

Ileal Interposition with Sleeve Gastrectomy for Type 2 Diabetes Mellitus and Metabolic Syndrome

58

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Abstract

“Diabesity,” ie a combination of type 2 diabetes mellitus (T2DM) and obesity, is increasing in epidemic proportions. Medical management of diabetes mellitus requires that patients remain compliant to their medication regimen and monitor the condition closely; patients are also required to make changes in lifestyle and diet. However, over time the pancreatic B cell function deteriorates and this leads to increased requirement of medications and may also lead to introduction of insulin based therapy. Laparoscopic ileal interposition (II) with sleeve gastrectomy (SG) is an evolving procedure that offers good control of type-2 diabetes and other metabolic derangements and also helps in weight reduction without causing significant malabsorption. In this chapter, the two versions of this procedure, jejunal (non-diverted) and duodenal (diverted) ileal interposition, along with patient selection criteria, mechanisms of action, postoperative care and follow up, and its advantages are described. This is a promising procedure for control of type 2 diabetes, hypertension, obesity, and associated metabolic abnormalities in obese but also in non-obese.

Keywords

Type-2 diabetes • Metabolic syndrome • Co-morbidities • Ileal interposition • GLP-1 • Incretins • Ileal brake • Remission

58.1 Introduction

The combination of type 2 diabetes mellitus (T2DM) and obesity—“Diabesity”—is increasing to epidemic proportions. In 2013, the estimated worldwide prevalence was 347 million, including 63.5 million in India. Effective medical management of diabetes mellitus requires changes in lifestyle and diet, coupled with good compliance with medication regimens and

close monitoring. However over time, pancreatic B cell function deteriorates and this may lead to increased requirement of medications and introduction of insulin based therapy [1, 2].

Bariatric surgery performed as a treatment for morbid obesity is associated with improvements in blood glucose control and resolution of T2DM, along with significant weight loss. The mechanisms for these improvements are under investigation and include caloric restriction through behavioral and hormonal changes, alterations in gut hormone release and gastrointestinal physiology and through malabsorption [3]. For non-obese patients with T2DM, the standard bariatric techniques may not be applicable, given that malabsorption and significant weight loss is not a desired or acceptable side effect in this patient group.

In view of this, Aureo DePaula from Brazil pioneered the development of ileal interposition combined with a variable BMI adjusted sleeve gastrectomy in 2003 [4, 5]. This operation was devised particularly for patients with T2DM with a

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lower body mass index (BMI) in the non-morbidly obese (BMI less than 35 kg/m²).

After the initial publication of successful outcomes in 2005, this procedure was also taken up in various centers worldwide. Moreover, extensive animal studies have been conducted in Cincinnati, USA to aide understanding. Studies have confirmed that ileal interposition with sleeve gastrectomy (II+SG) induces remission of T2DM in patients with BMI 23–34 kg/m², and is also effective in ameliorating other components of the metabolic syndrome [6–9].

58.2 Ileal Interposition with Sleeve Gastrectomy

Ileal interposition with variable sleeve involves transposing a 170 cm segment of terminal ileum to the jejunum or the duodenum, along with variable gastroplasty depending on the BMI of the patient (see Fig. 58.1).

There are two versions of the procedure:

- the jejunal ileal interposition with sleeve gastrectomy (JII+SG), when the ileal segment is interposed into the proximal jejunum, at 20–50 cm from ligament of Trietz, without any bowel exclusion
- the duodenal ileal interposition with sleeve gastrectomy (DII+SG) where the duodenum and proximal 50 cm of jejunum are excluded and bypassed [4, 6].

Variable sleeve gastrectomy



Fig. 58.1 BMI-adjusted sleeve gastrectomy

DePaula et al. reported the results of a randomized clinical trial (RCT), comparing these two versions and showed that DII+SG is more effective, even in severe disease [10].

58.2.1 Mechanisms of Action

The anatomical modifications after II+SG are thought to lead to resolution of T2DM through multiple actions, postulated in both foregut and hindgut theories [10]. Changes occur in gut microbiota, bile acid absorption and gut hormone release [11]. Increased post prandial glucagon like peptide-1 (GLP-1) release is thought to be a major factor responsible for the same (see Fig. 58.2) [12].

