Abstract

Background: Bariatric surgery offers the best solution in management of obesity and related metabolic ailments, paving the way for a concept termed metabolic surgery. We report the results of a novel surgical procedure on glycemic control and metabolic syndrome in poorly controlled type 2 diabetes.

Methods: Ten patients (four men, six women) underwent laparoscopic surgical procedure of sleeve gastrectomy and ileal interposition. All patients had diabetes for more than 3 years with poor control despite use of oral hypoglycemic agents (OHAs) and/or insulin. The primary outcome was remission of diabetes (hemoglobin A1c <7% without OHAs/insulin), and secondary outcomes were change in OHA requirement, components of metabolic syndrome, insulin resistance, and microalbuminuria.

Results: We report the preliminary postoperative follow-up data of 9.1 ± 5.3 months (range, 2–16 months). Participants had a mean age of 48.2 ± 9 years (range, 34–62 years), duration of diabetes of 11 ± 5.7 years (range, 4–25 years), and preoperative body mass index of 33.8 ± 6.5 kg/m². Seven patients had diabetes remission, and the remaining three showed significantly decreased OHA requirement. All participants had weight loss ranging between 15% and 30% and had remission of hypertension. Microalbuminuria (96.8 ± 19.1 vs. 46.7 ± 10.1 mg/L, P = 0.03568) and insulin resistance as assessed by homeostasis assessment model of insulin resistance (5.2 ± 2.1 vs. 1.8 ± 0.9, P = 0.0005) decreased significantly after surgery.

Conclusions: Our preliminary observations demonstrated the feasibility, safety, and efficacy of this novel surgical procedure in type 2 diabetes. Further long-term data from more patients are necessary to confirm these findings.

Introduction

Obesity and type 2 diabetes mellitus (T2DM) have reached epidemic proportions, and the scientific world is exploring new methods of tackling this diabesity. The Asian population has higher insulin resistance (IR) at the same body weight than the Western population. Surgical procedures offer the best treatment for obesity along with beneficial effects on hyperglycemia, hypertension, and dyslipidemia. Remission of diabetes is reported more in procedures that affect the entero-insular axis than pure restrictive procedures. Recent reports have identified improvement in glucose homeostasis after bariatric surgery that is independent of weight loss. Reduced incretin effect coupled with IR contributes significantly towards diabetes in nonobese individuals. Bariatric surgery in these nonobese patients also offers excellent benefits on control of diabetes and co-morbid ailments, leading to change in the concept as “metabolic surgery.”

With increasing number of bariatric surgeries performed, modifications have been explored to minimize the associated malabsorption and morbidity. Ileal interposition is a novel procedure that involves shift of an ileal segment proximally into the jejunum. This procedure coupled with sleeve gastrectomy results in effective glycemic control. This procedure does not involve bypass or diversion of food from the digestive hormones, thus minimizing the malabsorption. We started a prospective observational study to determine the effects of this novel procedure for treatment of poorly controlled T2DM in overweight or obese patients.
We report here the clinical data and postoperative results in the initial 10 patients.

Patients and Methods

We started a prospective study to evaluate the effects of ileal interposition with sleeve gastrectomy for treatment of T2DM in overweight or obese patients in January 2008. The hospital’s ethical committee approved the study, and all patients provided written informed consent. Of a total of 12 patients who were operated up to now, we report the preliminary data of first 10 patients. The patients were subdivided into two groups based on the duration of follow-up: Group A with follow-up of more than 10 months (n = 5) and Group B with follow-up of less than 10 months (n = 5).

The inclusion criteria were patients having T2DM of 3 years or more in duration with optimum prescribed therapy with hemoglobin A1c (HbA1c) > 8%, age between 30 and 75 years, body mass index (BMI) of 25–45 kg/m², stable weight for the last 3 months, and post-meal C-peptide level > 1.5 ng/mL. The exclusion criteria were duration of diabetes more than 25 years, post-meal C-peptide levels < 1 ng/mL, pregnancy, chronic kidney disease (glomerular filtration rate < 60 mL/min), coexisting severe hepatic/neurological/psychiatric disorder, and obesity due to nonendocrine illness.

Preoperative evaluation included history of T2DM and complications, physical examination for suitability of surgery, blood tests, urinalysis, and imaging studies. Fasting samples were analyzed for glucose, total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), triglycerides (TG), serum creatinine, and plasma insulin. Post-meal samples were taken for estimation of C-peptide and plasma glucose. The morning urine sample was used for estimation of microalbuminuria, and glomerular filtration rate was calculated using the modified Cockcroft-Gault equation. IR was derived from the homeostasis model assessment (HOMA) formula (HOMA-IR) using fasting blood glucose and insulin.

The operation was performed under general anesthesia with a standard six-port laparoscopic technique. The surgical procedure involves creation of a 170-cm segment of ileum, starting at 30 cm proximal to the ileocecal junction. This segment is interposed into jejunum, which was divided between 20 and 50 cm from the ligament of Treitz. All three anastomoses were performed side-by-side with an endo-GIA stapler (Ethicon Endo-surgery, Cincinnati, OH) with a 45-mm cartridge, and the stapler openings were closed by hand with a 3/0 polydioxanone suture in two layers. The sleeve gastrectomy was performed after devascularization of the greater curvature from the antrum to the fundus area. The lumen of the stomach was adjusted by a 32–58 French calibrator (Romsons International, New Delhi, India) that was placed along the lesser curvature. The endo-GIA stapler with 60-mm