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BAND PERSPECTIVE

Positive Trends in the US Gastric Band Device Market Despite the Economic Downturn

by Heather Paterson, BSc;
and Kamran Zamanian, PhD



INTRODUCTION

Obesity is considered a prevalent and growing disease both in the US and globally by multiple leading health organizations, such as the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC). According to the CDC, over the past 20 years there has been a considerable increase in the incidence of obesity in the US. In 2007, over 65 percent of US states had rates of obesity between 25 and 30 percent, and not a single state had levels less than 18 percent.¹

The use of the adjustable gastric band (AGB) to treat obesity in

the US is showing a very healthy increase. Current devices are made of inert materials such as silicone and are implanted around the proximal stomach to decrease food intake. The mechanism of action is not completely understood, but "satiety," rather than "restriction," seems to be a common theme among successful patients. These devices are used to treat the disease of morbid obesity, with the goal of ameliorating medical comorbid conditions and prevention of obesity related diseases. As the US continues to struggle with rapidly increasing obesity rates, the AGB market will increase through 2015.²

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SURGICAL PERSPECTIVE

Bariatric Surgery in Patients with Liver Cirrhosis and Portal Hypertension

by Juan Camilo Barreto, MD;
Michael G. Sarr, MD;
and James M. Swain, MD

THE PROBLEM

Cirrhosis is an unexpected finding at the time of bariatric surgery in about 1 to 2 percent of the patients undergoing elective bariatric surgery. The surgeon is then suddenly faced with several questions that may be difficult to address at the moment of a planned bariatric operation, with the patient already under general anesthesia. Would it be appropriate to continue with the planned elective bariatric procedure? Is it necessary to consider a different alternative, and if so, which one? Is portal hypertension present and, if so, is it an absolute contraindication to proceed?

A different situation occurs when a patient with known hepatic cirrhosis presents for consideration for bariatric surgery. What type of workup is required? At what point would a bariatric procedure be contraindicated? What about the patient with morbid obesity who is being evaluated for a liver transplant?

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EXERCISE PERSPECTIVE



Promoting a Physically Active Lifestyle in Bariatric Patients

by Carol Ewing Garber, PhD, FAHA, FACSM

INTRODUCTION

It is clear that a physically active lifestyle is important for good health and promoting and maintaining weight loss.¹⁻⁴ Following bariatric surgery, patients who are physically active lose more weight,⁵⁻⁷ and greater weight loss is associated with improved quality of life,⁵ reduced all-cause mortality, and mortality due to cancer, diabetes, and cardiovascular disease, with the greatest impact on mortality due to the reduction in cancer deaths.⁸ Exercise volumes of at least 1,000 to 1,200kcal per week (approximately 150 minutes per week) are ideal for most adults to attain the

majority of substantial health and fitness benefits of exercise, but as much as 1,800 to 2,200kcal per week (>250 minutes per week) in purposeful exercise and physical activity may be needed to promote and maintain weight loss, especially among persons who spend much of their time in sedentary pursuits.^{1,2,4}

There are many benefits of regular physical activity beyond weight loss that are particularly important to patients being treated with bariatric surgery, and that make physical activity a vital complementary health measure for these patients.

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LATIN AMERICAN SURGEONS: IT'S TIME TO BE RECOGNIZED p7

Positive Trends in the US Gastric Band Device Market Despite the Economic Downturn

by Heather Paterson, BSc; and Kamran Zamanian, PhD

Ms. Paterson is Research Analyst, and Dr. Zamanian is head of Research, iData Research Inc.



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MARKET CONDITIONS AND FORECAST

In 2008, the US market for AGB was valued at over \$300 million, which is a 27.5-percent increase over the previous year.³ Market growth has been driven by several factors, including increased awareness of the procedure, insurance coverage, consumer marketing, bariatric centers, and the perception by the general public that it is safer and easier to reverse than a traditional gastric bypass. The US gastric band market was serviced solely by Allergan until late 2007, when Ethicon entered the market after

acquiring the Swedish Adjustable Gastric Band and rebranding it the Realize™ Band. Likewise, the original LAP-BAND® has changed ownership several times. Competition and global market forces are expected to create a downward price shift, further driving patient interest. As long-term results become known with respect to safety and efficacy, the gastric band device market is estimated to grow at double-digit rates, more than tripling in value by 2015.⁴

ALTERNATIVE PROCEDURES

Although growth of gastric banding for obesity intervention is very steady, alternative methods can impact this market. These methods

include gastric bypass procedure (GBP), vertical sleeve gastrectomy (VSG), and future endoluminal therapies.

