

Safety and efficacy of the endoscopic duodenal–jejunal bypass liner prototype in severe or morbidly obese subjects implanted for up to 3 years

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Abstract

Background: The duodenal–jejunal bypass liner (DJBL) is an endoscopic device that mimics the duodenal–jejunal exclusion component of the Roux-en-Y gastric bypass. Previous studies assessing the efficacy of the DJBL have shown 10-40% excess weight loss (%EWL) and improvements in obesity-associated comorbidities. The aim of this study was to evaluate the safety and efficacy of a new DJBL prototype over a 3-year period. **Methods:** Morbidly obese subjects were enrolled in a single-arm, open-label, prospective trial. The subjects were offered the opportunity to continue with the trial annually and signed a new consent form. The primary endpoint was safety. The secondary endpoints were changes in weight and biochemical parameters from baseline. **Results:** The DJBL was implanted endoscopically in 80 subjects (age: 35±10 years; 69% female; weight: 109±17 kg; BMI: 42±5.4 kg/m²). Seventy-two severe adverse events (AEs) were observed in 55 patients (68%), of which nine subjects required a prolonged hospital stay and three subjects required major interventions. Overall, 23 subjects (29%) underwent early device removal due to AEs. Additionally, 95% of the patients experienced mild AEs that mainly consisted of abdominal pain. The severe AEs included a liver abscess (3), upper GI bleeding (4), cholangitis (1), and acute pancreatitis (1) and mostly occurred after 12 months of follow-up. Two patients presented a short esophageal perforation during explantation. These perforations were successfully managed with endoscopic closure in one subject and medical treatment in the other subject. In the completer population at 52 weeks (71 patients), 104 weeks (40 patients), and 156 weeks (11 patients), the mean %EWL were 44 ± 16, 40 ± 22, and 39 ± 20, respectively (p < 0.001). **Conclusion:** This study shows significant and sustained weight loss after 3 years of treatment with the new DJBL. However, the high frequency and severity of AEs preclude the use of this prototype for periods longer than 1 year..

Keywords

Obesity, Endobarrier, Bariatric, Endoscopy.