

EndoFLIP System shows the benefits intra-operative adjustment

ACCORDING TO THE results of a study presented at the 15th Annual Congress of the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO 2010), in Long Beach, CA, intra-operative adjustment is well tolerated with no patients in the study requiring their band to be loosened post-operatively.

Previous studies have suggested that titrating to a gastric band stoma diameter of approximately 6.5 to 7mm using 30mL inflation in an EndoFLIP EF-325 balloon catheter may place patients in the Green-Zone (Surgical Endoscopy Vol.24 Supplement 1, April 2010 and Gastroenterology Vol. 138, Issue 5, Supplement 1, May 2010, Page S-388). As a result, researchers at the Speciality Surgery Center of Fort Worth, TX, under the direction of Principal Investigator, Dr Robert G Snow, undertook a pilot study to determine if patients could tolerate an adjustment to this stoma size intra-operatively and to assess the effect of this adjustment on early post-operative weight loss.

Fifty historical controls (37 female) were randomly selected to serve as the basis for %EWL comparison. Demographic data on the controls was [mean (SD)]: Age 41.7(12.0) years, Weight 278.8 (8.0) lb, and BMI 44.5 (7.9). A total of 35 patients were enrolled in the study. Demographic data on the study subjects (28 Female) was: Age 44.4 (11.1) years, Weight 271.0 (9.9) lb, BMI 42.0 (7.5). A model EF-325 catheter was used which has an 8cm long image field. Patients were fitted with Model APS or APL gastric bands (Allergan). Peri-gastric fat was not removed during the surgical procedure.

After the band was fitted, the EndoFLIP system (Crospon), was used to inflate the balloon catheter with 30mL of a calibrated diluted saline solution. As the band was filled, the stoma size could be mea-

sured directly from the EndoFLIP system screen (Figure). A calibration table for each subject was prepared during this procedure. Patient follow-up sessions were conducted at a frequency per normal institutional practice, only in this instance band adjustments, where necessary, were made in 1mm stoma diameter increments/decrements with reference to the calibration table for that patient. To analyze %EWL improvement at one month, the investigators included patients who had a follow-up visit in weeks 4-6 post-operatively.

Outcomes

Follow up data was available for 39 controls and 23 study patients. Of the 35 patients, the band was 'sufficiently snug' in five of them (2 APS, 3 APL) that it was not possible to create a 7mm stoma. To achieve a 7mm stoma size in the remaining 30 subjects, the band fill volume required was: 2.2(1) mL for the APS and 1.7(1.6) mL for the APL bands. Percentage EWL for the historic controls at 4-6 weeks was 15.6(8.9) and % EWL for study subjects at one month was 20.8(10.8). The mean %EWL improvement was 5.1 (p<0.05). None of the 35 subjects required the band to be loosened post-operatively. Five of the 23 patients (30%) had greater than 30%EWL vs. one of the 39 controls.

Conclusion

The investigators concluded that intra-operative adjustment is well tolerated, with no patients in the study requiring their band to be loosened post-operatively, whilst at the same time permitting a 33%(5.1/15.6) %EWL improvement versus historic controls 4-6 weeks after surgery. In addition, even though they had a band adjust-

ment during surgery, no patient required their band to be loosened in the post-operative period.

"The results of this study are changing the way we look at adjusting bands, in that we are no longer waiting until a month after surgery for the patient's first band adjustment, so that they are now getting on a more aggressive weight loss trajectory straight after surgery," said Snow. "It is generally accepted that early weight loss is a good indicator for longer term success. Further studies are planned to assess whether the EndoFLIP system can be used in a similar manner for post-operative band adjustment with a goal of reducing the number of adjustments by targeting a more precise adjustment each time".

Additional studies are ongoing to assess %EWL differences at two, three, six, nine and 12 months.

"We are encouraged by the results of this study, and are currently introducing EndoFLIP in a number of other leading gastric band centres. This study has shown how gastric band surgery can be improved to get patients losing weight more quickly by bringing science to the band adjustment procedure," said Larry Fulton, VP Sales for the Americas, Crospon. "Whereas the study used the Allergan Lap-Band, the EndoFLIP may be used with any gastric band. The study clearly demonstrated that improved early weight loss was achieved, but it remains to be seen if this translates into long term weight loss outcomes".

The EndoFLIP product, which received the CE Mark in January 2009 and FDA clearance in December 2009, is claimed to be the first product of its kind by the manufacturer Crospon. The company has recently signed an exclusive UK distribution agreement with Ardmore healthcare, and has a direct sales presence in the US.

The EndoFLIP (Endolumenal Functional Lumen Imaging Probe) Imaging System is a new technology used to measure the dimensions and function of a variety of hollow organs and sphincteric regions throughout the gastrointestinal tract. These measurements are useful for different types of patients such as GERD patients, potential candidates for GERD surgery and bariatric surgery patients.

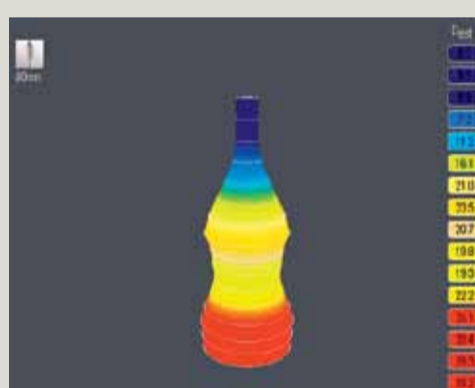


Endoflip monitor

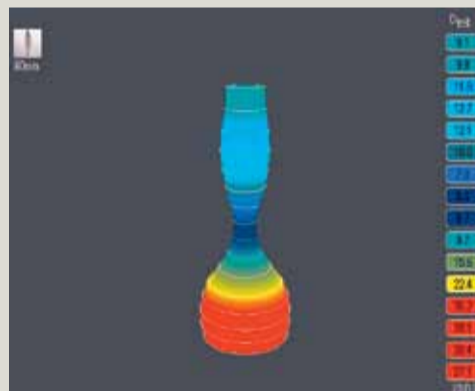
The EndoFLIP System injects a specially formulated conductive solution into a balloon catheter placed in the measurement area. The balloon contains an array of electrodes that measure voltage and the system uses these voltages to estimate the diameter at up to 16 points along the measurement area. The EndoFLIP System allows snapshots of this data to be saved and commented for reference.