The VSG is possibly the most important competitor to the AGB because of its simplicity and short learning curve compared with more complex operations. The VSG involves removal of up to 90 percent of the existing stomach, creating a long cylindrical stomach, which does not require rerouting of the food as in the gastric bypass. In addition, there is no foreign body or need for adjustments as in the AGB. However, long-term results are still lacking with only a few studies longer than five years. The short-term results

seem to trend to improved weight loss and fewer reoperations than the AGB. Eliminating the need for postoperative adjustments and the potential for increased performance makes the VSG an interesting alternative to the AGB and GBP, yet the perioperative risks are higher than the AGB and it is not reversible. Insurance coverage is limited for the VSG at this time.

The gastric bypass remains the procedure of choice for a large number of patients because of its efficacy, safety, and applicability for most patients. More complicated than either the AGB or VSG, the GBP involves partitioning the stomach to divert food through a conduit. The

As long-term results become known with respect to safety and efficacy, the gastric band device market is estimated to grow **AT DOUBLE-DIGIT RATES, MORE THAN TRIPLING IN VALUE BY 2015.⁴**

majority of the existing stomach and proximal intestine is bypassed so food is diverted to the small bowel through the Roux limb. The mechanism by which the GBP induces reduced calorie intake and immediate metabolic effects is still debated, but likely due to the complex interaction of incretins on both the end organs and central satiety centers. Long-term consequences of the GBP include nutritional malabsorption, weight regain, dumping syndrome, and ulceration, among others. **(Reference?)** Despite these issues, the GBP remains the standard by which all other operations are judged.

Endoluminal procedures are the least invasive and most experimental alternatives at this time. Given the growing problem of the obesity epidemic, it is hopeful that some of these procedures will find practical application.

PATIENT SUPPORT DRIVES SUCCESS

Patient support, primarily postoperatively, is a driver for the gastric band device market. After the stomach has completely healed, the band is adjusted, usually at 4 to 6 week intervals until early satiety after a meal is achieved. Although the device is customizable to each patient, it still requires each patient to commit to a process that includes modification of their previous diet and lifestyle.

Due to the importance of patient support, manufacturers aim to extend themselves beyond the operating room through interactive websites such as Ethicon's Realize mySuccess™. The websites are designed to assist the patient, acting as a long-term management and support system to achieve a healthy lifestyle. They are developed by both healthcare professionals and past patients to provide current users with planning, progress, nutrition, and fitness tracking. Each section contains comprehensive information to help develop and plan nutrition and exercise plans. The site acts to help patients through the gastric banding process, and even suggests physician visits where deemed necessary.

SINGLE PORT SURGERY TO DRIVE GROWTH

The AGB is designed to be implanted with minimally invasive techniques that may require using 5 to 6 small incisions. Although visibly small once healed, patients believe that fewer incisions impart less invasiveness and postoperative pain and are more cosmetically pleasing. Techniques have been developed to place the band with a single incision, yet they have yet to be proven as safe and efficient as current practice.

If the AGB can be placed with less pain and less visible scarring, the procedure will be more attractive to many patients and can help generate more volume in the future.

EXPANDING DEMOGRAPHIC FOR GASTRIC BAND SURGERY

As the safety profile for bariatric surgery, including AGB, continues to improve, the risk/benefit ratio has called into question the traditional National Institutes of Health (NIH) guidelines published almost 20 years ago. In conjunction with long-term comparative studies demonstrating the superiority of surgical interventions over conventional medical therapy with respect to disease-related mortality, and a significant reduction in actual operative mortality, surgical procedures should be offered to individuals beyond the original NIH recommendations. This demographic includes both adolescents (age less than 18 years) and those who have body mass indices (BMI) less than 35kg/m².

