Duodenal mucosal resurfacing before its use in clinical practice

To the Editor:

We read with interest the study by van Baar et al on hydrothermal duodenal mucosal resurfacing (DMR) to treat type 2 diabetes mellitus (T2DM). We believe that 2 issues deserve attention before its use in clinical practice.

In the study, no intraoperative adverse events (AEs) or procedure-related AEs were reported, except for the case with duodenal stenosis for ~1 month after the procedure. Moreover, previous studies indicated that postoperative AEs were mild and transient. The efficacy of DMR is mainly demonstrated by improved glycemic control (glycated hemoglobin A1c [HbA1c] and fasting blood glucose) and weight loss (correlated alanine transaminase) observed within 1 week and lasting for 2 years. The factors indicate that DMR is safe and efficient in patients with T2DM. However, the mechanism of DMR is unclear, and 2 concerns should be addressed before its use in clinical practice. One is the independent mucosa regeneration as the essence of DMR. Previously, we proposed that the regeneration of glucagon-like peptide-1 producing L cells may be involved in the mechanism of DMR to treat T2DM. It is a fact that patients receiving DMR treatment are followed up more regularly and closely with more health education on diet control and medication than are prerecruitment and unrecruited T2DM patients; that follow-up care also facilitates the formation of good habits and further contributes to the clinical management of T2DM. Consequently, indicators (eg, HbA1c and weight loss) in patients receiving DMR without follow-up care may be inferior to those of patients with follow-up care. Therefore, the independent role of DMR should be demonstrated after the confounding factors are controlled for, and the independent role of the whole process of treatment, apart from the DMR itself, should be explored. Further studies with larger sample sizes and randomized control trial grouping by the length of DMR, different follow-up intervals, and a comprehensive weight management program in patients with T2DM may distinguish the independent role of DMR from the bias of follow-up care.

DISCLOSURE

Both authors disclosed no financial relationships.

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Response

We thank Drs Yang and Hu for their questions. It is correct that the exact mechanism underlying duodenal mucosal resurfacing (DMR) remains unclear, as mentioned in our discussion. We are conducting additional mechanistic research, and we recently published 2 articles in which we report the results from our first mechanistic assessments: 1 report about the role of bile acids and a second report about changes in the microbiome. The changes we found are interesting and noteworthy, but the exact mechanism has still to be elucidated. In the upcoming months we will publish a third article to report our study of changes in the duodenal mucosa itself after DMR.

We agree with Drs Yang and Hu that our study patients were followed up more regularly and closely with more education on health and diet. The main goal of our feasibility study was to evaluate whether it was possible to discontinue insulin treatment in patients with type 2 diabetes by replacing it with DMR and GLP-1RA and to get an idea of the effect size of such a combined intervention. Because our small study was successful, it has been followed by an adequately powered, multicenter, sham controlled trial (Revitalize-1) to control for the addressed confounding factors. This mimics our prior approach, where we first conducted the uncontrolled Revitalize-1 study (DMR for patients...
with type 2 diabetes using oral glucose-lowering medication) and performed the sham controlled randomized Revita-2 trial thereafter. We are also designing our next study in which we will evaluate the length of DMR.

**DISCLOSURE**

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A few considerations for follow-up surveillance colonoscopy

To the Editor:

We read with great interest the study by Kobe et al.1 This study provides new evidence on the safety of colonoscopy follow-up, which is of clinical significance. However, we wish to further discuss some issues on surveillance colonoscopy.

Concerns regarding colonoscopy-related adverse events are major deterrents to patient compliance with colonoscopy.2 We summarize, in Supplementary Table 1, previously published meta-analyses reporting the incidence of colonoscopy-related adverse events in patients for colorectal cancer (CRC) screening and/or surveillance. Recent meta-analyses have revealed that the pooled rate of perforation was 0.07 to 1.3 per 1000 colonoscopies, that of post-colonoscopy bleeding was 0.8 to 3.0 per 1000 colonoscopies, and that of mortality was 0.1 per 1000 colonoscopies.3-7 This study corroborates the safety of surveillance colonoscopy, and the risk is comparable with the lower limit in meta-analyses. Additionally, this study identified adverse events on the immediately prior examination as a risk factor for follow-up adverse events. However, no clear definition was mentioned. Considering that the recommended surveillance interval for colonoscopy is every 5 to 10 years,8 the clinical applicability of this risk factor for longitudinal adverse events requires further consideration.

The balance of benefits between reduction of CRC and harm of adverse events seems to be more important in older adults.9 The benefits of endoscopy in older adults may be compromised owing to an expected higher adverse event rate.9 Kobe et al1 proposed that long-term programmatic surveillance was safe, inasmuch as major events were rare during follow-up. Ma et al10 indicated that screening endoscopy after age 75 years was associated with a lower risk of CRC incidence and mortality in a prospective cohort. An important message from these 2 articles is that continuation of screening among individuals older than 75 is worth considering.

In conclusion, long-term follow-up colonoscopy is safe and thus allows for more consideration of its cost effectiveness and clinical utility.

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