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Limitations in endoscopic sleeve gastroplasty outcomes data derived from surgery-based repositories

To the Editor:

We read the article by Gudur et al.[1] We have concerns regarding critical, but understandably inherent, limitations that portend significant implications regarding their interpretation and subsequent perception among clinicans and patients alike.

Endoscopic sleeve gastroplasty (ESG) is a novel procedure 10 years in evolution. The MERIT study reported ESG-related serious adverse events occurring in 2% of patients,[2] congruent with retrospective series estimating them to be between 0.5% and 2.2%.[3-8] In both studies, these adverse events were managed conservatively without intensive care or surgery.[2-8] Expected accommodative GI symptoms occur, whereas bleeding, perforations, neighboring visceral injury, and abscess formation are rare, and none were reported in MERIT.[2]

Gudur et al[1] analyzed a surgical database reporting what was described as 6000 ESG cases. The lack of granularity did not allow important ancillary details, such as adequate center volume meeting competency thresholds. This is critical, given the reportedly 6 early mortalities, which has not, to the best of our knowledge, been reported in the literature or conference proceedings. However, the most important, historically identified in the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP), relates to Current Procedural Terminology coding inaccuracies.[9] As such, surgical procedures may have been erroneously indexed as ESG.

This is suggested by a very unusual serious adverse event profile ascribed to ESG, such as "GI leaks." Leaks can complicate bariatric surgeries but not ESG. Similarly, stricturing necessitating balloon dilation has not been described with ESG, to the best of our knowledge. Last, we are unable to explain reported pneumonia cases after a procedure that does not result in GI reflux disease.[10] Whereas burgeoning bariatric endoscopy research is critical to advancing the field, we are concerned that these data pose inaccuracies stemming from possible incorrect Current Procedural Terminology coding, which is critical to the perception of ESG as a novel, safe, and effective weight loss option in the fight against obesity.

DISCLOSURE

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Response:

We thank Bazerbachi and colleagues[1] for their critical appraisal of our article[2] and believe they raise several important points.

We agree with the authors regarding the inherent limitations found in any large retrospective database analysis, and we acknowledge the possibility of data entry errors leading to inadvertent misclassification or misattribution. However, as noted in our methodology,[2] the MBSAQIP database is collected by annually certified clinical reviewers and regularly audited to ensure quality. These routine data integrity audits ensure and necessitate a <5% disagreement rate between the data and audit in order to be included for analysis. It is also important to note that the reference the authors provided highlighting the possible limitations of the MBSAQIP dataset was focused solely on the first year (2015) of the MBSAQIP database—data that were not included in our analysis (2016-2020).[3]

It is also important to highlight possible alternative explanations for Bazerbachi and colleagues' perceived abnormal adverse events (AEs). Whereas anastomotic leaks are predominately a surgical AE, the use of full-thickness suturing has been widely reported to lead to peritoneal fluid formation, abscesses, and perforations, as the authors note.[4] We would argue that any communication of the GI lumen that results in intraperitoneal fluid accumulation would be reasonably classified as a GI leak. Additionally, although we agree with the authors that the evidence linking endoscopic sleeve gastroplasty (ESG) to postprocedural GERD is limited, we also highlight that gastroesophageal reflux is not the sole cause of possible pneumonia, and more common clinical scenarios (such as procedurally associated aspiration pneumonia) represent a viable alternative explanation. An important distinction is that we defined AE as per good clinical practice, namely, that an AE is any unfavorable and unintended sign, symptom, or disease having been absent at baseline or, if present at baseline, appears to worsen and is temporally associated with medical treatment or procedure, regardless of the attribution (ie, relationship of event to medical treatment or procedure).[5]

In conclusion, inasmuch as our rate of major AEs for ESG was only 1.1% (lower than the MERIT trial's 2%), we argue that our results corroborate the excellent safety profile of ESG noted in previous studies, even outside a tightly regulated clinical trial. As adoption of ESG continues to grow worldwide, assessment for competency and its influence on AE rates will be increasingly important.

DISCLOSURE

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