Getting the full picture: let's always include sustainability in trials reporting new technology!

To the Editor:

We read with interest the report by Luo et al[1] of their noninferiority trial concluding that disposable gastroscopes are a viable alternative to their reusable counterparts for "routine examination, bedside first aid, and some certain circumstances."

Although we think that the recent increase in interest in the efficiency of disposable endoscopes is exciting, we are concerned about the apparent lack of attention given to sustainability and the environmental implications.[2] Single-use endoscopes challenge the principle of reusing—1 of the 3 pillars of environmental sustainability (reduce, reuse, recycle)—and have given rise to constructive debate. Demonstrating performance similar to that of reusable endoscopes is definitely an achievement, but focusing on "technical" outcomes cannot answer the bigger question posed when we consider the paradigm shift of proposing single-use endoscopes for routine procedures. Available data are concerning and suggest that a transition to single-use duodenoscopes alone would increase CO_2 emissions 20 times[3] and the net waste mass by 40%.[4]

There is a clear distinction between endoscope contamination and clinically relevant infection, given that most endoscope contaminations do not translate into clinical implications for patients. Human error seems to be the most common cause behind inadequate endoscope reprocessing and can be addressed by training programs and standardized education.[5] Whereas patient safety is paramount, the principle of achieving an "as low as reasonably practicable" infection risk is now considered by several scientific societies and healthcare institutions to balance clinical, societal, financial, and environmental costs.[6] To advance the discussion of this topic, studies of novel single-use endoscopes should disclose more about the materials used for production, life-cycle assessment, and plans for recycling components. Only by considering these factors in their trial design can future noninferiority trials account for all aspects of this difficult and societally relevant issue.

DISCLOSURE

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Vigilance for barotrauma with the use of topical mineral powder hemostasis

To the Editor:

We enjoyed reading the recent article by Sung et al,[1] "Use of topical mineral powder as monotherapy for treatment of active peptic ulcer bleeding." The authors noted 2 perforations that were not attributed to the use of topical mineralized powder (TMP) therapies. However, based on the literature and on our own experience, barotrauma is a

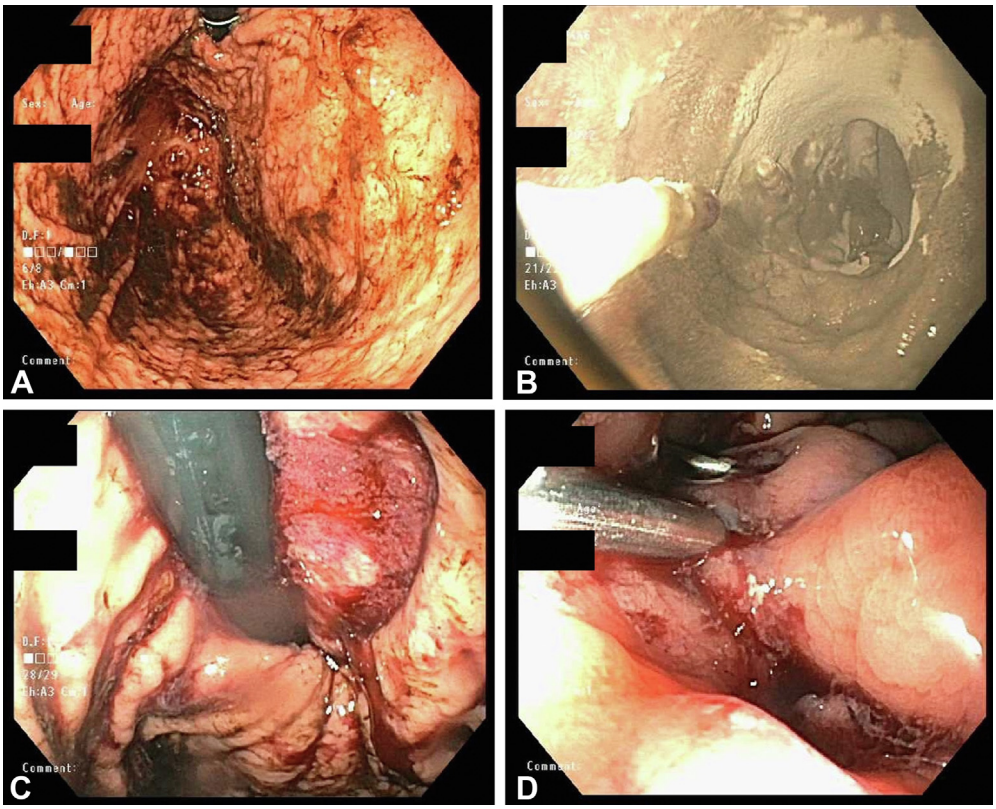

Figure 1. Endoscopic views of barotrauma to lesser curvature caused by insufflation of topical mineral powder.

known risk factor during endoscopy with TMP use. In our case, TMP was used for high-risk duodenal ulcers in an 80-year-old woman during an endoscopy for melena. On withdrawal, barotrauma, owing to rapid insufflation of the stomach, was noted in the lesser curvature (Figs. 1**A** to 1**D**).