58.2.2 Selection of Patients

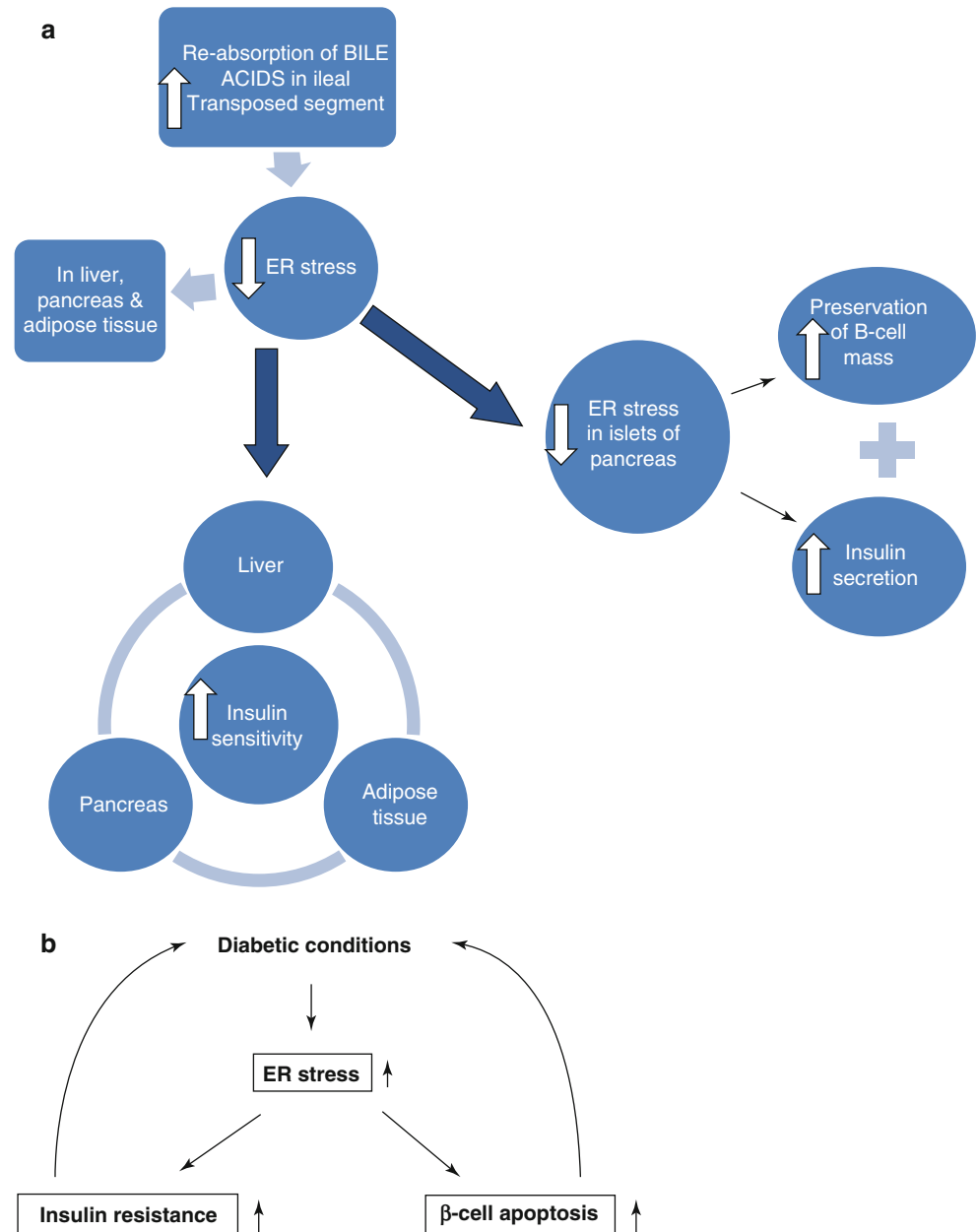
The indications for II+SG include

- Worsening T2DM of more than 1 year duration, with or without additional risk factors and comorbidities (microvascular or macrovascular complications)
- Diabetes with mild to moderate complications like nephropathy/retinopathy/nonhealing ulcers
- Diabetes with strong family history of complications
- Poor glycemic control despite optimum medical management
- Age between 20 and 70 years
- Stable weight for last 3 months (variation in weight less than 3 %)
- BMI more than 20 kg/m²
- Fluctuating glycemic control with comorbidity despite good HbA1c levels
- Stimulated C-peptide level more than 1 ng/mL.

