

Case report

Implantation of the duodenal-jejunal bypass sleeve under conscious sedation: a case series

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The duodenal-jejunal bypass liner (EndoBarrier[®], GI Dynamics, Lexington, MA) is a 60-cm impermeable fluoropolymer device, which, after endoscopic deployment in the proximal duodenum, functions to prevent partially digested food from contacting the proximal intestine [1,2]. The duodenal-jejunal bypass liner has been evaluated in clinical studies of patients with morbid obesity, where it has been shown to result in substantial weight loss after 12 or 24 weeks [3,4]. In obese patients with type 2 diabetes, improvements in glycemic control were evident within 1 week of device implantation and were sustained through 24 weeks [5]. In these and other clinical trials of the duodenal-jejunal bypass liner, device implantation has been performed under general endotracheal anesthesia. In this report, we present the first series of subjects in whom the duodenal-jejunal bypass liner was deployed under conscious sedation alone.

Case report

Three consecutive subjects who were enrolled in a non-randomized, prospective trial at the Pontificia Universidad Católica de Chile were selected for implantation of the duodenal-jejunal bypass liner under conscious sedation (Clinicaltrials.gov no. NCT00985491). The ethics committee of the Faculty of Medicine approved the trial. All study

participants provided written informed consent. These patients were selected based on the predictors of successful intubation (Mallampati grade [6] and the size of the mouth opening [Table 1]) in the event that conversion from conscious sedation to general endotracheal anesthesia was required.

The subjects were admitted to the hospital on the morning of device implantation after 12 hours of fasting. The subject characteristics are detailed in Table 1. The procedure was performed in the operating room, where conversion to general endotracheal anesthesia was readily available, if needed.

Conscious sedation was monitored by anesthesiologists using a 3-lead electrocardiogram, continuous pulse oximetry, automated noninvasive blood pressure recording, nasal capnography, and bispectral index scale (Aspect A-2000 BIS[™] Monitor, version 3.2 XP, Natick, MA). The subjects were sedated using dexmedetomidine .5 $\mu\text{g}/\text{kg}$ infused within 10 minutes and then continued at an infusion rate of .5 $\mu\text{g}/\text{kg}/\text{hr}$. Phentanyl .5 $\mu\text{g}/\text{kg}$ and propofol were administered using a target-controlled infusion rate started with effect site targets of .5–1.5 $\mu\text{g}/\text{mL}$ and adjusted to maintain bispectral index scale values of 60–75. Per-kilo doses were determined from the total body weight. All subjects were able to maintain spontaneous respiration with arterial oxygen saturation >92% on 2–4 L/min oxygen by nasal cannula.

The duodenal-jejunal bypass liner implantation was performed under endoscopic visualization and fluoroscopic guidance, as previously described [3]. The mean procedure time was 23 minutes (range 18–32), and all subjects were brought to the recovery room in stable condition. During the

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Table 1
Baseline characteristics

Pt. No.	Gender	Age (y)	Body weight (kg)	BMI (kg/m ²)	Co-morbidities	ASA physical status*	Mallampati grade [6]	Mouth opening (cm)
1	Male	31	129.5	48.3	Insulin resistance Depression	2	I	4
2	Male	28	116.1	36.0	Hypertension Fatty liver disease	2	I	4
3	Female	39	89	36.1	Type 2 diabetes Hypertension	2	I	4

Pt. No. = patient number; BMI = body mass index; ASA = American Society of Anesthesiologists.

* American Society of Anesthesiologists physical status classification (ASA physical status 2 indicates a patient with mild systemic disease; available from www.asahq.org/clinical/physicalstatus.htm, accessed June 13, 2011).

recovery phase, their vital signs remained stable, and no cases of clinically significant hypoxic episodes, vomiting, or adverse effects were observed. No subject had any recall of the procedure, and all were discharged the following day, tolerating a liquid diet.

Discussion

The development of the duodenal-jejunal bypass liner is in its early stages. A total of 96 patients have been treated with the duodenal-jejunal bypass liner in 5 clinical studies, with planned implant durations of 12–24 weeks [1,3–5,7]. In each of these studies, device implantation has been performed with the patient under general endotracheal anesthesia. Obesity and its associated comorbidities (e.g., restrictive lung disease, obstructive sleep apnea) can confer increased sensitivity to the effects of anesthesia, including the loss of pharyngeal muscle tone and superior airway obstruction [8]. Endoscopic implantation of the duodenal-jejunal bypass liner under conscious sedation might be preferable in select patients and might reduce the costs and decrease recovery time. The positive results presented in the present case series support the study of the duodenal-jejunal bypass liner using conscious sedation for device implantation. However, it is important to note that obesity can also increase the risk of complications during conscious sedation [9].

Bariatric surgery in obese subjects has been associated with long-term sustained weight loss and improved mortality compared with conventional medical treatment [10]. In addition, early onset and sustained improvement in type 2 diabetes has been reported [11]. Despite these benefits, the perceived risk of the surgical procedure raises concerns among physicians and patients and could explain in part why many obese patients do not consider bariatric surgery for the treatment of obesity [12].

In clinical studies, the duodenal-jejunal bypass liner has resulted in substantial weight loss [1,3–5,7] and was

reported to improve glucose metabolism in obese patients with type 2 diabetes [5]. These observations suggest that by preventing contact of partially digested food with the proximal intestine, the device might be mimicking the anatomic rearrangement of the Roux-en-Y gastric bypass procedure [11].

The use of conscious sedation during the implantation of the duodenal-jejunal bypass liner might make this treatment of obesity attractive to a larger number of obese patients by eliminating general endotracheal anesthesia as a perceived barrier to its use. It is important to note that additional study in a larger group of obese patients is necessary to establish the safety of the use of conscious sedation during duodenal-jejunal bypass liner implantation.

Disclosures

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