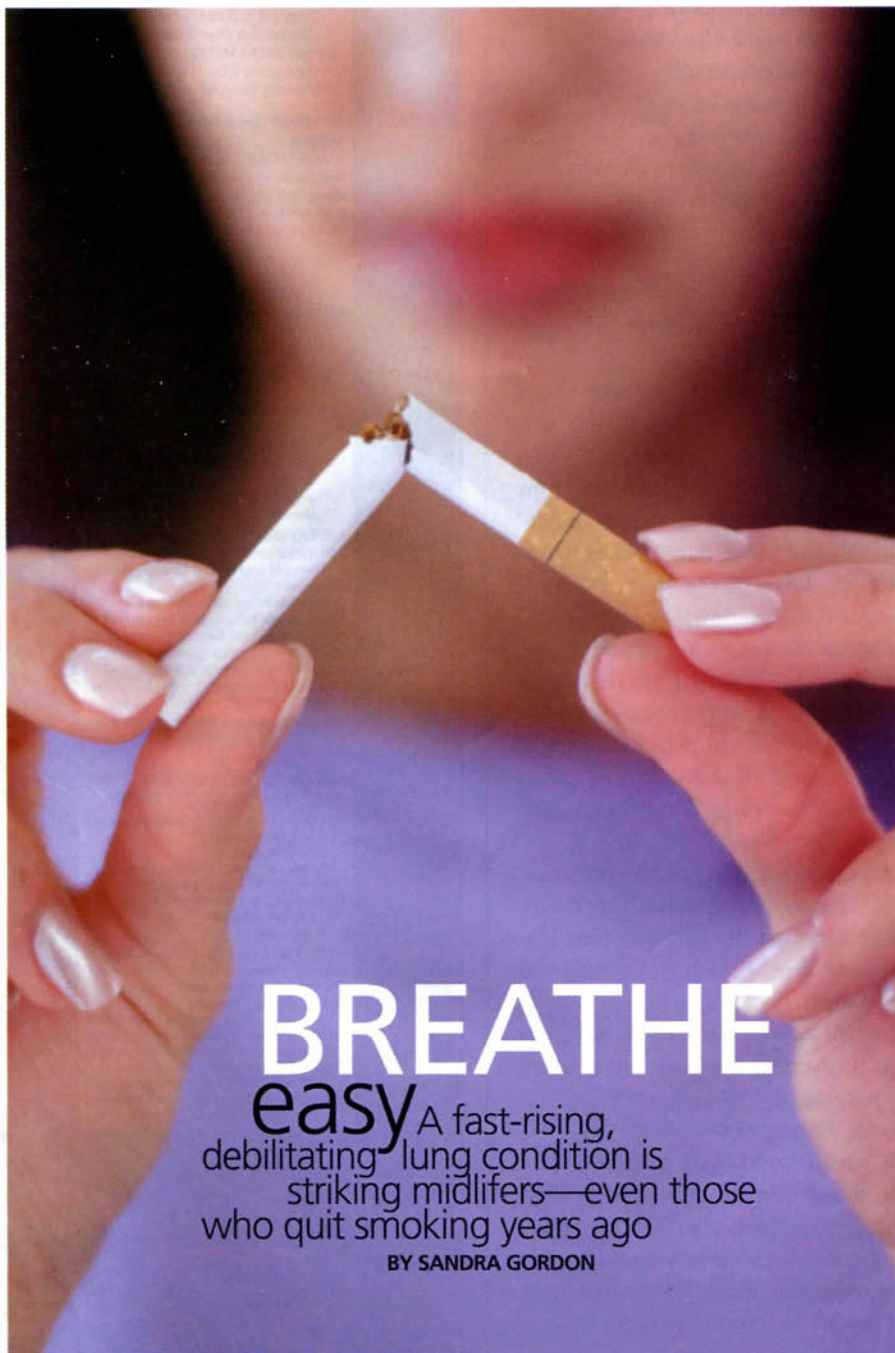
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# Vital & Vibrant