58.2.3 Exclusion Criteria

- Type 1 diabetes mellitus, latent autoimmune diabetes of adult (LADA) or maturity onset diabetes of the young (MODY) – through estimations of glutamic acid decarboxylase (GAD) antibody/islet cell antibody (ICA)/insulin auto-antibody (IAA2) and clinical course evaluation by the endocrinologists
- Undetectable fasting C-peptide and stimulated C-peptide less than 1 ng/mL
- Positive urine ketones
- Pregnancy
- Coexisting severe hepatic, pulmonary, renal (glomerular filtration rate (GFR) less than 30 mL/min), cardiovascular, neurological and psychiatric diseases

Fig. 58.2 (a) Major Role of the Transposed Ileal Segment – Reabsorption of Bile Acids causing Decreased Endoplasmic Reticulum Stress. (b) Continued Worsening of Diabetes due to Increased Endoplasmic Reticulum Stress



- Obesity due to organic illness
- Addiction to alcohol or illicit drugs

more likely to benefit the patient [13]. JII+SG was performed in patients with less severe disease and higher BMI, while DII+SG was used for those with higher DSRS and lower BMI (Table 58.1).

58.3 Preoperative Evaluation

Evaluation includes clinical history of T2DM, comorbidities and complications and thorough physical examination. Pancreatic B-cell function was estimated by measurement of serial serum C-peptide levels in response to a mixed meal test or OGTT, glucose load of 75 g. Patients with well-preserved B-cell function are more likely to benefit from surgery.

A 'Diabetes Severity and Remission Score' (DSRS) has been developed to determine which type of surgery was

58.4 Procedure

These operations can be performed totally laparoscopically, by a hybrid method or by combining laparoscopic and robotic surgery. When introducing the technique, the hybrid operation may be employed (laparoscopic sleeve gastrectomy, followed by small bowel surgery by mini-laparotomy). This allows the surgeon to understand the anatomical changes

Table 58.1 Diabetes severity & remission score

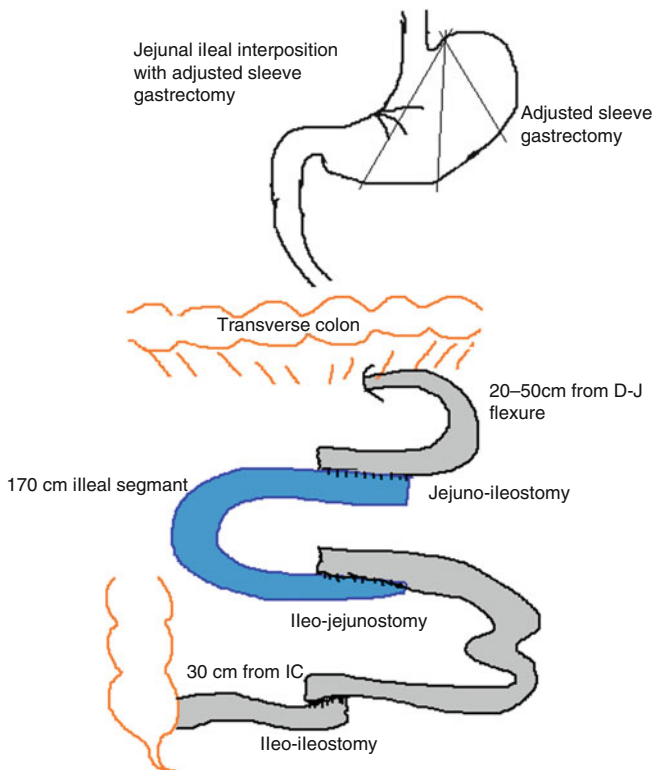
Parameters	Score	
	1	2
Age (years)	30–60	>60 or <30
BMI (kg/m ²)	>27	≤27
Duration of diabetes (years)	<10	≥10
Microvascular involvement (Nephro/retino/neuropathy)	Absent	Present
Macrovascular involvement (Cardio/cerebro/peripheral vascular)	Absent	Present
Mandatory insulin usage	No	Yes
Stimulated C-peptide (ng/ml)	≥4	<4

Grading of diabetic severity

Grade I diabetes if total score is 7–8

Grade II = 9–11

Grade III Severe diabetes if total score is 12–14

**Fig. 58.3** Jejunum ileal interposition with sleeve gastrectomy

more clearly, including the nature of the mesenteric defects created during ileal interposition which must be closed after each anastomosis.