The system allows a surgeon to set a consistent band stoma diameter at surgery for every patient. Consistent stoma size minimizes the risk of the band being too tight at the completion of surgery, and allows a surgeon to assess if sufficient peri-gastric fat has been removed to create an adequate stoma size. The system permits a surgeon to assess stoma size for patients where previous band-fill history is not available.

The EndoFLIP catheter may be deployed



Example of a sleeve being created by gastric imbrications.



Endoflip after the gastric band has been adjusted

into a stoma to measure its diameter, both to allow the assessment of whether stoma repair is required, or to assess whether adequate repair has been achieved i.e. sufficient stoma size reduction. This is particularly useful where endolumenal repair of the stoma is being undertaken, since the stoma may be distended and measured before additional pli-cations are made.



Endoflip system

Images courtesy of Crospon

Adolescents choose banding over bypass

ACCORDING TO A new study investigating the trends and outcomes of adolescents who undergo bariatric surgery in California, teenage patients are increasingly choosing laparoscopic adjustable gastric band (LAGB) over laparoscopic Roux-en-Y gastric bypass (LRYGB) procedures. The research is featured in the journal, Pediatrics (DeUgarte et al, October 2010;126;4:e746-e753). A previous 2008 paper, published in the Journal of the American College of Surgeons, estimated that the number of teen bariatric surgeries performed nationally increased five-fold between 1997 and 2003.

In the study entitled, 'Trends and Outcomes of Adolescent Bariatric Surgery in California, 2005-2007, patients younger than 21 years who underwent elective bariatric surgery between 2005 and 2007 were identified by researchers from the University of California (Los Angeles), from the California Office of Statewide Health Planning and Development database. Using multivariate logistic regression factors were identified associated with the type of surgery. Gastric banding is not yet approved for use in teenagers by the Food and Drug Administration (FDA). The patients group included some 18, 19 and 20-year-olds for whom the

surgery is FDA-approved.

A total of 590 adolescents (aged 13-20 years) underwent bariatric surgery in 86 hospitals. White adolescents represented 28% of those who were overweight but accounted for 65% of the procedures. While 43 percent of the overweight teenagers in California are female, 78 percent of the teenage surgical patients were girls. And while more than half of overweight Californian teens are Hispanic, only 21 percent of those who underwent surgery were.

Rates of LAGB increased 6.9-fold from 0.3 to 1.5 per 100,000 population (p<0.01), whereas LRYGB rates decreased from 3.8 to 2.7 per 100,000 population (P<0.01). Self-payers were more likely to undergo LAGB (relative risk [RR]: 3.51 [95% confidence interval: 2.11-5.32]) and less likely to undergo LRYGB (RR: 0.45 [95% confidence interval: 0.33-0.58]) compared with privately insured adolescents. The rate of major in-hospital complication was 1%, and no deaths were reported. Of the patients who received LAGB, 4.7% had band revision/removal. In contrast, 2.9% of those who received LRYGB required reoperations.

The authors conclude that white adoles-

cent girls disproportionately underwent bariatric surgery and although LAGB has not been approved by the US Food and Drug Administration for use in children, its use has increased dramatically.

Controversially, they also state that although 'manufacturers have touted the banding procedure as less invasive, many [medical] centers have abandoned gastric banding because of poor long-term results,' concerns about chronic oesophageal blockage, the need for frequent readjustments, and complications from the surgery.

The authors note that additional long-term studies are needed to fully assess the efficacy, safety, and health care costs of these procedures in adolescents.

"There is a perception that bariatric surgery in youth will help obese teens avoid a lifetime of illness," said Marc Michalsky (Surgical Director for the Center for Healthy Weight and Nutrition at Nationwide Children's Hospital), "However, if a patient undergoes one of these operations early, during their teenaged years, the result may be that they avoid the development of chronic obesity-related diseases that can result in permanent organ damage."

Does bariatric surgery improve cognitive function?

ACCORDING TO RESEARCH presented at Obesity 2010, 28th Annual Scientific Meeting of The Obesity Society, uncomplicated bariatric surgery does not impair a patient's cognitive function, and may improve it. Dr John Gunstad (Kent State University, Kent, OH), said that the study is the first to investigate whether bariatric surgery affects patients' cognition.

The study included 120 patients participating in the Longitudinal Assessment of Bariatric Surgery (LABS) research programme. After excluding individuals with conditions likely to influence cognitive function, Gunstad and his colleagues randomly assigned the patients to a surgery group or a control group (patients who did not undergo the surgery during the 12-week study period).

Both groups completed a

computerised cognitive test battery at baseline and 12 weeks later. Bonferroni-corrected post-tests revealed that 12 weeks after undergoing bariatric surgery, patients' test performance in attention, executive function, and language performance improved significantly (p<0.01). The control group's memory performance did not change from baseline to 12 weeks.

Repeated measures multivariate analysis of variances indicated no adverse effect of surgery on attention (p=0.65), executive function (p=0.79), or language performance (p=0.83). However, a group-by-time interaction emerged for memory (p<0.001). The results are particularly relevant because obesity may be associated with poor neurocognition, and all major surgeries involve some risk of cognitive dysfunction and postoperative