FEELING HEALTHY  
IN BODY AND MIND  
EDITED BY COURTENAY SMITH

THIS MONTH: THE SURPRISING SECRET TO SOOTHING STRESS + THE LATEST HEALTH NEWS



**BREATHE**  
**easy** A fast-rising,  
debilitating lung condition is  
striking midlifers—even those  
who quit smoking years ago  
BY SANDRA GORDON

# W

hen Bernadette Murphy smoked as a teenager and young adult in the Sixties, it was “cool,” despite the Surgeon General’s warnings that tobacco was linked to heart disease and lung cancer. Over the next 15 years, as Murphy worked her way up on Wall Street, smoking helped her unwind, and her half-pack-a-day habit escalated to two. At 30, becoming more mindful of her health, she quit cold turkey.

Still, the damage was done. When Murphy was in her forties, then a nonsmoker for over a decade, persistent congestion crept into her lungs. She happened to mention it during a routine checkup, which led to a diagnosis of chronic bronchitis, a respiratory illness considered part of a fast-increasing, debilitating midlife health problem: chronic obstructive pulmonary disease (COPD). Today, Murphy, even under a doctor’s regular care, is hypersusceptible to colds and flu. “I’m often short of breath, and I have a terrible cough,” she says. “I’ve been known to scatter crowds in art galleries.”

Murphy represents one of the 12 million Americans with COPD. The condition can start with subtle symptoms in the forties, and, if undetected, leaves the sufferer noticeably short of breath by the fifties and beyond.

Midlife women, especially ex- and current smokers, might be at higher risk of developing

PHOTO: MICHAEL KELI/FR/CORBIS



the disease. "There seems to be some evidence that, for the same amount of cigarette smoking, women may develop COPD of a more severe nature at an earlier age than men," says Dawn DeMeo, M.D., MPH, associate physician at the Brigham and Women's Hospital Center for Chest Diseases in Boston. It's possible that women who started smoking in adolescence may be at even greater risk, because cigarettes may have damaged their lungs while they were still growing and before having reached full capacity. In 2000, the number of women dying from COPD (59,936) surpassed the number of men (59,118), according to the National Heart, Lung, and Blood Institute.

COPD is the fourth leading cause of death in the U.S. and is expected to rise to number three by 2020. But the effects of the condition are felt long before it turns fatal. COPD can literally rob you of breath, leaving you unable to pursue your favorite activities. A recent American Lung Association survey revealed that COPD patients say their condition limits normal physical exertion (70 percent), social activities (53 percent), sleeping (50 percent) and the ability to work (51 percent).

#### GASPING FOR AIR

COPD is characterized by progressive inflammation that constricts the airways (emphysema and chronic bronchitis now fall under the umbrella term COPD). The condition is caused by inhaling noxious particles and gases found in cigarette smoke and environmental pollutants that gradually—over 10 to 30 years—destroy the lungs' alveoli, the tiny air sacs that exchange oxygen and carbon

## IS SPIROMETRY UNDERUSED? SOME EXPERTS SAY PRIMARY CARE DOCTORS SHOULD PERFORM THE TEST MORE OFTEN— AND WARN THAT WOMEN MAY NEED TO ASK FOR IT.

Right now, the American Lung Association recommends that you ask your doctor about spirometry if you answer yes to one or more of these questions: Are you a current or former smoker? Do you frequently experience a deep, chronic, wet cough? When completing routine activities, are you short of breath? Do you live in a heavy smog/high ozone area? Are you exposed to air pollution at work? In cold weather, does your chest get tight or do you find it difficult to breathe?

But some physicians go even further, and say that if you find you can't physically keep up with your peers, or if you have at least one bout of bronchitis per season, you should be evaluated. Others, like Alan M. Fein, M.D., chief of the Center for Pulmonary, Critical Care & Sleep Medicine at North Shore-Long Island Jewish Hospital in Manhasset, New York, say that because initial symptoms of COPD can be subtle, or even nonexistent, spirometry should be routine for those age 40 and older. Like having blood pressure measured and cholesterol checked, "Spirometry should be included in any general physical examination as part of routine preventative care," Fein says.

