COMMENTS AND OPINIONS

To Band or Bypass

Recently, 2 articles[1,2] have been published in the *Archives of Surgery* that question the safety and efficacy of laparoscopic adjustable gastric banding (LAGB). Although a scientific dialogue is essential for the advancement of medical and surgical practice, the dialogue must be balanced and fundamentally sound. These recent publications[1,2] fall short of this type of dialogue. Both studies contain various limitations and are contradictory to a preponderance of well-controlled clinical studies recently published in the peer-reviewed literature. Specifically, we would like to call your readers' attention to the following important facts.

Himpens and colleagues[1] describe a study in which patients who underwent LAGB experienced a respectable mean excess weight loss of up to 48% after 12 years; however, this was associated with a 60% reoperation rate, and 28% of these patients experienced band erosion. We believe the following limitations should be acknowledged: (1) this was a small single-center retrospective study (151 patients) with limited application to the broad population; (2) the study was conducted in Europe, where follow-up band adjustment had not been customary until recent changes in practice were adopted[3]; (3) weight loss data were reported for only 70 patients (46%), and follow-up was available for only 82 patients (54%) after 12 years (70 patients received in-office follow-up, and 12 patients appear to have received follow-up by correspondence); and (4) nearly half of the patients (n=69) were lost to follow-up.

From January 1994 to December 1997, the patients in this study[1] were among the first to be treated with LAGB anywhere in the world; consequently, the procedure was in its infancy. Himpens and colleagues[1] also reported outcomes using older band models (with a 9.75-cm adjustable band), not the newest generation of band systems that incorporate omniform technology to reduce the chance of band erosion. Furthermore, the surgeons used the perigastric technique, which is rarely used today in clinical practice because reoperation rates are reported to be up to 4-fold higher using this technique rather than the state-of-the-art pars flaccida technique.[4] Band adjustments were conducted using a primitive radiological technique, without clear definition of criteria. Follow-up visits were infrequent: 2 to 4 follow-up visits in the first year and twice per year thereafter, but it is unclear whether even this limited degree of follow-up was achieved. Adequate patient education and guidance seems to have been lacking, and the contact method suggests there were minimal efforts to monitor patients' progress over the years. Most notably, the reported band erosion rates were uniquely high (28%), suggesting potential technical error. Indeed, a review of the literature suggests that band erosion rates are typically much lower after LAGB (0.2%, with 2909 patients).[5] The highest reported band erosion rate that we have found is 15% in a small study (N=33).[6] Finally, essential information regarding the patients who were converted to a Roux-en-Y gastric bypass (RYGB), such as percentage of excess weight loss, length of follow-up, and data on complications, is missing.

Campos and colleagues[2] describe a retrospective cohort study of 100 consecutive patients who underwent LAGB and who were matched to 100 patients who underwent an RYGB; all of these patients were treated between January 1, 2004, and January 31, 2008 (a mean of 2 band procedures per month). One-year outcomes were reported: (1) mean excess weight loss (36% of LAGB patients vs 64% of RYGB patients); (2) "resolution" of diabetes, with improvement being labeled "resolved" (50% of LAGB patients vs 76% of RYGB patients); (3) reoperations (13% of LAGB patients vs 2% of RYGB patients); and (4) band erosion (2% of LAGB patients).

Despite a 4-year inclusion period, Campos and colleagues[2] provide no explanation as to why outcomes were limited to 1 year. This is particularly pertinent given that a previous randomized prospective trial[7] reported similar percentages of excess weight loss, favoring RYGB, but with a higher morbidity and mortality rate for RYGB at time points greater than 1 year. Trials have demonstrated that LAGB, with proper band adjustments, tends to provide a steady, yet slower and potentially healthier (due to less lean body mass loss) weight reduction over 1 to 3 years.[8] In contrast, an RYGB often yields a precipitous and indiscriminate weight loss of lean body mass (muscle and bone) vs fat loss, which reaches its lowest point and then is often followed by weight regain.[9] Therefore, by limiting follow-up to 1 year, Campos and colleagues[2] risk biasing their conclusions by not allowing the LAGB patients to reach their full potential excess weight loss.

The study's conclusion of the comparative safety of LAGB and RYGB is more unsettling and contradicts numerous carefully controlled clinical trials, including the Longitudinal Assessment of Bariatric Surgery, conducted in the Centers of Excellence, which revealed statistically significantly higher morbidity and mortality rates for RYGB than for LAGB.[10] In summary, arriving at a decision "to band or to bypass" from the small, single-center studies presented by Himpens et al[1] and Campos et al[2] would be inappropriate.

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Corrected on September 19, 2011

ministrative, technical, and material support: Okerson. *Study supervision:* Oefelein and Okerson.

Financial Disclosure: Drs Oefelein and Okerson received stock options as employees of Allergan Inc.