As of December 2008, Allergan began a study using LAP-BAND® in adolescents ages 14 to 17. Research is also being conducted on patients with lower BMIs, between 30 and 40kg/m². Data submission to the FDA for both studies is expected to occur before 2011.⁶

STRATEGIC ALLIANCE ENHANCES MARKET PRESENCE

The acquisition of the Swedish Adjustable Gastric Band by Ethicon Endosurgery and the rebranding of the product as the Realize™ Band has increased competition in the band market. Direct to customer marketing and the strategic alliance between Allergan and Covidien have been effective in providing increased public awareness and support for the training of AGB surgeons. Interestingly, both Ethicon and Covidien also market different procedures, the GBP and VSG, which can impact further growth in the AGB market.

OBESITY TO INCREASE STEADILY THROUGH 2015

Obesity rates are increasing across the US, leading this condition to be widely accepted as an epidemic. An estimated 18 million Americans were classified as being morbidly obese in 2008.⁷ Morbid obesity is defined as having a BMI of 40 or more, or at least 35 in conjunction with a weight-related disease, such as asthma, hypertension, or type 2 diabetes.

The number of obese Americans could reach over 25 million by 2015.⁸ This will be a strong driver for bariatric surgery, especially minimally invasive surgery such as the AGB that can be performed in a cost-efficient manner with long-term

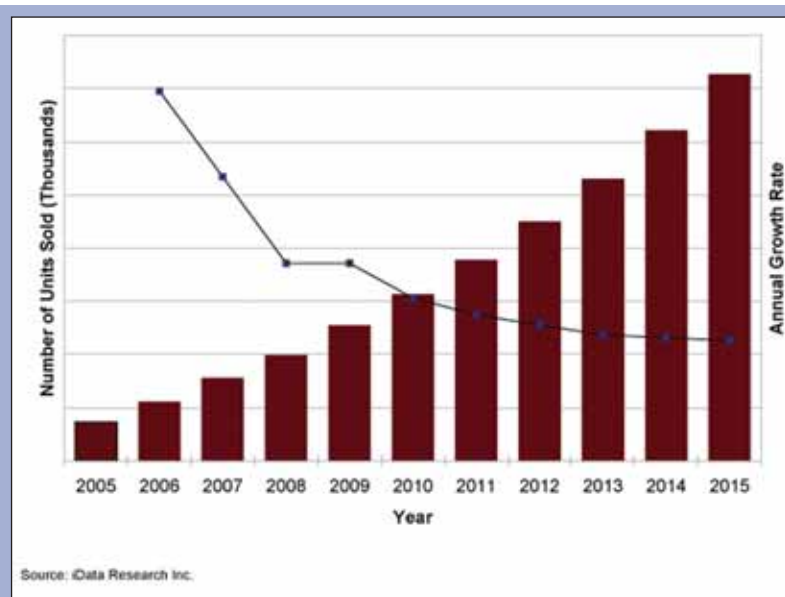


FIGURE 1. Number of gastric bands sold in US, 2005–2015. Adapted from US Market for Laparoscopic Devices. Vancouver, British Columbia: iData Research Inc. May 2009.