There is evidence that spirometry is underused. According to the National Heart, Lung, and Blood Institute, some 24 million adults have evidence of impaired lung function, but only half that number have been diagnosed with COPD, which indicates the condition may be going undetected. A similar conclusion was reached by a study published in the journal *Chest*, which determined that women are more likely to have symptoms missed. When 192 primary care physicians examined the medical histories of 154 men and 38 women who had COPD, the doctors were significantly more likely to suspect the men of having the condition. "If you're a woman, particularly if you were or are a smoker, alert your doctor and be proactive about spirometry," urges Christopher Cooper, M.D., professor of medicine and physiology at the David Geffen School of Medicine in Los Angeles.

dioxide to and from the blood. (Picture the lungs as an upside-down tree; the alveoli are its leaves.) COPD also constricts bronchi—the lungs' upper airways, or branches of the tree—that bring air down to the alveoli, robbing your body of oxygen.

Cigarette smoking past or present (which induces inflammation, damages the infrastructure of lung tissue and increases mucous production) is involved in 80 to 90 percent of all COPD cases. Most experts believe that to get COPD, you need a substantial smoking history—one pack a day for 20 years, or two packs a day for 10 years. But they agree that in unusual cases it might take far less. In fact, roughly 10 percent of those with COPD have never taken a puff. "The risk is linear—the more and longer you smoked, the greater your risk," says Norman H.

Edelman, M.D., medical consultant for the American Lung Association.

Other risk factors include genetic abnormalities (COPD tends to run in families; also, an estimated 1 percent of the population has a known genetic susceptibility to emphysema called alpha 1 antitrypsin deficiency); long-term, occupational exposure to lung irritants such as air pollution, chemical fumes, vapors and dust; and a history of severe and frequent respiratory infections that damaged the lungs. The prevalence of COPD also increases with age. "Think of COPD as the cumulative response to the burden of everything that has ever been inhaled over a lifetime," says A. Sonia Buist, M.D., an international COPD expert and a professor of medicine at the Oregon Health & Science University in Portland.

#### MISSED SIGNALS

What concerns experts most: Midlifers often mistake the earliest symptoms of COPD (chronic cough and shortness of breath) for signs of aging, and can lose a vital opportunity to prevent the most debilitating effects of the disease.

Starting around age 20, when lungs stop growing, we all begin losing a little lung capacity—an estimated 30 milliliters annually. The lungs of someone who smokes cigarettes or who has COPD may degenerate as much as 100 to 200 times faster.

In healthy people, the rate of loss over a typical life span isn't noticeable. Our lungs, designed for maximum exercise, come with capacity to spare. "People who don't have lung disease never get to the point where they're limited by their lungs," says Richard Casaburi, M.D., Ph.D., professor of medicine and chief of



**Brief summary. Please see full prescribing information for complete product information.**

**BenzaClin™ Topical Gel** (clindamycin - benzoyl peroxide gel)

**Topical Gel:** clindamycin (1%) as clindamycin phosphate, benzoyl peroxide (5%)

**For Dermatological Use Only - Not for Ophthalmic Use**

**\*Reconstitute Before Dispensing\***

**INDICATIONS AND USAGE**

BenzaClin Topical Gel is indicated for the topical treatment of acne vulgaris.

**CONTRAINDICATIONS**

BenzaClin Topical Gel is contraindicated in those individuals who have shown hypersensitivity to any of its components or to lincosamides. It is also contraindicated in those having a history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis.

