

AN INNOVATIVE SURGICAL DM STRATEGY FOR PATIENTS WHO STRUGGLE WITH WEIGHT CONTROL

For various reasons, managed care organizations have been hesitant to cover some treatments for obesity. Early results suggest that the BioEnterics LAP-BAND System can be the centerpiece of an effective disease management program to control obesity.

By Rhonda Greenapple, MSPH, and Annamaria Profit

The U.S. Food and Drug Administration last year approved INAMED Health's BioEnterics LAP-BAND Adjustable Gastric Banding System¹, thus introducing a powerful surgical tool for weight loss. The LAP-BAND System, which provides a unique adjustable component to restrictive bariatric-surgery options, has been shown to reduce complication rates, hospital stays, and the costs of traditional restrictive surgical options for obesity (BioEnterics 2001).

When coupled with a comprehensive patient-assessment and obesity-management program, the LAP-BAND System gives managed care medical directors a viable, cost-effective choice for combating obesity and related comorbidities among their members. It also provides an alternative to coverage of cumbersome restrictive procedures and more-costly malabsorptive open surgical options.

¹Lap-Band is a registered trademark of BioEnterics Corp.

Prevalence and implications

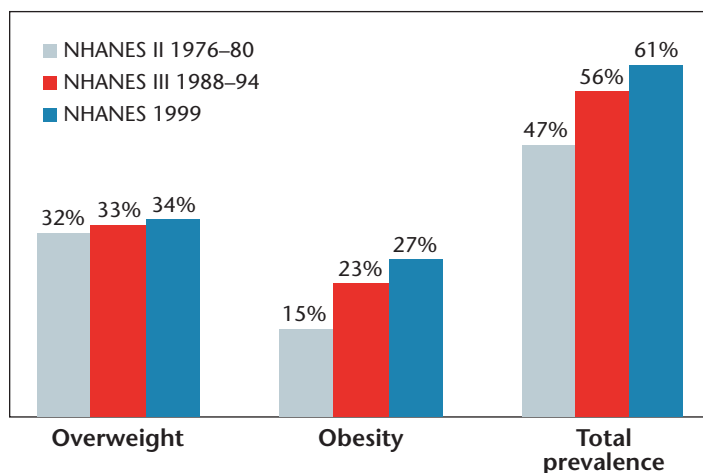
Obesity and the comorbidities associated with it have become global health crises. In the United States, according to the most current National Health and Nutrition Survey (NHANES 1999), 61 percent of adults are either overweight or obese (James 2001). That's up from 56 percent in NHANES III (1988–94) and 47 percent in NHANES II (1976–80). Nationally, the rate of obesity (body mass index of 30 kg/m² or greater) escalated from 15 percent in NHANES II to 27 percent in NHANES 1999 (Figure 1). According to current estimates, those percentages will continue to escalate as Americans age, adding to the nearly \$100 billion combined direct and indirect economic burden that obesity imposes (Table 1).

The Center for Disease Control's National Center for Chronic Disease Prevention and Health Promotion estimates that direct and indirect costs associated with overweight and obesity in the United States in 2000 totaled \$117 billion (CDC 2002a). By 2030, \$300–\$400 billion per year will be spent in the United States to cover the health care needs of the aging baby boomer population (CDC 1999). A significant portion of those costs will be related to obesity and its comorbidities.

In a Kaiser Permanente retrospective cohort study of costs associated with overweight and obesity, researchers found that health care cost ratios escalated appreciably as BMI rates increased (Table 2).

Despite the high costs associated with overweight and obesity in the U.S., nonsurgical medical management has failed. While numerous studies and National Heart, Lung, and Blood Institute guidelines promote the advantages of diet, exercise, prescription drugs, behavioral therapy, and physician monitoring for compliance in achieving and maintaining ideal weight ranges (Freedman 2001, NHLBI 1998), the rapidly escalating incidence and prevalence of overweight and obesity reflects the failure of these approaches. Motivated patients who pur-

FIGURE 1 Escalating prevalence of overweight and obesity in the United States, 1976–99



SOURCE: NCHS 1999

TABLE 1 Costs related to obesity and related comorbidities (billions)