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In reply

I was puzzled by the letter from Drs Oefelein and Okerson of Allergan Inc, the company located in Irvine, California, that produces and commercializes the Lap Band. They state that scientific dialogue "must be balanced and fundamentally sound" and indicate that they wish to call attention to several "facts" about our study[1] and the study by Himpens et al,[2] both of which were recently published in the Archives of Surgery. *In recounting these facts, however, Oefelein and Okerson made numerous inaccurate statements, not only about our study but also about many of other studies they cite. Whether this is due to carelessness or to a biased interpretation of the facts, it is important to set the record straight.*

First, Oefelein and Okerson indicate that we had a band erosion rate of 2%. However, our Table 3 indicates that 1 of 93 patients (1%) in our study experienced laparoscopic gastric banding (LB) erosion.[1] The Comment section does refer to a 2% LB erosion rate but clearly indicates that this is what another study found.

Second, Oefelein and Okerson ask why outcomes in our study were limited to 1 year. Our study design was chosen to maximize comparability of perioperative and longer-term outcomes. This is important because most published studies of LB and laparoscopic Roux-en-Y gastric bypass (RYGB) are limited by significant differences in baseline patient characteristics and by long-term follow-up rates of just 50% to 70%.[3] In our study,[1] when the 100th patient who underwent LB reached the minimum 1-year follow-up, patients were then pair-matched, and all outcomes analyzed. Nevertheless, our discussion stated that our "weight loss outcomes at 2 years in the 79% of both of our study groups who had completed 2-year follow-up were also better after RYGB" (P<.01). No deaths occurred in either group.

Third, Oefelein and Okerson incorrectly state "a previous randomized prospective trial" reported "a higher morbidity and mortality rate for RYGB at time points greater than 1 year." In fact, mortality at all time points in that trial[4] was similar for both groups; there was no perioperative mortality, and the only death, which occurred 8 months postoperatively in the RYGB group, was related to alcohol and drug abuse.

Fourth, Oefelein and Okerson then propose that LB "tends to provide a steady, yet slower . . . weight reduction over 1 to 3 years" and that RYGB "often yields a precipitous and indiscriminate weight loss . . . which reaches its lowest point and then is often followed by weight regain." The first statement could be correct if one were to ignore the 20% to 50% of LB patients unaccounted for in the reports used as the basis for the 2 statements. All 4 previous controlled US or European comparative studies with more complete and long-term follow-up[4-7] and many other comparative studies with different designs[8] show a higher failure rate for LB and better weight loss for RYGB. Regarding the important issue of the quality of weight loss, with current clinical practice for monitoring protein intake after bariatric surgery and the routine use of Roux limbs no greater than 150 cm, protein malnutrition after RYGB is close to zero.[9]

Finally, regarding our conclusion about comparative safety being unsettling and contradicting numerous carefully controlled clinical trials. We acknowledged that our study sample was not large enough to distinguish differences in rare events like mortality; however, the mortality rates reported in the Longitudinal Assessment of Bariatric Surgery (LABS) Consortium study[10] for laparoscopic RYGB (0.2%) and LB (0%) might not be directly comparable because the groups differed significantly with respect to patient baseline characteristics and because selection bias and confounding by severity likely affected the difference in mortality rates.[11,12] Moreover, the LABS study only presented 30-day complication rates; thus, the high rates of reoperations reported by us and many others[3,8] (data that are needed to account for the high rates of failure and device-related problems observed after LB) are not yet accounted for. We look forward to the publication of the long-term results of the LABS Consortium.

I believe that, in any advanced bariatric surgical practice, all surgical options should be available to patients, including any of the commercially available banding systems. However, before a decision is made, patients should be informed of all the risks, benefits, and long-term outcomes involved with each procedure.

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Financial Disclosure: None reported.

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In reply

Thank you for giving us the opportunity to reply to the letter by Drs Oefelein and Okerson concerning our study that was published in Archives.[1] *Regrettably, the message of our study apparently did not come across. We did not condemn laparoscopic adjustable band gastroplasty (LAGB). We wanted to stress the importance of a better follow-up policy.*

Understandably, the analysis by Oefelein and Okerson is biased by an obvious conflict of interest. This clearly impairs the value of their argument, but it does not excuse the condescending tone of their letter.

First, they state that "this was a small single-center retrospective study . . . with limited application to the broad population." In fact, our cohort of patients consisted of unselected and consecutive morbidly obese individuals who, therefore, were quite well representative of the broad population. Our study was conducted at the Saint-Pierre University Hospital, a recognized bariatric center, where hundreds of surgeons from all over the world, including the United States, have benefited from training in LAGB. As mentioned in the text, the very first ever LAGB was performed at this center, as was the first robotic gastroplasty.[2]

Second, they state that "the study was conducted in Europe." May we remind Oefelein and Okerson that, at that time, and for more than 5 years after, the LAGB procedure simply did not exist in the United States. Patients from our study were actually included in the US Food and Drug Administration data bank, which eventually lead to its acceptance in the United States. Our "primitive radiological technique" was apparently good enough for the US Food and Drug Administration.