The operation is performed under general anesthesia with a standard six port laparoscopic technique. Once the greater omentum is disconnected from the greater curve of stomach, from antrum to fundus, a variable sleeve gastrectomy, adjusted to the BMI, is performed first (see Fig. 58.3, which depicts diagrammatic representation of the procedure)

58.4.1 Jejunum Ileal Interposition (Non-Diverted) with Variable Sleeve Gastrectomy

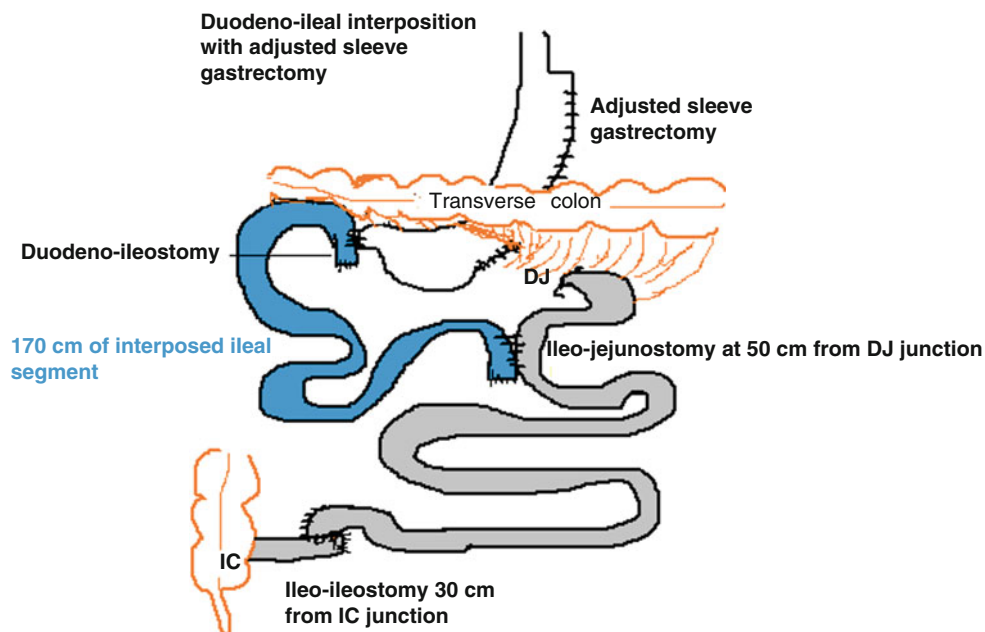
1. Sleeve gastrectomy is followed by staple line reinforcement with continuous sutures of 3-0 polydioxanone, or reinforcement, with glue.
2. Transection of jejunum between 20 and 50 cm from ligament of Trietz with suture marking of the proximal and distal margins for identification. If BMI is more than 35, transection is done at 50 cm, to give a greater ileal brake effect, for better weight control.
3. Second small bowel transection at 30 cm proximal to ileo-caecal valve (ICV), with sufficient division of mesentery for freedom of movement for a relaxed anastomosis, with marking of the transected ends.
4. Third transection at 200 cm proximal to ICV, creating the ileal segment of 170 cm. The ileal segment is run through to reconfirm correct placement of marking sutures and also the base of mesentery is checked to ensure it is broad-based with good vascular supply for the whole segment (see Video 58.1).
5. Distal anastomosis is created first (ileo-ileal) to reestablish continuity, with endostapler using white 45 mm cartridge, and 3-0 polydioxanone single layer suture closure for the stapler opening. The mesenteric gap is closed with 3-0 polypropylene interrupted sutures (see Videos 58.2 and 58.3).
6. The second anastomosis is the proximal one (jejuno-ileal) and is performed as above.
7. The third anastomosis (ileo-jejunal), in similar fashion, is made after retracing the bowel to confirm the appropriate limbs.
8. After hemostasis is secured, the resected gastric tissue is removed. Drain placement is at the surgeon's discretion.