	Direct costs	Indirect costs	Total costs by category (1995)
Overweight and obesity	\$51.6	\$47.6	\$99.2
Heart disease	\$7.0	(not available)	\$40.4
Type 2 diabetes	\$32.4	\$30.7	\$63.1
Osteoporosis	\$4.3	\$12.9	\$17.2
Hypertension	\$3.2	(not available)	(not available)
Cancer: breast	\$0.8	\$1.5	\$2.3
Cancer: endometrial	\$0.3	\$0.5	\$0.8
Cancer: colon	\$1.0	\$1.8	\$2.8

SOURCE: NIDDK 2000

sue comprehensive weight-loss programs, in accordance with NHLBI guidelines and coupled with a physician's direction, can expect to lose 5 to 10 percent of preintervention body weight over a six-month period. The overwhelming majority, however, will regain more than 100 percent of lost weight (Yanovski 2002, CDC 2002b).

Coverage of these disease management approaches as part of a total health-and-fitness program, while laudable, does not address escalating health care costs for those who are obese and suffer from comorbidities that ravage a body whose vital systems are challenged by the problems associated with age and obesity. These patients need aggressive weight-loss strategies that are specifically targeted to the chronic burdens associated with obesity, as well as coverage of those strategies to help them achieve and maintain weight-loss goals.

Evolution to bariatric surgery

The BioEnterics LAP-BAND Adjustable Gastric Banding System introduces a new generation of technical and surgical innovation to a specialty that is relatively young. According to a report by Winifred S. Hayes (Hayes Report), surgical procedures for obesity have been developed over the last 30 years to promote aggressive weight loss and to reduce morbidity in patients with a BMI ≥ 40 kg/m². The procedures most commonly used can be divided into two categories: restrictive (limiting the amount of food that can be eaten at one time) and malabsorptive (reducing the amount of food that can be absorbed at one time). First-generation surgeries consisted of open malabsorption procedures, such as the jejunocolic and jejunoileal bypasses. However, these procedures required precise surgical techniques, and were subject to potentially life-threatening complications. The second-generation gastric bypass, biliopancreatic diversion with/without duodenal switch

TABLE 2 Correlation between BMI and health care costs

BMI	≥ 25.0 – 29.9 (N=474) ratio:1 (range)	≥ 30 (N=367) ratio:1 (range)
Prescription drugs	1.37 (1.12–1.66)	2.05 (1.62–2.55)
Outpatient services	0.96 (0.83–1.13)	1.14 (0.97–1.37)
Inpatient care	1.20 (0.81–1.86)	1.38 (0.91–2.14)
All medical care	1.10 (0.91–1.35)	1.36 (1.11–1.68)

Based on costs for a normal sample (N=545, BMI ≥ 20.0 to ≥ 29.9) with average health care costs of \$1,631 per year. Ratios are based on weighted mean annualized utilization/costs relative to subjects with a BMI of 20 to 24.9 kg/m². All measures weighted by number of months follow-up.

SOURCE: Thompson 2001

(BPD/DS), evolved as an attempt to deliver the benefits of the bypass procedure without the risks of the earlier procedure, but the infection and complication rates associated with open procedures persisted (Hayes 2001).

Less-invasive and restrictive procedures came next, and were intended to induce weight loss without the significant side effects and complications of malabsorption and other bypass procedures while maintaining normal gastric function. The first-generation restrictive procedure, horizontal banded gastroplasty, was an open procedure that stapled the end of the stomach, creating a horizontal gastric pouch that limited food intake. Poor outcomes with this procedure led to a change to another open procedure — vertical banded gastroplasty (VBG), which uses the thicker muscles of the lesser curvature and avoided the fundal region. This procedure became the second-generation restrictive surgery. However, complication rates, persistent gastrointestinal side effects, inconsistent outcomes, and high reoperation rates led to clinical dissatisfaction with VBG over the next two decades, and resulted in three other developments in gastric bariatric surgery.

