

A.C.G. van Baar¹, J. Devière², G. Costamagna³, M.P. Galvão Neto⁴, L. Rodriguez⁵, R.J. Haidry⁶, J.J.G.H.M Bergman¹. On behalf of Revita-1 Investigators.

¹Department of Gastroenterology and Hepatology, Academic Medical Center, Amsterdam, the Netherlands; ²Department of Gastroenterology, Erasme University Hospital, Brussels, Belgium; ³Department of Digestive Endoscopy, Policlinico Gemelli, Catholic University of Rome, Rome, Italy; ⁴Bariatric Endoscopy Service, Gastro Obeso Center, São Paulo, Brazil & Florida International University, Miami, FL, United States of America; ⁵Department of Surgery, CCO Clinical Center for Diabetes, Obesity and Reflux, Santiago, Chile; ⁶Department of Gastroenterology, University College Hospital, London, United Kingdom.

Background

Duodenal mucosal resurfacing (DMR) is an endoscopic procedure involving balloon catheter-based thermal ablation of duodenal mucosa for the treatment of type 2 diabetes (T2D). A first-in-human single center study has reported robust improvements in glycaemic control after DMR.¹

Objective

To report the early safety, feasibility, and efficacy of DMR in a multicenter study in subjects with T2D.

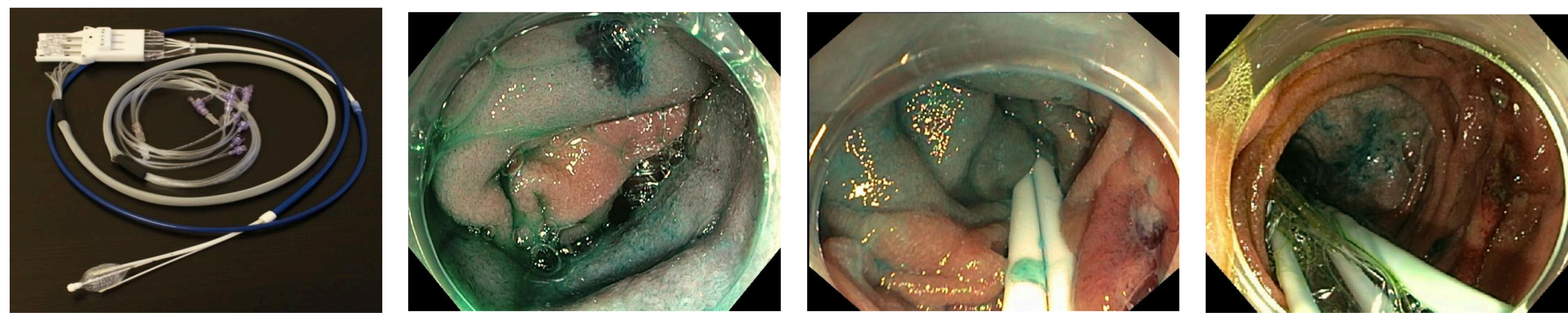
Methods

Study sites The 5 endoscopists from the 5 participating centers received a day of didactic and hands-on DMR training in a porcine model.

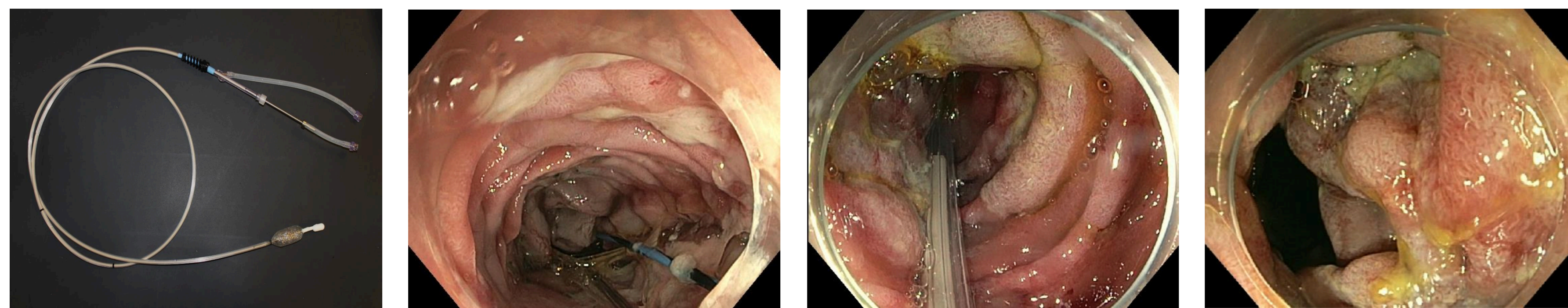
Subjects Patients with T2D on oral glucose-lowering medication.

