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SURGERY FOR OBESITY AND RELATED DISEASES

Letter

To the Editor

We have read with interest the manuscript "Evaluating the safety of intragastric balloon: an analysis of the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program" by Dang et al. [1]. In this retrospective analysis based on the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program database, the authors conclude that the intragastric balloon (IGB) is associated with a higher adverse event rate than laparoscopic bariatric surgery due to a 4 times higher 30-day nonoperative intervention rate. The authors also suggested that the use of IGB should be reconsidered due to its poor safety profile compared with laparoscopic bariatric surgery.

The conclusion of the study does not seem appropriate, and some points regarding both the methodology and the results should be discussed.

First, we will debate the methodology, discussing the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program database. As the name of the database demonstrates, it was designed to maintain data on bariatric surgeries and not on bariatric endoscopy procedures. In the "data source" session of the manuscript, the authors themselves clarify that the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program database data registry collects prospective, risk-adjusted data based on standardized definitions for preoperative, intraoperative, and postoperative variables that are specific for metabolic and bariatric surgery and not for endoscopy procedures [2].

The authors pool "nonoperative reintervention," which consists mostly of endoscopic interventions, into "'adverse outcomes," which are assessed as part of a diverse composite clinical endpoint, including death, anastomotic leak, postoperative bleed, venous thromboembolism, operative reintervention, unplanned intubation, length of stay >7 days, acute renal failure, cardiac arrest and cardiopulmonary resuscitation, coma for >24 hours, cerebral vascular accident, and myocardial infarction. We note that "nonoperative reintervention" is significant between groups and affects the primary outcome. As "nonoperative reintervention" includes simple endoscopic procedures, should this really be given as much weight as death?

Furthermore, readmission rate is higher in the surgical cohort; however, this is not explored. These patients can be very ill and may have complicated conditions, including fistulas, stenosis, infections, hernias, and sepsis, compared with IGB patients who are typically admitted for hydration.

Another relevant fact that was not discussed in the article [1] is that data collected on the use of IGB began in 2016, with a relatively low number of procedures (781 IGB collected from 791 bariatric surgery centers compared with 144,627 laparoscopic bariatric surgeries). This number highlights a limited experience with IGB. The average number of cases per center and where centers were on their learning curves was also not clear, both of which could affect the rate of nonoperative reintervention.

Regarding the results, although the surgery presented higher rates of postprocedure bleeding (.4% versus .3%), leaks (.3% versus 0%), operative reinterventions (.9% versus .7%), coma for >24 hours (4 cases versus 0), cerebral vascular accidents (13 cases versus 0), and hospital readmission (3.8% versus 2.2% in all patient's analysis), there was no statistical difference between groups (see Table 2 from the original manuscript [1]). However, in the propensity-matched analysis, the nonoperative reinterventions rate was higher in the IGB group with statistical significance (4.2% versus 1.0%, $P < .001$). Overall, adverse outcomes were also significantly higher in the IGB cohort (5.0% versus 2.6%, $P = .024$) because it included the nonoperative interventions. Of the reasons for nonoperative interventions, 55.2% were nausea and vomiting, 37.9% were other complaints, and 3.4% were abdominal pain and bleeding. A total of 2.8% IGB were removed early, and no death was reported.

It is essential to understand that nausea, vomiting, and abdominal discomfort are expected side effects of the IGB use, especially in the first week; because of this, pa-

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tients should be properly instructed and medicated (proton pump inhibitors and antiemetics) to avoid early removals [3]. These symptoms are expected and become easier to manage with increased experience. Additionally, IGB had lower length of stay and shorter procedure time with statistical difference ($P < .01$).

The literature demonstrates the efficacy and safety of the IGB through evidence 1a and 1b studies [4,5]. In a systematic review and meta-analysis [4], including only randomized trials, IGB was shown to be effective in decreasing body mass index and weight loss. Another study, a meta-analysis [5], confirmed the safety and efficacy of IGB, reporting no deaths in the 15 included randomized trials. This study showed that all IGBs (fluid and gas filled) were associated with high incidence (>50%) of self-limiting accommodative symptoms, including nausea and vomiting; however, typically, this was successfully managed without early removal [5].