58.4.2 Duodenal Ileal Interposition (Diverted) with Variable Sleeve Gastrectomy

In this technique the duodenum is transected 3–4 cm distal to pylorus, and the ileal segment is interposed from that point, to 50 cm distal to D-J flexure, so that food bypasses the duodenum and proximal jejunum (Fig. 58.4).

1. The lumen of the stomach is cannulated with a 36–60 French calibrator. Non-obese patients undergo fundectomy, leaving a good volume of residual stomach. Division of the greater omentum along the greater curvature of the stomach is continued onto the duodenum, 3–4 cm beyond the pylorus.
2. After posterior duodenal dissection is done, identifying the gastro-duodenal artery and pancreatic tissue, the

Fig. 58.4 Duodenal ileal interposition with sleeve gastrectomy



3. A distal ileal segment of 170 cm is created.
4. Continuity of small bowel is restored by ileo-ileal anastomosis.
5. The proximal end of the transected ileal segment is interposed and anastomosed in iso-peristaltic manner, to the proximal duodenum. This anastomosis is done end-to-side in one or two layers using intracorporeal suturing with 3-0 polydioxanone (see Videos 58.6 and 58.7).
6. A point in the jejunum, at 50 cm from the ligament of Treitz is measured, and anastomosed to the distal part of the interposed ileum, in a side to side fashion, using stapler and 3-0 polydioxanone sutures (see Video 58.8).
7. All anastomoses are performed functionally using linear staplers with care taken to close the mesenteric defects using interrupted 3-0 polypropylene sutures (see Video 58.9).
8. Since the endoscopic access to the bile duct is lost, a concomitant cholecystectomy is always done if gallstones are present (even if they are asymptomatic) or whenever signs of cholecystitis are seen, and also for all patients from non-urban areas; this makes up 40–80 % of the patients.
9. The 10 and 12 mm trocar openings are closed with 1-0 polydioxanone sutures using a suture passing instrument, after removing the gastric specimen ± the gallbladder, and placing a flat penrose drain along the sleeve and the duodenal stump.

58.5 Postoperative Regimen

Postoperatively, the plasma glucose levels are to be measured three hourly, with insulin used according to sliding scale. The patients are kept on a liquid diet, started 24–36 h after surgery, for 5–7 days. This is followed by semisolid diet for another 7 days, and finally a solid diet. The patients are discharged between the third and fifth postoperative day with vitamin supplements including B1, B12, D, high protein drinks and calcium and iron supplements. Upper gastrointestinal endoscopy is performed for patients with symptoms of dysphagia to check for gastric stricture. Routine follow up visits, including clinical and laboratory evaluation, are scheduled at 1, 3, 6, 9 and 12 months and every 6 months thereafter and following parameters checked:

- Fasting and postprandial glucose
- HbA1c
- diabetes medication usage (agents, doses and frequency)
- weight loss (expressed in BMI and percentage of weight loss), and
- resolution or improvement of associated metabolic abnormalities and complications.

In addition screening test for malabsorption including estimation of iron (serum ferritin, total body stores, saturation), vitamin B12, proteins with liver function tests, serum parathormone (PTH), vitamin D3 and calcium are also performed at 3 monthly intervals.

58.6 Results from Our Series (of 490 Patients Operated in India and Istanbul; 10.2 % Had Jejunal II and 89.8 % Underwent Duodenal II)

Within our two centers a total of 490 patients underwent surgery between February 2008 and December 2013. The mean age of the patients was 43.5 years, and the mean BMI was 29.5 and 63 % of patients had BMI less than 35. The mean duration of diabetes prior to surgery was 9.5 years and the mean preoperative HbA1c was 9.8 %. The duration of operation ranged from 240 to 360 min while duration of hospital stay was between 4 and 6 days. Patients were followed up for 10–72 months, with a mean of 24 months; complete remission, HbA1c less than 6 without any medication, was achieved in 72 % of the cases, while partial remission, HbA1c <6.5 % without any medication, was achieved in 81.5 % of the patients. Mean weight loss was 23.5 % (18–28 %). Resolution of hypertension was seen in 92.5 % (blood pressure less than 130/80 mmHg), dyslipidemia in 89.5 % and microalbuminuria in 80 %. At 2 years mean fall in HbA1c (26.5 %) was more than the reduction in BMI (21 %; range between 15 and 25 %).