**WARNINGS**

**ORALLY AND PARENTERALLY ADMINISTERED CLINDAMYCIN HAS BEEN ASSOCIATED WITH SEVERE COLITIS WHICH MAY RESULT IN PATIENT DEATH. USE OF THE TOPICAL FORMULATION OF CLINDAMYCIN RESULTS IN ABSORPTION OF THE ANTIBIOTIC FROM THE SKIN SURFACE. DIARRHEA, BLOODY DIARRHEA, AND COLITIS (INCLUDING PSEUDOMEMBRANOUS COLITIS) HAVE BEEN REPORTED WITH THE USE OF TOPICAL AND SYSTEMIC CLINDAMYCIN. STUDIES INDICATE A TOXIN(S) PRODUCED BY CLOSTRIDIA IS ONE PRIMARY CAUSE OF ANTIBIOTIC-ASSOCIATED COLITIS. THE COLITIS IS USUALLY CHARACTERIZED BY SEVERE PERSISTENT DIARRHEA AND SEVERE ABDOMINAL CRAMPS AND MAY BE ASSOCIATED WITH THE PASSAGE OF BLOOD AND MUCUS. ENDOSCOPIC EXAMINATION MAY REVEAL PSEUDOMEMBRANOUS COLITIS. STOOL CULTURE FOR *Clostridium Difficile* AND STOOL ASSAY FOR *C. difficile* TOXIN MAY BE HELPFUL DIAGNOSTICALLY. WHEN SIGNIFICANT DIARRHEA OCCURS, THE DRUG SHOULD BE DISCONTINUED. LARGE BOWEL ENDOSCOPY SHOULD BE CONSIDERED TO ESTABLISH A DEFINITIVE DIAGNOSIS IN CASES OF SEVERE DIARRHEA. ANTIPERISTALTIC AGENTS SUCH AS OPIATES AND DIPHENOXYLATE WITH ATROPINE MAY PROLONG AND/OR WORSEN THE CONDITION. DIARRHEA, COLITIS, AND PSEUDOMEMBRANOUS COLITIS HAVE BEEN OBSERVED TO BEGIN UP TO SEVERAL WEEKS FOLLOWING CESSATION OF ORAL AND PARENTERAL THERAPY WITH CLINDAMYCIN.**

Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation and treatment with an antibacterial drug clinically effective against *C. difficile* colitis.

**PRECAUTIONS**

**General:** For dermatological use only; not for ophthalmic use. Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy effect may occur, especially with the use of peeling, desquamating, or abrasive agents.

The use of antibiotic agents may be associated with the overgrowth of nonsusceptible organisms including fungi. If this occurs, discontinue use of this medication and take appropriate measures.

Avoid contact with eyes and mucous membranes.

Clindamycin and erythromycin containing products should not be used in combination. *In vitro* studies have shown antagonism between these two antimicrobials. The clinical significance of this *in vitro* antagonism is not known.

**Information for Patients:** Patients using BenzaClin Topical Gel should receive the following information and instructions:

1. BenzaClin Topical Gel is to be used as directed by the physician. It is for external use only. Avoid contact with eyes, and inside the nose, mouth, and all mucous membranes, as this product may be irritating.
2. This medication should not be used for any disorder other than that for which it was prescribed.
3. Patients should not use any other topical acne preparation unless otherwise directed by physician.
4. Patients should report any signs of local adverse reactions to their physician.
5. BenzaClin Topical Gel may bleach hair or colored fabric.
6. BenzaClin Topical Gel can be stored at room temperature up to 25°C (77°F) for 10 weeks. Do not freeze. Discard any unused product after 10 weeks.
7. Before applying BenzaClin Topical Gel to affected areas wash the skin gently, then rinse with warm water and pat dry.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Benzoyl peroxide has been shown to be a tumor promoter and progression agent in a number of animal studies. The clinical significance of this is unknown. Benzoyl peroxide in acetone at doses of 5 and 10 mg administered twice per week induced skin tumors in transgenic Tg.AC mice in a study using 20 weeks of topical treatment.

Genotoxicity studies were not conducted with BenzaClin Topical Gel. Clindamycin phosphate was not genotoxic in *Salmonella typhimurium* or in a rat micronucleus test. Clindamycin phosphate sulfoxide, an oxidative degradation product of clindamycin phosphate and benzoyl peroxide, was not clastogenic in a mouse micronucleus test. Benzoyl peroxide has been found to cause DNA strand breaks in a variety of mammalian cell types, to be mutagenic in *S. typhimurium* tests by some but not all investigators, and to cause sister chromatid exchanges in Chinese hamster ovary cells. Studies have not been performed with BenzaClin Topical Gel or benzoyl peroxide to evaluate the effect on fertility. Fertility studies in rats treated orally with up to 300 mg/kg/day of clindamycin (approximately 120 times the amount of clindamycin in the highest recommended adult human dose of 2.5 g BenzaClin Topical Gel, based on mg/m<sup>2</sup>) revealed no effects on fertility or mating ability.