Duodenal Mucosal Resurfacing

Step 1. Duodenal lumen sizing and lifting with submucosal expansion catheter.



Step 2. Mucosal ablation (length 9 cm) with thermal ablation catheter.



Medication & diet

Sulfonylureas (SU): Stopped 4 weeks before DMR to mitigate hypoglycaemia risk.

Proton pump inhibitor: From 1 week before up until 4 weeks after DMR.

Diet: Graduated diet for 2 weeks post DMR.

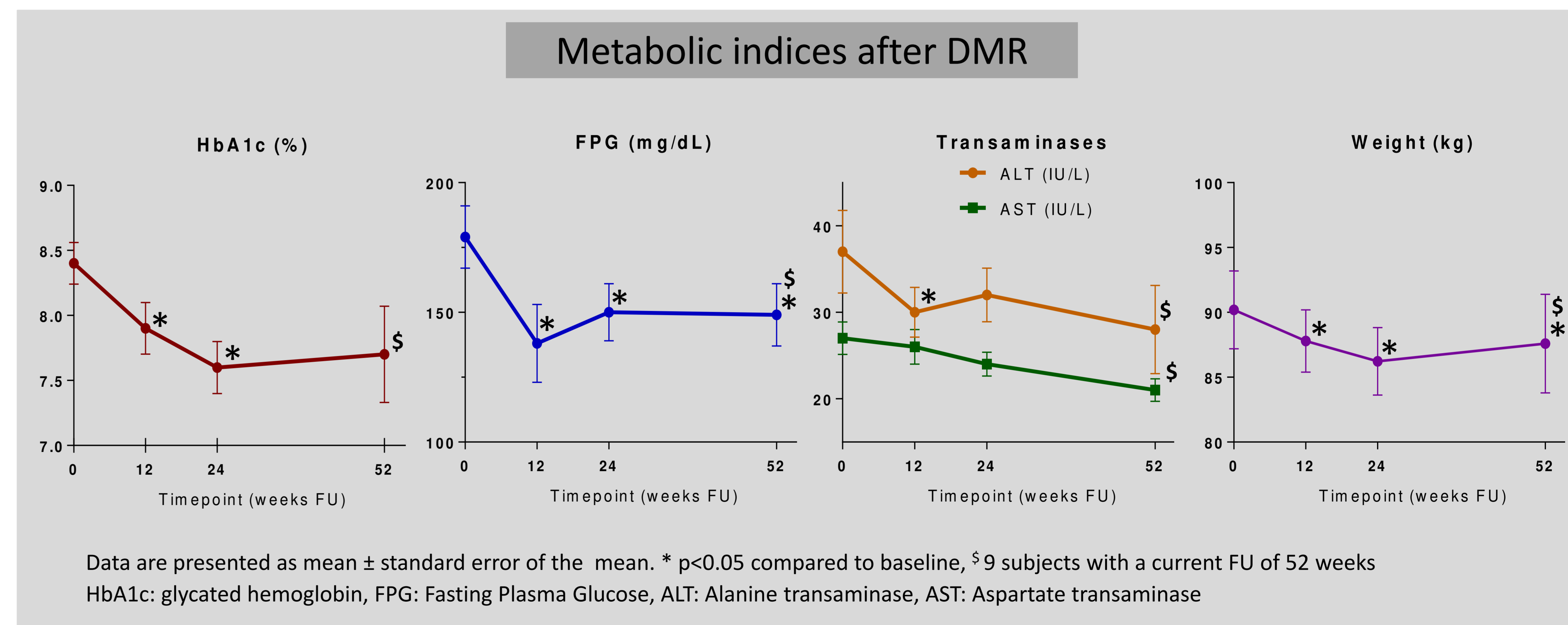
Results

In total, 22 of the 28 included subjects (aged 56 ± 8) with T2D (HbA1c $8.4 \pm 0.7\%$) received full DMR treatment of 3 ablation zones corresponding with 9 cm duodenal length. Current follow-up (FU) is 24 weeks for the full cohort and 52 weeks for 9 subjects.

Safety The procedure was well tolerated by all subjects. There were no procedure-related severe adverse events including no duodenal stenoses. Adverse events were mostly (80%) mild in severity.

Feasibility The procedure was implemented according to protocol across all sites. The median procedure time was 86 minutes (IQR 69 – 118 minutes).

Efficacy Metabolic indices improved after DMR despite protocol-driven withdrawal of SU therapy in the majority of subjects (figure below).



Conclusion

The novel endoscopic catheter-based DMR procedure can be implemented in a multicenter setting for the management of T2D. We report a favourable safety and tolerability profile with further evidence of the improved glycaemic and hepatic measures elicited by DMR. Further assessment of clinical applicability, and efficacy and safety of the DMR procedure is necessary.