58.7 Complications (Encountered in Our Series of 490 Patients)

The major problems were food intolerance, with difficulty in drinking liquids or eating solids (e.g. water, rice, spicy foods), food getting stuck at mid-chest level, dislike for some food items or vomiting after any intake, was seen in 12 % and diarrhea and abdominal pain seen in 4 %. Total complication rate in this series of patients was 7.75 %, 38 out of 490, and mortality rate from procedure was 0.2 %.

58.7.1 Postoperative Problems

58.7.1.1 During Hospital Stay

During the hospital stay, anastomotic leaks occurred in five patients from either the ileo-ileal (four patients) or the ileo-jejunal (one patient) anastomosis (they were all reoperated and the leaks were sutured laparoscopically). Bile leak from duodenal stump occurred in two patients and was managed conservatively. Four patients had intra-luminal bleeding with melena – all settled completely with transfusions and conservative treatment. Three patients had intra-peritoneal bleed; they were re-operated successfully – 1 re-laparoscopy and 2 had laparotomy. One patient underwent a diagnostic laparoscopy for abdominal pain on fourth postoperative day (POD), which was negative; this same patient underwent laparotomy

3 days later, as X-ray showed free gas under diaphragm, wherein an ileal perforation was found proximal to a loop adherent to uterine fundus and this was sutured followed by uneventful recovery. Intraabdominal abscess seen in one patient was treated with percutaneous drainage; there were two patients with wound infections which were treated with dressings and one patient developed atelectasis which was managed with Continuous Positive Airway Pressure (CPAP), mucolytics and pulmonary physiotherapy.

58.7.1.2 After Discharge

The major reason for readmission was food intolerance (manifested as poor intake, vomiting, weakness, rapid weight loss) in 26 patients, or diarrhea and abdominal pain. All were given parenteral nutrition for 1–2 days, mostly daycare, ± antibiotics and probiotics, and they all improved.

Abdominal exploration (laparoscopic/open) was done for recurrent abdominal pain; ventral incisional hernia; gastric stasis following only ileal interposition without a sleeve gastrectomy (he developed repeated vomiting, which did not settle with conservative treatment and so a sleeve gastrectomy was added after 2 weeks). Anastomotic ulcer, (duodeno-ileal), was seen in a smoker and it healed with medication and stoppage of smoking. Gallstones in 46 patients and renal stones in two patients (treated with calcium citrate to prevent further oxalate stone formation) were also encountered. Coronary stenting, tuberculosis, esophageal fungal infection and postoperative depression were the other complications seen.

Procedure related mortality took place in one patient who developed biliary peritonitis and sepsis due to leak from the ileo-jejunal anastomosis; the other causes that resulted in mortality were diarrhea with poor intake and anuria leading to metabolic acidosis in two patients while severe urinary tract infection leading to septicemia lead to death in one patient

Recurrence of diabetes after complete remission occurred in six patients and four patients had to resume insulin, after 1 year of stopping it.

58.8 Nutritional Stability

All patients were given supplements for 6 months postoperatively and subsequently only if there was a deficiency, which was quite rare to find and required in 15 patients. There is minimal/no malabsorption after this procedure. It is postulated that jejunalization of interposed ileum occurs, where the absorption is enhanced for all nutrients (there is hypertrophy of the mucosal absorptive surface along with an increase of GLP-2, as an adaptive response), while the enteroendocrine function is retained (Table 58.2).

58.9 Long Term Results

The biliopancreatic diversion with duodenal switch (BPD-DS) gives the highest remission of diabetes, even in the long term of more than 10 years (excluding the very severe diabetics), with a recurrence rate of 5–10 % [14].

With gastric bypass, recurrence of diabetes, in comparable groups, is between 30 and 45 % within 5 years; [15, 16] for the sleeve gastrectomy it is between 50 and 55 %; in the other procedures it is still not documented clearly.

With ileal interposition, our 5 year follow up appears to indicate a recurrence rate of less than two percent.

Studies confirm that ileal interposition with sleeve gastrectomy (II+SG) induces remission of T2DM in most patients, even with a BMI between 23 and 34 kg/m², and is effective in ameliorating other components of the metabolic syndrome [6–9].

DePaula et al. reported the results of a randomized clinical trial (RCT), comparing these two versions and showed that DII+SG is more effective, even in severe disease [10] (Tables 58.3 and 58.4).