**Pregnancy: Teratogenic Effects: Pregnancy Category C:**

Animal reproductive/developmental toxicity studies have not been conducted with BenzaClin Topical Gel or benzoyl peroxide. Developmental toxicity studies performed in rats and mice using oral doses of clindamycin up to 600 mg/kg/day (240 and 120 times amount of clindamycin in the highest recommended adult human dose based on mg/m<sup>2</sup>, respectively) or subcutaneous doses of clindamycin up to 250 mg/kg/day (100 and 50 times the amount of clindamycin in the highest recommended adult human dose based on mg/m<sup>2</sup>, respectively) revealed no evidence of teratogenicity.

There are no well-controlled trials in pregnant women treated with BenzaClin Topical Gel. It also is not known whether BenzaClin Topical Gel can cause fetal harm when administered to a pregnant woman.

**Nursing Women:** It is not known whether BenzaClin Topical Gel is excreted in human milk after topical application. However, orally and parenterally administered clindamycin has been reported to appear in breast milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**Pediatric Use:** Safety and effectiveness of this product in pediatric patients below the age of 12 have not been established.

**ADVERSE REACTIONS**

During clinical trials, the most frequently reported adverse event in the BenzaClin treatment group was dry skin (12%). The table below lists local adverse events reported by at least 1% of patients in the BenzaClin and vehicle groups.

Local Adverse Events - all causalities in ≥ 1% of patients

	BenzaClin n = 420	Vehicle n = 188
Application site reaction	13 (3%)	1 (<1%)
Dry skin	50 (12%)	10 (6%)
Pruritus	8 (2%)	1 (<1%)
Peeling	9 (2%)	-
Erythema	6 (1%)	1 (<1%)
Sunburn	5 (1%)	-

The actual incidence of dry skin might have been greater were it not for the use of a moisturizer in these studies.

**DOSAGE AND ADMINISTRATION**

BenzaClin Topical Gel should be applied twice daily, morning and evening, or as directed by a physician, to affected areas after the skin is gently washed, rinsed with warm water and patted dry.

**HOW SUPPLIED AND COMPOUNDING INSTRUCTIONS**

Size (Net Weight)	NDC 0066-	Benzoyl Peroxide Gel	Active Clindamycin Powder (In plastic vial)	Purified Water To Be Added to each vial
25 grams	0494-25	19.7g	0.3g (1 vial)*	5 mL
50 grams	0494-50	41.4g	0.6 g (2 vials)*	5 mL

\*Each vial contains 0.3g clindamycin phosphate

**Prior to dispensing, tap each vial until powder flows freely. Add 5 mL of purified water to each vial (to the mark) and immediately shake to completely dissolve clindamycin. If needed, add additional purified water to bring level up to the mark. Add the solution in each vial to the gel and stir until homogenous in appearance (1 to 1½ minutes).**

BenzaClin Topical Gel (as reconstituted) can be stored at room temperature up to 25°C (77°F) for 10 weeks. Place a 10-week expiration date on the label immediately following mixing. Store at room temperature up to 25°C (77°F). (See USP).

**Do not freeze. Keep tightly closed. Keep out of the reach of children.**

US Patents 5,446,028; 5,767,098; 6,013,637

Prescribing Information as of April 2003.

Rx Only

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pulmonary medicine at Harbor-UCLA Research and Education Institute in Torrance, California. Shortness of breath over time is due not to the lungs' function, but to the deterioration of muscles and the cardiovascular system from lack of exercise and normal aging.

