Improvement in Hepatic Transaminases Over 12 Months After Single Procedure Duodenal Mucosal Resurfacing in Type 2 Diabetes Patients

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Type 2 diabetes (T2D) and fatty liver disease are often overlapping metabolic disorders, and insulin resistance is thought to be a common pathogenic driver. Moreover, simultaneous improvement of both conditions has been observed with insulin sensitizing interventions.¹ Duodenal Mucosal Resurfacing (DMR), a minimally invasive endoscopic procedure, has shown efficacy in improving metabolic indices in T2D likely via insulin sensitizing mechanism.²

To assess the 12 months efficacy data of a single DMR procedure in patients with uncontrolled T2D.

**Methods**

**Revita-1 study** Single arm, open label, multicentre study (NCT02879383).

**Subjects** Aged 25-75 years with T2D, HbA1c 7.5-10.0%, on oral glucose-lowering medication, treated in the first part of the study (Revita-1A) with dual catheter.

**Duodenal Mucosal Resurfacing**

- Step 1. Duodenal mucosal lifting
- Step 2. Mucosal circumferential ablation 9cm

**Glucoregulatory medication** Sulfonylureas were discontinued 4 weeks before DMR. Other glucose lowering medication was kept stable for ≥6 months post DMR with subsequent medication modifications following local/international guidelines.

**Postprocedural diet** Gradually normalized diet for 2 weeks post DMR.

**Efficacy analysis** We stratified patients with ≥1 ablation (3cm) into baseline alanine aminotransferase (ALT) level tertiles: lowest <28 U/L, middle 28-37 U/L, and highest ≥37 U/L. Change from baseline in ALT, aspartate aminotransferase (AST), body weight, homeostasis model assessment index (HOMA-IR) and HbA1c were analyzed using repeated measures ANOVA with Bonferroni correction.

**Results**

**Full cohort (n=27) demographics:**
- Age 55±9 y; BMI 32.5±4.2 kg/m²; ALT 37±21 U/L; HbA1c 8.7±1.0%; length DMR 8.1±0.4 cm (mean±SD)
- Although not displayed, qualitatively similar pattern of responses were observed with AST.

**High ALT tertile (n=9) demographics:**
- Age 50±11 y; BMI 33.6±2.4 kg/m²; ALT 59±22 U/L; HbA1c 8.9±0.8%; length DMR 8.0±0.7 cm (mean±SD)

**Background**

**Objective**

To assess the 12 months efficacy data of a single DMR procedure in patients with uncontrolled T2D.

**Conclusion**

A single DMR procedure in T2D patients produced significant reductions in Hba1c and hepatic transaminases for 12 months. In the high baseline ALT subgroup, decrease in ALT levels was more pronounced, patients appeared to be more obese and insulin resistant (BMI and HOMA-IR) and experienced the same improvement in glycemia (HbA1c) observed in the full cohort. Further studies are planned to quantify the efficacy, safety and durability of the hepatic and glycemic effects associated with DMR.

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¹Ferrannini, E. et al. Diabetes Care 2009

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