The Roux-en-Y gastric bypass, developed in

the wake of unsatisfactory VBG outcomes, combines restrictive and malabsorptive techniques, and is currently the most common bypass procedure. Laparoscopic surgery, introduced as a solution to high complication rates of open surgery, proliferated with laparoscopic versions of the earlier procedures and the development of the laparoscopic adjustable gastric banding procedure (Nilsell 2001, Balsiger 2000).

LAP-BAND clinical experience in the U.S.

The BioEnterics LAP-BAND Adjustable Gastric Banding System has been the gold standard in Europe and Australia since 1993, but was approved in the U.S. only in June 2001.

The LAP-BAND System has been finding a niche in the bariatric surgery community. This has occurred slowly, in part due to INAMED Health's policy to restrict use of the LAP-BAND System to U.S. bariatric surgeons who have met strict training and proctorship criteria² and who have the laparoscopic surgical experience recommended by the American Society of Bariatric Surgeons (SAGES/ASBS 2000) — a level comparable to successful European and Australian LAP-BAND surgeons.

Criteria for use of the LAP-BAND System in a surgical practice include:

- Advanced laparoscopic skills and experience, ability to suture laparoscopically, and completion of at least 25 laparoscopic Nissen fundoplication procedures
- Completion of at least 25 bariatric procedures or completion of a comprehensive bariatric-surgery course detailing issues of patient selection, procedural options, perioperative care, and long-term management, such as provided by the American Society for Bariatric Surgery
- Commitment and ability to make the LAP-BAND System a significant component of a multidisciplinary bariatric practice that includes long-term support and follow-up
- A comprehensive bariatric patient-support program that includes access to appropriate hospital facilities, nutrition and exercise counseling, and psychological, general medicine and radiological support personnel
- Commitment and ability to perform at least 25 LAP-BAND System procedures each year

² BioEnterics Training/Workshops: Available at: <http://www.bioenterics.com/us/surgeon/lapband/training/index.html>.

- Willingness and ability to be proctored for initial procedures by surgeons experienced in the placement and use of the LAP-BAND System
- Willingness and ability to have inservices for operating-room staff by trained product specialists.

This commitment to standards of excellence in bariatric practice; extensive training; and strict adherence to a comprehensive program involving patient selection, assessment, perioperative and follow-up care, and long-term patient support, have led to success for surgical practices that follow the INAMED Health and ASBS guidelines for LAP-BAND System implantations.

Physician-practice profiles

Christine Ren, MD, director of New York University's Program for Weight Loss Surgery <http://www.thinforlife.org> and assistant professor in NYU's department of surgery, successfully integrated the LAP-BAND System into her practice, which, on the elective side, is 100 percent bariatric and 98 percent laparoscopic.

Ren now incorporates the LAP-BAND System into comprehensive weight-loss programs with about 60 percent of her patients. Her patients (70 percent female and mostly between 30 and 45 years old), have an average BMI ranging from ≥ 38 to ≥ 45 kg/m² and have tried formal and informal diet programs, fad diets, over-the-counter products, and other weight-loss options. Thirty to forty percent have been through medical weight-loss programs, including prescription drugs. All have failed either to lose weight or to keep it off for a significant length of time, and all have regained the weight and added more.

Patients are referred to Ren by their friends or primary care physicians, or find her through an Internet search. "Rarely do internists or endocrinologists refer patients for surgical treatment of obesity, because they don't see it as a viable or safe option," says Ren, "despite the fact that I treat their patients every day."

Ren's patients present with major medical comorbidities that affect all nine major organ systems. They also experience significant emotional symptoms related to the social and psychological stigma of obesity. These comorbidities and patients' fundamental quality of life are demonstratively improved after surgery.



CHRISTINE REN, MD: *"Most patients are going to do very well with restrictive surgery, and the safest method is the LAP-BAND."*

In her practice, Ren, a diplomate of the American Board of Surgery and of the National Board of Medical Examiners, performs four types of bariatric surgery. Two are restrictive procedures: gastric bypass and surgery with the LAP-BAND System. Two are malabsorptive procedures: biliopancreatic diversion with/without duodenal switch. The procedure that is appropriate for each patient depends on the answers to two questions: What is the patient's goal in having surgery? What is the cost to the patient, in terms of risks and benefits?

