Duodenal Mucosal Resurfacing Elicits Improvement in Glycemic and Hepatic Parameters in Type 2 Diabetes: 1 Year Multicenter Study Results

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Introduction

- Duodenal resection via bariatric surgery is associated with early improvement of glycemic regulation which cannot be explained by induced metabolotropic processes alone. It is suggested that bypassing, excluding or altering nutrient presentation to the duodenum elicits distinct gut hormone responses which may improve glycemic control.
- Duodenal Mucosal Resurfacing (DMR) is a novel endoscopic procedure which has been shown to improve glycemic control at 6 months in type 2 diabetes (T2D). It is thought to exert insulin-sensitizing effects. DMR elicits calorie-basin independent mucosal healing following by hydrothermal ablation.

Methods

- We conducted a single arm, open label, international multicenter study.
- Patient Population
  - Age 25-75 years, HbA1c 7.5-10.0%, and using oral glucose lowering medication with a preserved insulin secretion defined as
- Follow-up
  - At baseline and 1, 3, 6, 9, and 12 months after DMR,
- Medication
  - Sulfonlureas and meglitinides were discontinued 4 weeks before DMR to mitigate the risk of hypoglycemia. Other glucose lowering medication was kept stable for at least 6 months post DMR and adjusted according to local guidelines thereafter.
- Safety
  - No unanticipated adverse device events were reported. One serious adverse event (SAE) was reported and considered to be procedure related (mild fever (8° C) and a decrease in procalcitonin level the first day after DMR that resolved quickly without sequelae. Seven additional SAEs were reported that were not procedure/device related.
- Efficacy
  - The DMR procedure was complete (length of 9-10 centimeters) in 37/37 patients with 37/37 in the per-protocol population.
- Table 1. Clinical characteristics at screening and baseline. Data are mean (standard deviation).

<table>
<thead>
<tr>
<th>Indices</th>
<th>12 months</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (%)</td>
<td>&gt;4.8±2.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>FPG (mg/dL)</td>
<td>&gt;140</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>HOMA-IR</td>
<td>&gt;2.5</td>
<td>&lt;0.001</td>
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<tr>
<td>Weight (kg)</td>
<td>&gt;81</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>ALT (U/L)</td>
<td>&gt;106</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>AST (U/L)</td>
<td>&gt;66</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Results

- Forty-six patients with T2D received a single DMR procedure. Baseline characteristics are shown in Table 1.

Conclusion

Single DMR treatment elicited significant and clinically relevant reductions in glycemic and hepatic parameters that were sustained at 12 months, suggesting considerable potential of DMR for the treatment of T2D. A randomized, sham-controlled study is underway.