Duodenal Mucosal Resurfacing Improves Glycemic, Lipid and Hepatic Fat Measures in Type 2 Diabetes

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Introduction

Duodenal Mucosal Resurfacing (DMR) is currently being investigated as a treatment for insulin-resistant metabolic disease including Type 2 diabetes (T2D).1

Data from the recent multicenter, single-arm Revita Study in T2D patients demonstrated sustained reductions through 12 months in HbA1c, fasting plasma glucose (FPG), Homeostatic Model Assessment Index (HOMA-IR), and liver transaminases (ALT, AST).

Objective

Revita 2-clinical trial (NCT02791663) is a blinded, sham-controlled study designed to evaluate the effects of DMR on glycemic and hepatic parameters in T2D patients. Ablation of the duodenal ligament (at the level of Treitz) was performed through magnetic resonance imaging proton density fat fraction (MRI-PDFF).

Method

The study involved a randomized phase of the protocol. Sites were required to conduct 1-5 ablations per site in the open-label phase, followed by a randomized phase of the protocol. Sites were required to conduct 1-4 (open-label) training cases.

Eligible subjects participated in 4 week run-in period to confirm stable baseline glycemic, as well as weight and lipid profiles. Subjects were randomized to receive DMR and MRI-PDFF data from the 11 of 24 subjects who had success data out to 12 weeks. 24 of 24 subjects underwent liver MR-PDFF, and we report hepatic MRI-PDFF data from the 11 of 24 subjects who had success liver data (defined as MRI-PDFF <5% at baseline).

Inclusion Criteria:

- Aged 28-75 years
- HbA1c >7.5-15.0%
- BMI 24.0-40 kg/m
- Fasting insulin >10 uIU/ml
- Sub-optimally controlled on one or more oral anti-diabetic medication

Exclusion Criteria:

- History of chronic or acute pancreatitis
- Known autoimmune disease, as evidenced by a positive Anti-GAD test,
- Current use of Insulin or GLP-1 drugs
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Key procedural metrics including procedure time, defined as catheter in to catheter out duration, and number of ablations completed vs. intended ablations were observed (Table 3).

Efficacy

- Compared to baseline, significant improvement in all parameters of HbA1c and other metabolic parameters were observed (Table 2).

No unanticipated adverse device effects were reported.

No device or procedure related serious AEs were reported.

Conclusions

- DMR offers a safe and significant potential for the treatment of high uncontrolled metabolic diseases, including in patients with both T2D and NAFLD/NASH.

Data from the randomized cohort is expected later this year.