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Final results of multi-center, prospective, controlled trial of the duodeno-jejunal bypass liner for the treatment of type 2 Diabetes mellitus in obese patients: Efficacy and factors predicting a suboptimal effect

Marek Benes, Julius Spicak, Pavel Drastich and **Tomas Hucl**
Institute of Clinical and Experimental Medicine, Czech

Introduction: The global increase in obesity incidence results in an increase of type 2 diabetes mellitus (T2DM). Surgical treatment has proven to be effective; however it carries a high risk of complications. The duodenal-jejunal bypass liner (EndoBarrier®, GI Dynamics, EB) 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 patients with T2 diabetes mellitus (T2DM).

Aims & Methods: This is a final report of a prospective, controlled, multicentre study aimed to determine the effectiveness of EB and to identify factors associated with a sub-optimal outcome of EB.

Results: 70 subjects (45 with an implant, 25 controls) were included in the study. The groups were comparable with respect to age, gender, BMI (mean 41.7 vs. 39.5 kg/m2), T2DM duration (7.8 vs. 8.3 years), HbA1c level (88 vs. 86 mmol/mol) and T2DM treatment. In the EB group, all devices were successfully implanted. Only six devices had to be explanted prior to the end of the 10 months study period (bleeding, dislocation and need for ERCP because of choledocholithiasis). The mean procedure time was 17 minutes for an implantation and 16 minutes for an explantation. At 10 months, there was significantly greater weight loss and %EWL (19% vs. 7% and 43 vs. 12) and significantly improved long term compensation of T2DM marker HbA1c (decreased by 25 vs. 10 mmol/mol) in the EB group. T2DM medicinal treatment could be reduced in more device subjects than controls. There was no serious adverse event. Mild abdominal pain and nausea after implantation were experienced by 60% of patients during first 14 days after implantation, 30% of patients during the first month and 10% of patients after one month. Lower initial BMI and lower body height were identified as negative prognostic factors for pain, but positive for efficacy of EB.

Conclusion: The EB is safe when implanted for 10 months, and results in significant weight loss and HbA1c reduction. This suggests that this novel device is a candidate for the primary therapy of morbid obesity and T2DM. Lower initial BMI and lower body height could be negative prognostic factor for pain, but positive for efficacy.

mabx@ikem.cz