

Six month results of a multi-center, prospective, randomized trial of the endoscopic Duodenal-Jejunal Bypass Liner for the treatment of type 2 diabetes in obese subjects

P. Koehestanie MD, B. Meesters MD, I.M.C. Janssen MD, N. Bouvy MD, PhD, J.W. Greve MD, PhD

Correspondence: P. Koehestanie, MD, Email address: pkoehestanie@rijnstate.nl, Tel: +31880053567

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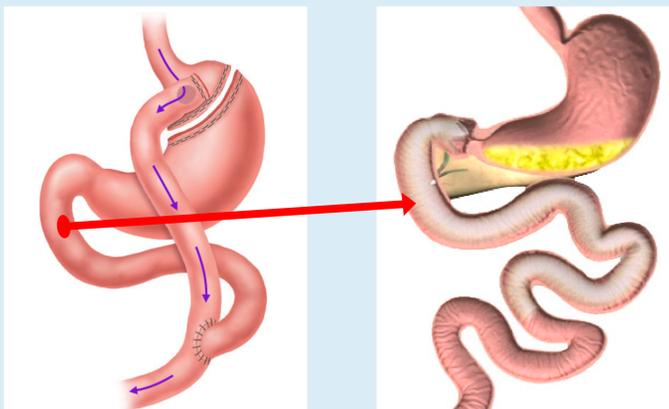
Background

The worldwide increase in obesity results in an exponential increase in type 2 diabetes mellitus (T2DM). Surgical treatment has proven to be very effective however with the risk of serious complications. The duodenal-jejunal bypass liner (DJBL, Endobarrier®, GI Dynamics) is an endoscopic implant that mimics the intestinal bypass portion of the Roux-en-Y gastric bypass. It results in weight loss and improvements in glucose control in obese subjects with T2DM.

Method

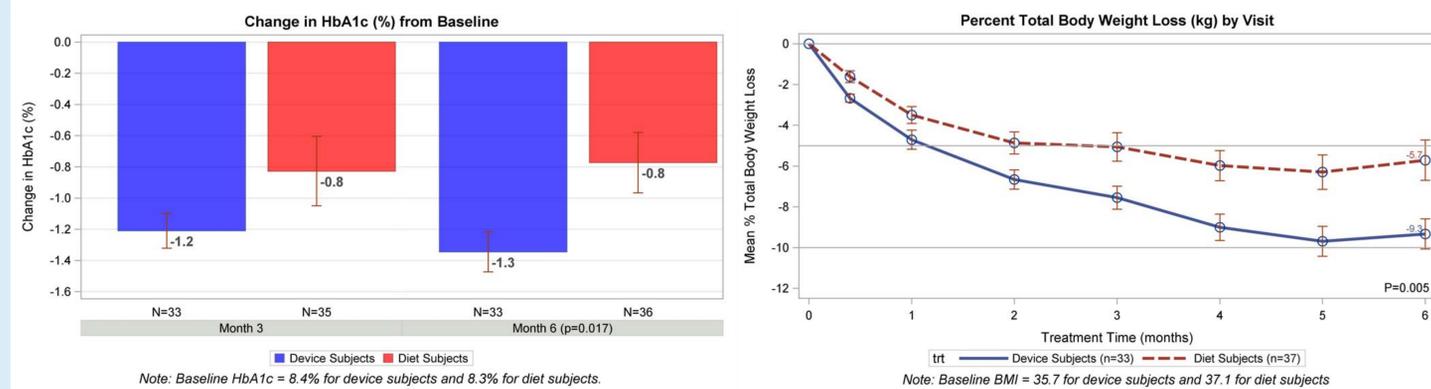
This is an interim report of an ongoing one year study. In a prospective, randomized, diet controlled, multicentre study, 77 subjects were included, 38 device and 39 diet controls, treatment 6 months with 6 month follow-up. The groups were comparable with respect to age, gender, BMI (mean 35.7 vs. 37.1 kg/m²), duration of T2DM (5.2 vs. 5.3 years), HbA1c (8.4 % vs 8.3 %) and T2DM treatment.

