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US experience with the LAP-BAND system

Christine J Ren M.D. [a], Santiago Horgan M.D. [b], Jaime Ponce M.D. [c]

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Abstract

Laparoscopic adjustable gastric banding is the most commonly performed operation for morbid obesity in Europe and Australia and has been shown to result in significant long-term weight loss. The US Food and Drug Administration (FDA)–monitored clinical trial results with the LAP-BAND system (INAMED Health, Santa Barbara, CA) did not reproduce the results of studies performed elsewhere in the world. This article reviews data from the first and second FDA clinical trials as well as data from continuing US clinical experience. Four American surgeons at 4 centers have performed more than 500 LAP-BAND procedures not included in the first 2 FDA clinical trials. Of these patients, 115 have been followed for at least 9 months, and 43 have been followed for at least 12 months. A retrospective analysis of prospective data gathered from these patients is presented. The percent excess weight loss was 35.6% at 9 months and 41.6% at 12 months. The average body mass index decreased from 47.5 to 38.8 in 9 months and from 47.5 to 37.3 in 12 months. There were no deaths related to the insertion of the device. Of 15 complications requiring operative management (13%) in 12 patients, there were 8 port displacements or tubing breaks (7%), 2 elective explantations (2%), 2 cases of gastric prolapse (2%), 1 gastric pouch dilatation (<1%), 1 port abscess (<1%), and 1 hemorrhage (<1%). Clinical experience with the LAP-BAND system in the United States shows the device to be a safe and effective treatment for morbid obesity, with results comparable to the international data. The combination of proper surgical technique and close patient follow-up with frequent band adjustments, performed in a comprehensive bariatric program setting, may make the LAP-BAND system a powerful surgical tool in the treatment of morbid obesity.

Section snippets

FDA trials A and B

The first FDA-monitored clinical trial to evaluate the LAP-BAND system in morbidly obese patients began in April 1995 [11] and is called Trial A (or LAP-BAND Adjustable Gastric Banding [LAGB] System for Treatment of Clinically Severe Obesity). The last patient in Trial A was implanted in June 1998. Trial A included 8 centers and 299 patients who were followed for 36 months. Of the 299 patients, 292 received the LAP-BAND and 7 received an earlier version of the device, called the adjustable

Study description

A retrospective review was conducted of prospective data collected on patients undergoing LAP-BAND surgery at 4 US medical centers between October 2000 and July 2002 (some patients were implanted before FDA approval of the LAP-BAND in June 2001). Four surgeons (Jeff W. Allen, M.D., Santiago Horgan, M.D., Jaime Ponce, M.D., and Christine J. Ren, M.D.) performed LAP-BAND surgery on 534 patients, 115 of whom completed at least 9 months of follow-up. Forty-three patients have completed at least 12

Results

All 115 patients underwent laparoscopic adjustable gastric banding using the LAP-BAND system and completed a minimum follow-up of 9 months, with the longest follow-up being 18 months. Of 115 patients, 98 were women and 17 were men, with an average age of 42 years (range: 18 to 69) and an average BMI of 47.5 (range: 35.5 to 70). Average body weight was 132 kg (range: 86 to 256 kg).

The average %EWL at 9 and 12 months was 35.6% ± SD 15.26 (range: 1.5% to 83%, n = 115) and 41.6% ± SD 19.3 (range:

Conclusion

The bariatric surgeon must incorporate all technical, clinical, and social skills for complete care of the patient. A deficiency in any of these factors may have significant impact on results. LAP-BAND surgery is one of numerous options for weight loss in the morbidly obese. As in any other procedure for this patient population, the 2 tenets of success are technique and follow-up. However, with the LAP-BAND procedure, a third factor is crucial to success: adjustments.

Our experience with the

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