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|-------------------------|--|
| Session type | Abstract Submission |
| Topic | Novel technologies and gastrointestinal devices for diabetes |
| topics 1 | Yes |
| topics 2 | I confirm |
| Presentation preference | Oral Presentation |
| Abstract title | DUODENAL JEJUNAL BYPASS LINER FOR DIABESITY – RISK VERSUS BENEFIT DATA FROM THE ASSOCIATION OF BRITISH CLINICAL DIABETOLOGISTS (ABCD) WORLDWIDE ENDOBARRIER REGISTRY |
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Abstract text **Background and Aims:**

There is uncertainty over risk-to-benefit ratio of proximal intestinal exclusion with EndoBarrier, a novel endoscopic duodenal-jejunal liner device for diabetes.

Methods:

During 2017, an independent, secure, online registry was established under the auspices of ABCD, to collect EndoBarrier safety and efficacy data worldwide.

Results

By October 2018, data had been entered on 540 patients {mean±SD age 52.1± 10.7years, 61% male, 85% euorpid, 64.2% diabetes, BMI 41.3±10.0kg/m²} from 13 centres in 7 countries: Australia, Austria, Brazil, Czech-Republic, Israel, Netherlands and United-Kingdom. In those with both baseline and removal data, mean±SD weight fell by 13.6±10.1kg from 120.7±26.4 to 107.1±24.8kg(n= 447,p<0.001), HbA1c from 8.2±1.8 to 6.9±1.1%(n =334,p<0.001), systolic BP from 138.7±18.3 to 130.3±17.1mmHg(n=189,p<0.001) and cholesterol from 4.7±1.2 to 4.2±1.0mmol/L(n =247,p<0.001). Table 1 shows the impact of EndoBarrier depending on the initial HbA1c. There were 30(5.6%) serious adverse events(SAE) and 64(11.9%) less-serious SAEs (table 2). All SAE patients made a full recovery. The median(range) weight loss in those with early removal for gastrointestinal-bleed was 7.4(0-29) and with for liver abscess was 17.2(7–24.5)kg.

Table 1. Impact of EndoBarrier on HbA1c depending on baseline HbA1c.

Conclusion – the higher the baseline HbA1c the greater the impact. Values are mean±SD

| HbA1c (%) | n | Baseline | At removal | Difference | P value |
|-----------|-----|------------|------------|------------|---------|
| All HbA1c | 334 | 8.2±1.8 | 6.9±1.1 | 1.4±1.2 | <0.001 |
| ≥ 7 | 246 | 8.9±1.5 to | 7.3±1.0 | 1.6±1.4 | <0.001 |
| ≥ 7.5 | 212 | 9.2±1.4 | 7.4±1.0 | 1.8±1.4 | <0.001 |
| ≥ 8 | 169 | 9.6±1.4 | 7.5±1.0 | 2.0±1.5 | <0.001 |
| ≥ 9 | 95 | 10.5±1.2 | 7.7±1.1 | 2.8±1.4 | <0.001 |

Table 2. Serious adverse events in 540 EndoBarrier treated patients.

| Serous Adverse Event | n | % |
|--|-----------|------------|
| Early removal because of GI bleed | 18 | 3.3 |
| Liver abscess (early removal = 6/7; found at time of routine explant = 1/5) | 7 | 1.3 |
| Early removal because of pancreatitis | 2 | 0.4 |
| Early removal because of cholecystitis | 1 | 0.2 |
| Abdominal abscess due to small perforation of bowel in relation to Endobarrier | 1 | 0.2 |
| Liver abscess after prolonged implant* | 1 | 0.2 |
| Total | 30 | 5.6 |
| Less serious adverse event | n | % |