Ren advocates "the safest and most effective procedure for each patient. However, most patients are going to do very well with restrictive surgery, and the safest method is the LAP-BAND," she says. Her patients average a 47-percent excess weight loss (EWL) at one year.

"The VBG is antiquated, has zero benefit over the LAP-BAND, and because of the inability to adjust the band to accommodate clinical symptoms, the long-term success is very low," says Ren.

Whichever procedure is appropriate in an individual case, a patient's interest is Ren's first consideration. The patient must be an active participant in the bariatric treatment, or it will not work. Ren sees herself as a coach, providing specific information based on her experience, surgical options, and the patient's preferences, then allowing the patient to choose a specific procedure.

There are limitations that go with choice, however. For example, patients who enjoy high-calorie liquids and sweets are not good LAP-BAND candidates; their food choices defeat the LAP-BAND's restrictive function.

The most critical element of the surgical weight-loss program, Ren emphasizes, is frequent patient follow-up during the first year. She insists that patients adhere to a strict follow-up schedule, and she calls them to encourage them to keep follow-up appointments. She sees patients six weeks after surgery, then at regular intervals — usually once a month during the first year. Then she will see them every two to three months during the second year, and annually thereafter.

This frequent follow-up by the surgeon, especially during the first year, is critical to successful outcomes, and has been one of the factors in the success of the LAP-BAND in European and Australian practices. Ren worries that American surgeons, who generally relegate their post-

operative patients to primary care practitioners, will not meet the challenges of meeting ASBS and NHLBI long-term follow-up guidelines.

Jeffery W. Allen, MD, of the University of Louisville School of Medicine's Center for Advanced Surgical Technologies and a partner in University Surgical Associates, is another LAP-BAND advocate. His practice, whose professional staff includes a nutritionist, program coordinator, psychologist, and program support, is based at Norton Hospital in a seven-hospital network and features state-of-the-art diagnostic equipment.

Allen has a diverse patient population — mostly female (75 percent), mostly white, but also black, Asian, Indian, and others. The majority are adults in their 40s, but successful bariatric patients have been as old as 67. Weight-loss outcomes with the LAP-BAND System at nine months average 44 percent EWL. Much of this

success is due to a rigorous follow-up program, which starts two weeks after surgery. Four weeks after this first follow-up visit, patients return for band adjustments, which are conducted four times in the first year and more frequently if needed. At a minimum, patients are seen six times in the first year, then annually. They also attend a monthly support group.

Using a checklist designed for the assessment process, patients report having tried an average of seven acceptable weight-loss programs before opting for surgery. Presenting comorbidities commonly include sleep apnea, diabetes, hypertension, arthritis, and low-back and joint pain from the skeletal load associated with obesity. Postoperatively, patients report significant improvement in quality of life. Allen's practice has studied the resolution of low-back pain in LAP-BAND System patients and found that 90 percent of patients with severe back pain had significant improvement after nine months.

Allen, who is certified by the American Board of Surgery, offers four surgical options, including VBG and the LAP-BAND System — which he views as similar, with the important exception of the adjustability of the LAP-BAND System. VBG outcomes are less attractive; while weight loss is comparable to the LAP-BAND System at three to six months, VBG weight loss slows considerably afterward because the pouch expands and there is no way to adjust the band to accommodate these changes. Other operations Allen performs include the Roux-en-Y gastric bypass and BPD/DS.

According to Allen, the VBG is falling out of



JEFFERY W. ALLEN, MD: *"In its time, the VBG was good, but now we have something better."*

favor with clinicians because of its high reoperation and failure rates. "In its time, the VBG was good, but now we have something better," he says. "If insurers covered the VBG, they should cover the LAP-BAND System. It's less expensive, hospital stays are shorter, patients return to normal activity faster, and outcomes are better."

In addition, the LAP-BAND System is adjustable, so that if a woman who has had surgery becomes pregnant, the band — which is tightened or loosened by adding or removing saline — can be temporarily emptied to accommodate her increased nutritional needs.

Jaime Ponce, MD, FACS, first encountered the LAP-BAND System in Mexico, at the Medical University in Monterrey, where he was an associate professor. Ponce, who is certified by the American Board of Surgery, has a general and bariatric surgery practice in the Dalton Surgical Group and the Hamilton Surgical Weight Management Center «<http://www.hamiltonhealth.com/weight/staff.asp>» in Dalton, Ga.