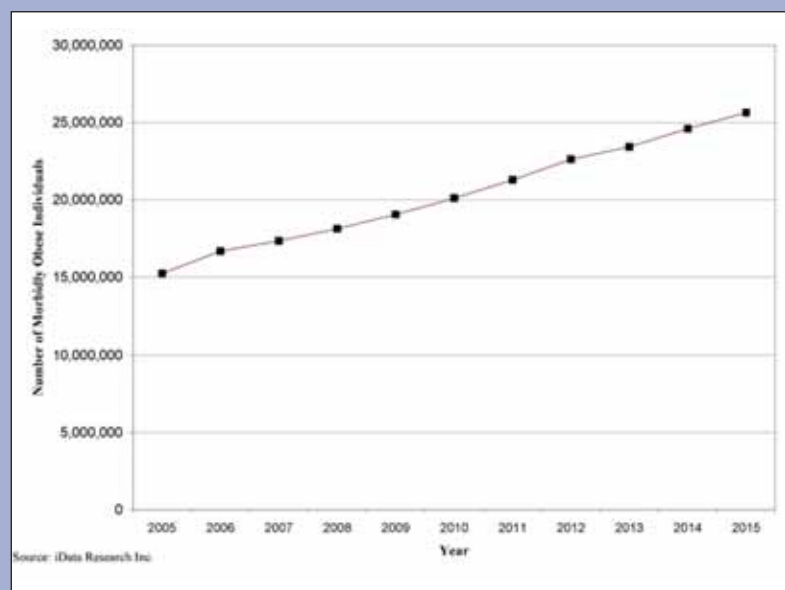


FIGURE 2. Growth of morbid obesity in the US, 2005–2015. Adapted from US Market for Laparoscopic Devices. Vancouver, British Columbia: iData Research Inc. May 2009.

results. Lack of nonsurgical therapies with acceptable performance compared to bariatric surgery also supports growth for all procedures, rather than a simple zero-sum shift from one procedure to another. **(AUT: OK AS EDITED?)**

GROWTH ESTIMATED DESPITE GLOBAL ECONOMIC CRISIS

The global economic crisis beginning in 2008 has decreased the demand for gastric band devices, especially due to their elective nature. Despite the economic downturn, the gastric band market is still expected to show double-digit growth, as patient health concerns override the financial constraints. **(Reference?)**

ALLERGAN AND ETHICON CONTROL THE BAND MARKET

In 2008, Allergan was the leader in the gastric band market with their LAP-BAND® product. Innovation has been a strong driver for Allergan with the 2007 release of the LAP-BAND AP®, an advanced model that accommodates the severely obese.

The same year, Allergan acquired EndoArt SA, which pioneered a remote-controlled gastric band: the EasyBand™. It is predicted that this type of gastric banding will affect future trends in the US bariatric surgery market pending approval. Allergan has also expanded their reach in sales and marketing through the aforementioned alliance with Covidien for education and training for their LAP-BAND® product.

An emerging competitor in 2008 was Ethicon, which managed to achieve double-digit share in a formerly monopolized market. The REALIZE™ Band has shown strong growth, especially through the company's pioneering of online bariatric support through their website, Realize mySuccess™. While Allergan's LAP-BAND® and Ethicon's REALIZE™ Band function similarly, Ethicon was the first to focus on extensive patient support. As described in further detail already, this online assistance proved to be a competitive factor for a company relatively new to the market—so much so that Allergan currently has

THE VSG IS POSSIBLY THE MOST IMPORTANT COMPETITOR to the AGB because of its simplicity and short learning curve compared with more complex operations.

a similar site under development.

In terms of brand selection, it is unclear what the role of patient and surgeon preference will have as opposed to the traditional hospital-centric focus based on cost and existing buying agreements. The presence of more than one band company will likely be beneficial in terms of more competitive pricing structures and innovative developments.

CONCLUSION

Gastric banding is a critical component of the US market for laparoscopic devices. In 2008, it was the fastest growing segment in the US laparoscopic device market, and over 40 percent of bariatric surgical procedures involved gastric banding.⁹ In 2008, gastric bands

represented almost 12 percent of the multi-billion dollar market for medical devices involved in laparoscopy. **(AUT: Is this your conclusion? If so, adding a couple of general recap sentences summing things up would be beneficial here.)**

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DISCLOSURES

The information in this article is taken from a detailed and comprehensive report, *US Market for Laparoscopic Devices 2009*, which is available for purchase from iData Research Inc. Heather Paterson, BSc, is with iData Research Inc. She has disclosed that she holds no interest or securities in any company mentioned herein.

Kamran Zamanian, PhD, is with iData Research Inc. He has disclosed that he holds no interest or securities in any company mentioned herein. For more information about this and other reports on the endoscope industry, please call toll-free: (866) 964-3282, info@idataresearch.net, or visit their website at www.idataresearch.net. iData Research is an international market research and consulting group focused on providing market intelligence for the medical device, dental, and pharmaceutical industries. ■

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