Duodenal mucosal resurfacing before its use in clinical practice

To the Editor:

We read with interest the study by van Baar et al \(^1\) 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. \(^2\) 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.

Hang Yang, MD  
Bing Hu, MD

Department of Gastroenterology  
West China Hospital  
Sichuan University

Chengdu, Sichuan, China

REFERENCES


Response

We thank Drs Yang and Hu \(^1\) for their questions.

It is correct that the exact mechanism underlying duodenal mucosal resurfacing (DMR) remains unclear, as mentioned in our discussion. \(^3\) 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 \(^2\) and a second report about changes in the microbiome. \(^4\) 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 \(^1\) 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 Revita-1 study (DMR for patients...