The risks of barotrauma with TMP should not be ignored. The U.S. Food and Drug Administration notes that TMP can increase bowel lumen volume by 3 liters and that bentonite powder can expand 10% to 15% in the presence of blood.[2] Therefore, the rapid delivery of carbon dioxide and the gastric insufflation associated with this device are significant, and the literature states that perforations were associated with device use for this exact reason.[3] The authors did not believe that the device caused the perforation because the target lesion and site of perforation were distant from one another. However, we have noted barotrauma at the lesser curvature even though the target lesion was in the duodenum. The lesser curvature may be at increased risk of barotrauma owing to lower compliance compared with other sites in the foregut.[4,5] Hence, the use of TMP devices may cause trauma at the lesser curvature or gastroesophageal junction regardless of the site of the target lesion.

Endoscopists at our institution now routinely evaluate the lesser curvature and the gastroesophageal junction after TMP use to assess for barotrauma. Care should be taken when oxygen is used instead of carbon dioxide for insufflation, during prolonged cases, and in instances where there are concerns about impending perforation.

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Double bare self-expandable metal stent for distal malignant biliary obstruction

To the Editor:

Park et al[1] reported no significant differences in the 6-month stent patency rates and mortality between partially covered and uncovered double bare self-expandable metal stents (PCDBSs vs UCDBSs) for unresectable distal malignant biliary obstruction. This randomized controlled multicenter trial is of great significance for clinical practice, yet we would like to share our reservations for further research.

First, as shown in the baseline characteristics section, the length of the stricture was longer in PCDBSs than in UCDBSs (2.8 ± 1.3 vs $2.4 \pm 1.2, P = .010$). The length or the degree of stricture might be correlated with disease severity and stent patency,[2] and longer biliary stricture was an independent risk factor for worse survival after metal stent insertion,[3] which is also in accord with the fact that the rate of tumor overgrowth was higher in the PCDBS group than in the UCDBS group (5.5% vs 0.8%). Therefore, we hypothesize that the PCDBS group had selection bias, which would weaken the effect of PCDBSs on stent patency and overall survival, and a propensity-matching analysis may be required.

Second, we would like to know whether there was a significant difference in the total incidence of single adverse events between the 2 groups, regardless of the 2-week time limit, so as to better verify the overall impact of whether or not the novel metal stent is covered on the risk of adverse events.[4]

Third, the authors did not disclose the details of revision for stent dysfunction, which might have had some influence on stent patency and overall survival. For example, radiofrequency ablation can be performed by both endoscopic and percutaneous routes. As a novel adjunctive procedure and a promising therapeutic option in patients with malignant biliary obstruction, radiofrequency ablation can achieve local tumor control, resulting in improved biliary stent patency and a potential survival benefit.[5]

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Response:

On behalf of our co-authors, we would like to express our appreciation for the comments made by Li and Liu[1] about our study.[2] Those authors point out that the longer length of the malignant stricture in partial covered double bare metal stent (PCDBS) could lead to a significant difference in the higher incidence of tumor overgrowth in the PCDBS group. As they pointed out, the length of stricture in the PCDBS group was longer than that in the uncovered double bare metal stent (UCDBS) group (2.8 ± 1.3 vs 2.4 ± 1.2; $p = .010$).[2] However, the stent lengths for both groups were not meaningfully different (7.0 [6.0-8.0] vs 6.0 [6.0-7.0]; $p = .430$).[2] Therefore, the differences in stricture length in both groups could not affect the duration of stent patency. Furthermore, the results of our study are completely in accord with those of previous comparative studies[3-5] between single-layer covered stents and uncovered stents. In general, the rate of ingrowth is less in covered stents because of the membrane-covered mesh of the stent, whereas this benefit may be offset by the increased rate of overgrowth at the edges of the covered stent.[6] Consequently, the difference in stent overgrowth between PCDBS and UCDBS can be attributed to the characteristics of membrane. In addition, selection bias is generally defined as the bias introduced by the selection of individuals, groups, or data for analysis in such a way that proper randomization is not achieved, thereby failing to ensure that the sample obtained is representative of the population intended to be analyzed. Our study is the largest randomized trial to compare covered stents with uncovered stents, and consecutive patients were included by strict criteria. Therefore, there is only a slim chance that selection bias affected of our study. In terms of the total