For people with COPD, however, long-term, irreversible damage to the lungs prevents the body from getting oxygen and translates into huffing and puffing that is all too easily written off as "I'm just out of shape." Most people who have COPD don't get diagnosed until symptoms escalate, usually in their mid-fifties, when they find themselves panting during minor activities, such as climbing a flight of stairs, walking the golf course or even carrying a bag of groceries. By that stage, their lungs may already be in a state of significant disrepair, putting them on the fast track to disability. "When somebody with COPD first comes into my office, it's not

## MIDLIFERS OFTEN MISTAKE SYMPTOMS FOR SIGNS OF AGING, AND CAN LOSE A VITAL OPPORTUNITY TO PREVENT DEBILITATING EFFECTS.

unusual to find that nearly half their lung function has already vanished," says Neil Schachter, M.D., medical director of the respiratory care department of the Mount Sinai Medical Center and author of *Life and Breath*. Chronic cough and phlegm are other missed signs, often predating shortness of breath by a decade, and explained away as an on-going cold or "smoker's cough."

### DAMAGE CONTROL

Still, COPD can be halted, or even prevented. Ask your doctor if you need a simple six-second lung-function test called spirometry (see "Is Spirometry Underused?" on page 116), which will show if you're losing lung capacity faster than normal for your age, height, sex, weight and race. You simply breathe into a mouthpiece attached to a computerized machine that measures airflow volume. If your output is less than 70 percent of what's expected, you may have COPD. (Beginning in the thirties, a half-percent decline in lung function each year for your age, sex, race and weight is considered par for normal aging over a lifetime.) Further tests, such as chest X rays and arterial blood-gas tests, can confirm the diagnosis.

To slow the progress of the disease (or avoid it altogether), the most important thing you can do is stop smoking. "Your lungs don't regenerate, but they do get worse at a much slower rate, and eventually return to the rate at which a non-smoker's lungs deteriorate," says Casaburi. (For quitting how-tos, log on to [www.lungusa.org/tobacco](http://www.lungusa.org/tobacco).)

You should steer clear of secondhand smoke and outdoor pollution when possible. Also, be sure to get a flu shot and ask your doctor if you need a pneumococcal vaccine; anyone with COPD is more susceptible to both illnesses, which can increase the risk of death.

A range of prescription drugs help relieve symptoms and can slow the progress of the disease. Medications include long



and short-acting bronchodilators to widen constricted airways, as well as inhaled steroids to reduce airway inflammation. One of the most promising new drugs, Spiriva, was recently approved by the FDA. It's a long-acting bronchodilator that patients inhale once a day to relieve symptoms and improve exercise performance. The extent to which another medication, tiotropium, alters the underlying inflammatory process of COPD and extends life is currently being addressed in a four-year clinical trial.

Because COPD is progressive, lung function can be expected to worsen over time, but medications help people stay active. For more advanced disease, six to ten weeks of monitored exercise therapy in a pulmonary rehabilitation center may be

recommended to strengthen the heart and muscles and to reduce the stress on the lungs. Exercise routines usually involve a treadmill, StairMaster or stationary bike, combined with a strength-training and flexibility routine. Systemic (pill-form) corticosteroids, such as Prednisone, might be added to the drug regimen as needed to control inflammation as a last resort. Oxygen therapy (wearing a portable oxygen tank) might become necessary; it protects against heart damage, curbs shortness of breath and has been proven to extend life. "My granddaughter calls me 'the oxygen express' because we go to the head of any line," says Roberta Kerekes, an ex-smoker who was diagnosed with COPD at age 54 in 1993.

Lung transplant, or a procedure called lung-volume

**FOR THE SAME AMOUNT OF CIGARETTE SMOKING, WOMEN MAY DEVELOP MORE SEVERE COPD AT AN EARLIER AGE THAN MEN.**

reduction surgery (LVRS) are other possibilities. LVRS excises the worst parts of the lung so healthier areas have more room to expand. The treatment has shown promise in improving day-to-day functioning for some people with advanced emphysema, according to early results from the National Emphysema Treatment and Trial.

Skyrocketing rates of COPD have led to one positive outcome: a new health-

care initiative, called the National Lung Health Education Program, sponsored by an alliance of government agencies and medical professional associations. The program aims to raise awareness about the dangers of COPD among the public, and educate primary care physicians about the need to recognize and screen for the condition—and improve patients' chances of getting diagnosed early, when treatments will be most effective. (For more information, visit [www.nlhep.org](http://www.nlhep.org).) ■

*Sandra Gordon is the coauthor of "The Shy Single" and "Best Baby Products."*

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