Third, they state that follow-up was available for only 54% of patients after 12 years. I challenge Oefelein and Okerson to find a study, especially in the United States, where higher long-term follow-up rates have been achieved.[3]

The erosion issue is interesting. Possible facilitating factors (the type of band or the perigastric approach) were actually extensively discussed and refuted in our article.[1] *Moreover, blaming technical flaws during the operation does not seem realistic considering that the median lag time between the operation and the erosion was more than 2 years. We mentioned in our article that the high incidence of band erosion that we found could be attributable to our policy of systematically performing gastroscopy on our patients. Erosion rates can obviously only be evaluated by performing endoscopy for all patients; the numbers referenced in the letter therefore do not reach scientific evidence.*

Finally, the allegedly missing "essential information regarding the patients who were converted to a Roux-en-Y gastric bypass (RYGB)" can be found in an older study published in another journal.[4] *It confirms the deleterious effect of LAGB performed before RYGB.*

Table. Absolute Numbers of the Most Common Bariatric Procedures in Belgium (1999-2010), by Year[a]

Procedure	1989	1990	1991	1992	1993	1998	1999	2000	2001
Gastric bypass (241 452-463)	483	474	549	515	522	848	1012	965	1108
Sleeve gastrectomy (241 474-485)	1109	995	940	870	755	619	644	580	553
Gastric banding (241 533-544)	158	253	693	1105	1175	1873	2654	2850	3487
Total	1750	1722	2182	2490	2452	3340	4310	4395	5148

Procedure	2002	2003	2004	2005	2006	2007	2008	2009	2010
Gastric bypass (241 452-463)	1503	2136	3342	4034	4712	4683	1151	929	855
Sleeve gastrectomy (241 474-485)	209	482	640	640	603	506	353	313	279
Gastric banding (241 533-544)	3264	4482	5495	4322	3568	2725	528	336	285
Mason/sleeve-tomie (241 776-780)	0	0	0	0	0	6	45	33	42
Mason/sleeve-scopie (241 791-802)	0	0	0	0	0	25	395	709	1042
Gastric banding (241 813-824)	0	0	0	0	0	122	1714	1692	1345
Bypass/Scopinaro-tomie (241 835-846)	0	0	0	0	0	47	432	473	295
Bypass/Scopinaro-scopie (241 1850-861)	0	0	0	0	0	185	3079	4519	5547
Total	4976	7100	9477	8996	8883	8299	7697	9004	9690

[a]Source: RIZIV/INAMI (Rijksinstituut Voor Ziekte–en Invaliditeitsverzekering/Institut National d'Assurance Maladie–Invalidité; Belgian Public Health Service). The numbers in parentheses are the RIZIV/INAMI code numbers for the procedures (the first is ambulatory, the second in-hospital). Sleeve-tomie is Flemish for open sleeve, and sleeve-scopie is Flemish for laparoscopic sleeve.

*Drs Oefelein and Okerson state that our study is "contradictory to a preponderance of well-controlled clinical studies recently published in the peer-reviewed literature." However, it is clearly not contradictory to the natural evolution of the procedure, at least in Europe. For example, in Belgium, the share of LAGB procedures in the total number of bariatric procedures dropped from 58% in 2004 to 17% in 2010 (***Table***).*

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Financial Disclosure: None reported.

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Reminder of the Metrics of Endosurgical Innovation

Congratulations to Curet[1] for putting the horse (innovations) back in front of the cart (clinical outcomes) for the journey of a new generation of surgeons obsessed with a desire to be different,[2] forgetting the maxim *primum non nocere*. Laparoscopic cholecystectomy, the index endosurgery, continues to be haunted by the adverse outcome of bile duct injury, which is an index metric for assessing endosurgical innovations. Contemporary scientific discourse on endosurgical innovations aims to make bile duct injury a "never event," underscoring the quest for zero tolerance for any compromise-prone innovation.[3] However, even after 2 decades of proficiency, the rates of bile duct injury remain higher than expected despite continuous improvement in technology and innovations. Conventional surgery is also single incision; single-incision laparoscopic surgery (SILS) just camouflages the site of incision.

In laparoscopic cholecystectomy, the ports are less than 10 mm in diameter, thus facilitating better wound healing, which has made this type of surgery more popular than conventional surgery. This benefit is lost in SILS, both in the short term (with hematoma, seroma, and/or dehiscence) and in the long term (with scar hypertrophy and/or herniation), reversing the metrics of progress from conventional surgery to laparoscopic cholecystectomy. Surgery is progressively benchmarked by metrics of mortality, morbidity, and patient-related outcomes. Persuance of SILS with a handicapped navigation due to technical and/or cognitive challenges, in the absence of a critical view and in the absence of a demonstrated proficiency outside the human body, entails a compromise on bile duct injury–related morbidity.[1,3] The patient-related outcomes of satisfaction and cosmesis cannot be ethically used to barter away morbidity. Surgical progress cannot be reversed by metrics of convenience, prioritizing nonfunctional patient-related outcomes over mortality and morbidity. Cosmesis seems suspect in light of concerns related to umbilicotomies.[4] The irrelevance of an additional 3- to 5-mm–size port for the majority of the population is obvious given the belly button aesthetics with enhanced safety vs cosmesis sans safety.[4] The death of Rep John Murtha is a reminder lest we lose a kingdom for a nail.

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Financial Disclosure: None reported.

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