Another recent systematic review including 6101 patients demonstrated that serious complications such as mortality (.05%), gastric ulcers (.3%), gastric perforations (.1%), and balloon migration (.09%) are rare, making the IGB an acceptable option as a weight loss intervention. This review showed that a significant proportion of patients experienced nausea, vomiting, and abdominal pain and because of that recommend close clinical monitoring during the full duration of IGB treatment. Similar to Dang et al. [1], the early removal rate was 3.5%, and the most common reason was abdominal pain, nausea, and vomiting [3].

IGB has been used in many countries for years, and it has been effective in weight loss with low rates of adverse effects [3–5]. For example, the Brazilian data on the use of IGB encompassed 41,863 cases, with a mean percentage total weight loss of 18.4%. The early removal rate due to intolerance was 2.2%, and the adverse event rate after the adaptation period was 2.5%, including .9% hyperinflation and .8% spontaneous deflation of the device. There were 12 deaths (.03%) reported during the IGB use, with just 3 directly attributable to the IGB. The IGB-related causes were gastric rupture due to overfeeding in a super-obese patient, pulmonary aspiration due to persistent emesis 4 days after implant, and a pulmonary embolism [6].

Based on the results discussed, the authors should be more tempered in their conclusion that IGB is unsafe. The study itself demonstrates the safety of IGB by showing no IGB-related deaths, unlike surgery where 131 patients died (.1% in all patient's analysis), and a lower rate of operative reintervention in the IGB group [1].

In summary, the literature demonstrates several randomized studies, including systematic reviews and metanalysis (evidence 1a and 1b) showing the safety and effectiveness of the IGB as demonstrated in this commentary. Therefore, authors should take more care in drawing conclusions related to database results (retrospective analysis). The Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program database is a database for bariatric surgical procedures with a small number of endoscopic procedures that may not represent typical endoscopic practice. Additionally, it is important to understand that the IGB placement is not a procedure to substitute any bariatric surgery, but it is another device in the armamentarium that we can offer to patients in the early stages of obesity.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.soard.2018.10.006.

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Authors' Response

Thank you for your interest in our analysis of intragastric balloons (IGB) using the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program database [1]. We agree that intragastric balloons are a topical subject due to their increasing use in clinical practice.

The message of our study was that IGBs have no role in sustained, long-term weight loss as there is no evidence supporting this. The 3 systematic reviews that are referenced in the commentary only demonstrate modest weight loss at 6 months with very limited 12-month data [2–4]. It is important to note that many of the primary studies on IGB were industry-funded, which was not assessed to be a risk of bias in any of these systematic reviews. However, these are important biases, as a recent Cochrane Systematic review found that industry-sponsored studies lead to more favorable efficacy outcomes than non–industry-sponsored studies [5]. The authors of the commentary also have conflicts of interest in favor of IGB, as the senior authors are consultants for and have received grants from IGB manufacturers.

We would also challenge the use of the Brazilian data as evidence of weight loss as this was self-reported data derived from questionnaires given to endoscopists before a consensus meeting [6]. Furthermore, given the effectiveness of new pharmacologic therapies for weight loss, such as high-dose liraglutide [7], IGBs are no longer a sound option for short- or long-term weight loss.

Although the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program database maintains data specific to bariatric surgery, it is important to analyze the use of IGBs by bariatric surgeons. As our analysis demonstrated, IGBs are being used mostly for primary weight loss rather than as a bridge to bariatric surgery. A comparison of IGB against bariatric surgery is fair, in this context, given that it is being used by bariatric surgeons. By comparing IGB with bariatric surgery, we are finding that bariatric surgery is at least as safe as IGB and requires less reinterventions, which alone is an important message.

As critical appraisal is important for clinical research, we are appreciative of your commentary on our study. We look forward to collaborating with you and *Surgery for Obesity and Related Diseases* in the future.

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