To Ponce, the unique benefit of the LAP-BAND System is the adjustable band, which allows the surgeon to customize the diameter of the band to accommodate an individual patient's diet. The band can be altered over time to produce satiety as the size of the pouch and the patient's body changes with weight loss. Because satiety — or lack of it — drives most patients' feelings of hunger, adjusting the band allows the surgeon to control the degree and regularity of the patient's hunger pangs, and helps the patient extend the initial effects of the restriction procedure over a long period.

Ponce's surgical practice is about 50 percent bariatric. His patients are about 90 percent female, with an average age in the 40s (patients range from 18 to 62), white, and with income levels that can support private payment of the LAP-BAND System procedure — often a necessity, in that health insurers have been slow to cover the procedure.

Comorbidities in his patients cover a range of age- and obesity-related diseases. About 20 percent are diabetic. Most have tried weight-loss programs — including medical weight-loss therapy, over-the-counter drugs, and commercial programs — for five years or longer, to no avail. Whatever weight-loss successes they have had eventually have been reversed.

Preoperative BMIs for Ponce's patients average 47–48 kg/m², but some patients have regis-

tered BMIs as high as 74kg/m². The focused patient population, intensive follow-up program, and surgical advantages of the LAP-BAND System have produced significant results, which Ponce is about to publish. Of 250 procedures that Ponce has conducted, outcomes for the LAP-BAND System are impressive: complication rates near zero, no deaths, no erosions, three port-connection ruptures, one readmission for edema of the stoma, and one open procedure. The post-operative BMIs demonstrate an average 60 percent EWL at 18 months.

Ponce suggests that the obesity epidemic — and the comorbidities that come with it — will continue unabated unless the health care system's treatment policies change.

"Trends will escalate and candidates for

bariatric surgery will multiply. Health care institutions should be willing to dedicate resources to treating these difficult and challenging patients, who incur a majority of the medical costs and use a significant percentage of health care resources," he says. "Institutions should invest in programs that reduce or eliminate obesity and its comorbidities."

Ponce also believes that over the long term, health insurers could reap savings on treatment of obesity-related conditions if they gave serious consideration to coverage of what he calls "the only obesity treatment option that really works."

Legal issues of surgery

Walter Lindstrom Jr., Esq., founder of the Obesity Law & Advocacy Center, in San Diego, is an experienced insurance lawyer and gastric bypass patient whose first obesity case was an appeal for his own surgery. The center «<http://www.obesitylaw.com>» has resolved hundreds of appeals and grievances on behalf of patients seeking medical and surgical treatment for morbid obesity, and has litigated employment discrimination related to obesity in various states.

According to Lindstrom, the principal legal issues regarding obesity and/or bariatric surgery are coverage (including the nature and extent of coverage), amount of reasonable reimbursement, exclusions to coverage for specific procedures, and determination of medical necessity. The center works with governmental and bariatric organizations to demonstrate to insurers that covering bariatric surgery is not only good medicine, but good business.



JAIME PONCE, MD:

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To Lindstrom, the key to gaining universal coverage for bariatric procedures involves a strategy of educating payers about the health benefits, positive clinical outcomes, and short- and long-term cost savings associated with them, as well as the specialized practitioner skills necessary to establish an effective bariatric program.

Lindstrom, a regular member of the faculty for the American Society for Bariatric Surgery (ASBS) Essentials courses, sees insurers responding favorably to positive outcomes.

"Insurance companies are becoming more sophisticated about providers who render these treatments. It is not unreasonable for payers to limit coverage to expert physicians who do more procedures, where outcomes are better for the bariatric population at large. Good medicine, ultimately, should govern appropriate access to treatment.

"Insurance companies," he continues, "will continue to recognize the efficacy of the treatment, but will also realize that surgeons who perform occasional bariatric procedures will have neither the experience nor the level of positive outcomes that bariatric surgeons, who are specialized, will have. Using the example of heart transplants, you're not going to have a transplant just anywhere — you're going to go to a hospital that specializes in heart transplants."

