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Session type Abstract Submission

Topic Randomized clinical trials comparing surgery vs medical treatment for diabetes

topics 1 Yes

topics 2 I confirm

Presentation preference

Oral Presentation

Abstact number WCITD19-0095

Abstract title EVALUATION OF THE EFFICACY AND SAFETY OF ENDOSCOPICALLY ACHIEVED PROXIMAL INTESTINAL EXCLUSION AS AN ADJUNCT TO

GLUCAGON-LIKE PEPTIDE-1 THERAPY IN DIABESITY: REVISE-DIABESITY RANDOMISED CLINICAL TRIAL

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Abstract text Background and Aims:

Innovative and effective treatments are needed to combat the global diabesity pandemic. Aims were to evaluate 1. efficacy and safety of endoscopic proximal intestinal exclusion, using Endobarrier, added to GLP-1RA therapy compared to either treatment alone, 2. maintenance following device removal.

Methods:

In this UK multicentre, open-label trial (ISRCTN00151053), adults with suboptimally controlled type 2 diabetes (T2D, HbA1c≥7.5%) and obesity (BMl≥35kg/m2) despite GLP-1RA (liraglutide 1.2mg daily) therapy were randomised to i) additional Endobarrier (EL_{1.2}) (ii) Endobarrier without GLP-1RA (E); (iii) liraglutide 1.8mg daily (L_{1.8}). Participants were seen 3-monthly for up to 1-year with device *in-situ* and up to 1-year post-removal.

Results

Of 70 treated (aged 52.2±10.1years, diabetes duration 11.2(7.8-14.9)years, BMI 40.9±4.7kg/m2, HbA1c 9.5±1.6%) there were no significant between-group differences and data were available in 63 (90%) at end-of-study (1-year post-device removal). Over 2-years, weight and HbA1c changed - 4.8±7.9kg and -1.6±1.9% (EL1.2, p=0.001), -5.0±8.3kg and -0.6±1.9% (E) and -1.9±4.8kg and -1.3±1.8% (L1.8). HbA1c reduction of >1% was maintained in 13/22 (59.1%) (EL1.2), 7/20 (35.0%) (E) and 10/21 (47.6%) in L1.8. There were 5 (10.4%) early device removals due to gastrointestinal symptoms and 5 Endobarrier-treated patients (10.4%) had serious device-related adverse events (bleed, obstruction, complex removal, liver abscess) with resolution in all cases.

Conclusions:

This is the first study to demonstrate combination proximal intestinal exclusion with GLP-1RA therapy is effective, well tolerated and has an acceptable safety profile. In patients with diabesity, treatment with Endobarrier is augmented by GLP-1RA therapy, with clinical benefit and advantage over either treatment alone.

Keywords

Endobarrier

GLP-1

type 2 diabetes
Obesity
device