Roux-en-Y Gastric bypass VS Duodenal-Jejunal bypass



Results

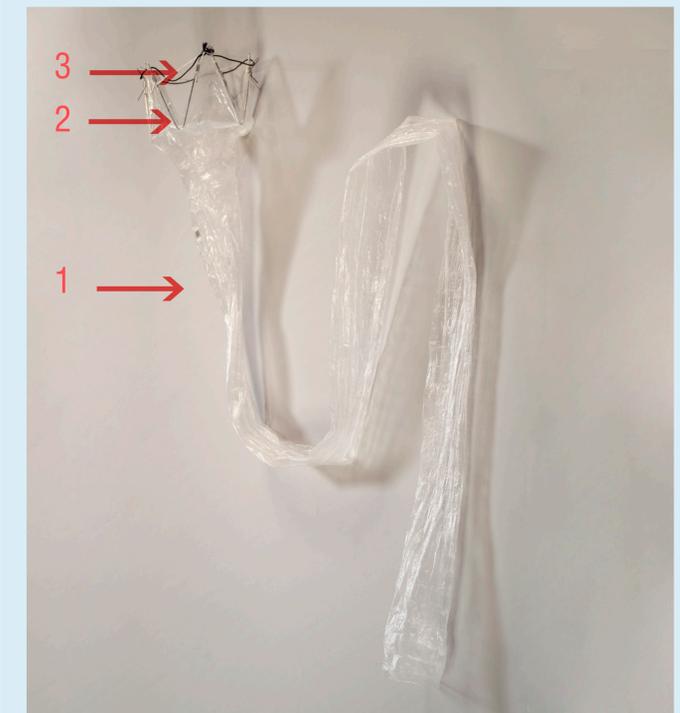
In the device group thirty four devices were successfully implanted (3 implant failures 1 withdrawal). Only one device was explanted prior to the initial protocol end point because of DJBL obstruction and continuous epigastric pain. The remaining patients all completed the study. Mean procedure time was 32.2 minutes (range: 9–137 minutes) for a successful implantation and 11.4 minutes (range: 4–65 minutes) for explantation. During the study period the 26 (68.4%) DJBL patients had at least one adverse event, mainly abdominal pain and nausea during the first week after implantation. At six months there was significantly better weight loss and significantly improved HbA1c % in the device group. Medicinal treatment was reduced in more device subjects than controls.



Complications (all minor)

System Organ Class/Preferred Terms	Device (N=38) n (%)	Control (N=39) n (%)	Total (N=77) n (%)
Number of Subjects with at Least One Adverse Event	26 (68.4)	19 (48.7)	45 (58.4)
Gastrointestinal disorders			
Abdominal pain	25 (65.8)	5 (6.5)	30 (39)
Constipation	3 (7.9)	3 (7.7)	6 (7.8)
Diarrhoea	0	3 (7.7)	3 (3.9)
Melaena	1	0	1 (1.3)
Nausea	5 (13.2)	3 (7.7)	8 (10.4)
Vomiting	4 (10.5)	2 (5.1)	6 (7.8)
Bleeding	1 (2.6)	0	1 (1.3)
Hepatobiliary disorders (Cholelithiasis)	1 (2.6)	0	1 (1.3)
Metabolism and nutrition disorders			
Hyperglycaemia	0	1 (2.6)	1 (1.3)
Hypertriglyceridaemia	1 (2.6)	0	1 (1.3)
Hypoglycaemia	7 (18.4)	7 (17.9)	14 (18.2)
Iron deficiency	1 (2.6)	0	1 (1.3)
Vitamin D deficiency	1 (2.6)	2 (5.1)	3 (3.9)
Musculoskeletal and connective tissue disorders			
Back pain	2 (5.3)	1 (2.6)	3 (3.9)
Flank pain	1 (2.6)	0	1 (1.3)
Respiratory, thoracic and mediastinal disorders			
Pharyngeal oedema	1 (2.6)	0	1 (1.3)
Pharyngolaryngeal pain	1 (2.6)	0	1 (1.3)

DJBL



DJBL is comprised of an impermeable fluoropolymer sleeve of 60 cm (1) and a nitinol anchor with barbs (2). The polypropylene drawstring (3) is necessary for removal of the device.

Conclusion

The DJBL is a safe and effective treatment for T2DM in obese subjects. It shows better results in terms of HbA1c reduction, weight loss and significantly medication reduction compared to an intensive diet treatment.