Developing a strategy

It is critically important for health insurers and managed care companies to understand the emerging obesity pandemic and related comorbidities, then choose effective solutions. The BioEnterics LAP-BAND Adjustable Gastric Banding System is a demonstrable improvement from earlier surgical techniques to control obesity. When incorporated as part of a multifaceted disease management and behavior modification program, the procedure is an important step in helping patients improve quality of life by reducing obesity-related comorbidities.

As managed care organizations recognize that the big-dollar expenses in the future will be not in acute illness but chronic illness, many are embracing evidence-based care as the standard for treatment of chronic conditions. In the past, MCOs have been hesitant to cover obesity-management programs and surgery, in part because of poor success rates. Early clinical outcomes for the LAP-BAND System appear promising — an encouraging sign for potential positive downstream financial outcomes resulting from reduced morbidity and mortality.

References

- Balsiger BM, Poggio JL, Mai J, et al. Ten and more years after vertical banded gastroplasty as primary operation for morbid obesity. *J Gastrointest Surg.* 2000;4:598–605.
- BioEnterics Corporation. A Surgical Aid in the Treatment of Morbid Obesity: LAP-BAND Adjustable Banding System Information for Patients. Available at: http://www.rsapc1.com/laparoscopic_surgery/lap_banding_system.pdf. Accessed Aug. 5, 2002.
- CDC (U.S. Centers for Disease Control). Preventing the diseases of aging. *Chronic Disease Notes and Reports.* 1999;12:1–2.
- CDC. Physical Activity and Good Nutrition: Essential Elements To Prevent Chronic Diseases and Obesity at a Glance 2002 (2002b). Available at: <http://www.cdc.gov/nccdphp/dnpa/dnpaaag.htm>. Accessed Aug. 5, 2002.
- CDC. The Burden of Chronic Diseases and Their Risk Factors 2002 (2002a). Available at: http://www.cdc.gov/nccdphp/burdenbook2002/Burden_Book_2000.pdf. Accessed Aug. 5, 2002.
- Freedman MR, King J, Kennedy E. Popular diets: a scientific review. *Obesity Research.* 2001;9(suppl 1):15–40S.
- Hayes Medical Technology Directory Report: Laparoscopic Bariatric Surgery. Lansdale, Pa.:Winifred S. Hayes Inc. 2001(Oct):1–7.
- James PT, Leach R, Kalamara E, et al. The worldwide obesity epidemic. *Obesity Research.* 2001;9(suppl 4):228S.
- NCHS (National Center for Health Statistics). Prevalence of Overweight and Obesity Among Adults: United States 1999;table 2:2. Available at: <http://www.cdc.gov/nchs/products/pubs/pubd/hestats/obese/obse99.htm>. Accessed Aug. 5, 2002.
- NHLBI (National Heart, Lung, and Blood Institute). Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: Executive Summary. 1998:x.
- NIDDK (National Institute of Diabetes and Digestive and Kidney Diseases). Statistics Related to Overweight and Obesity. 2000. Available at: <http://www.niddk.nih.gov/health/nutrit/pubs/statobes.htm>. Accessed Aug. 5, 2002.
- Nilsell K, Thorne A, Sjostedt S, et al. Prospective randomized comparison of adjustable gastric banding and vertical banded gastroplasty for morbid obesity. *Eur J Surg.* 2001;167(7):504–509.
- SAGES/ASBS (Society of American Gastrointestinal Endoscopic Surgeons/American Society for Bariatric Surgery). SAGES Guidelines for Laparoscopic and Conventional Surgical Treatment of Morbid Obesity. Publication #30. 2000. Available at: http://www.endoscopy-sages.com/sg_pub30.html. Accessed Aug. 5, 2002.
- Thompson D, Brown JB, Nichols GA, et al. Body mass index and future health care costs: a retrospective cohort study. *Obesity Research.* 2001;9:210.
- Yanovski SZ, Yanovski JA. Obesity. *NEJM.* 2002;346:591–602.

For more information about the LAP-BAND System, call 877-LAP-BAND, Option 3, or visit <http://www.inamed.com>.