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Regular article

US experience with the LAP-BAND system

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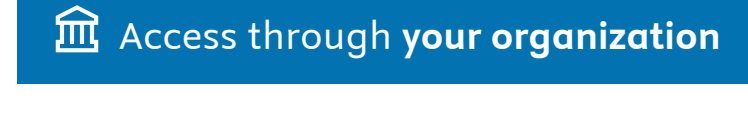
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Abstract

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.

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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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