Table 58.2 Nutritional Stability at 1 year post-surgery (without supplements)

Nutritional data	Pre-op	Post-op
Total proteins	7.03±0.48	6.46±0.69
Se albumin	4.4±0.35	3.69±0.55
Se calcium	9.42±0.63	9.4±1.03
Vit D	17.49±14.65	20.33±13.8
Vit B-12	430.2±183.2	413.9±209.9
Se iron	98.55±55.6	82.47±47.6

Table 58.3 Comparison of results from different centers

Published data	2-Center Ugale & Celik	Tinoco	Aureo DePaula	Ramen Goel	Kota & Ugale
Number of patients	490	30	454	5	43
Gender ratio (male/female)	320/170	10/20	322/132	2/3	25/18
Mean age (years)	43.5	49.7±8.9	53.6	47.4	47.2
Mean BMI	29.5	30.8±5.1	29.7	29.4	33.2
Duration (years)	9.5	9.9±4.4	10.8	8.4	10.1
HbA1c	9.8	9.5±1.7	8.8	9.6	9.6
Follow up (months)	24	13.0±3.3	39.2	6	20.2
Complete remission (%)	72		60.1		
Partial remission (%)	81.5	80	86.4	80	78.6
Mean weight loss (kg)	23.5			23.2	22.5 %
Hospital stay (days)	5	3.17±0.79	3.3	8.33	4.1
HbA1c		6.2±0.8	6.2	6.22	6.4
Remission HTN	92.5		87.5	100	90
Remission dyslipidemia	89.5		87		
Remission microalbuminuria	80		71.1		

BMI body mass index, HTN hypertension

58.10 Advantages of Ileal Interposition

In the nonobese T2DM, insulin resistance is not essential to the development of diabetes, implying an essential role for impaired insulin secretion. This operation re-regulates the body's own mechanism in such a way that more insulin is produced in the body at the required time, in conjunction with food intake, so as to mimic the normal pattern of insulin secretion. This is achieved through GLP-1 from the ileum; this mechanism is still intact in these diabetics. The proportionate incretin response does not cause post prandial hypoglycemia. Hence, this operation would be effective in type 2 diabetics with enough pancreatic B-cell reserve.

The transposed segment retains its ability to absorb nutrients, in fact some report an increase in absorbance capacity; this helps to ensure nutritional stability, which is a great

Table 58.4 Comparison with other procedures

Procedure	Remission [partial] of diabetes (%) [HbA1c <6.5 without medication]
Adjustable gastric banding	40–50
Sleeve gastrectomy	50–70
Roux-en-Y gastric bypass	50–90
Biliopancreatic diversion/duodenal switch	90–98
Ileal interposition with sleeve gastrectomy	70–90
Sleeve with duodenojejunal bypass	25–70
Minigastric bypass	80–90
Gastric plication	Uncertain

Refs. [11, 17, 18]

advantage as compared with other bariatric procedures. Since the main emphasis is on the ileal interposition and not the sleeve, the preserved gastric volume can be tailored according to the BMI; hence lower BMI patients can have a good capacity of stomach. It is important to note that any procedure causing increased GLP-1 will require a gastric resection, to prevent gastric stasis which is caused by GLP-1; hence the ileal interposition should not be done alone, without at least an adjusted sleeve gastrectomy.

58.11 Future Trends

It is likely in the future that greater utilization of procedures, which combine the advantages of different mechanisms, to address all the different pathophysiological aspects of a complex disease like diabetes, are more likely to be used. While extensive research goes on to find easier solutions to treat type 2 diabetes (including stem cells and pancreatic transplantation), the surgical trends may shift more towards least malabsorptive with better efficacy; procedures relying on mechanical restriction partly or primarily, which seem to have higher recurrences, may be replaced by those with mainly functional restriction (through better hormonal action and feedback) [12].

Key Learning Points

- This procedure is another modification of gastrointestinal anatomy, resulting in multiple metabolic benefits
- Duodenal (Diverted) Ileal Interposition with a BMI-adjusted Sleeve Gastrectomy is a very effective metabolic procedure where malabsorption/malnutrition is minimal or absent
- This operation combines the advantages of the Sleeve with that of the Ileal transposition
- It is a challenging procedure, but technically feasible, with morbidity and mortality comparable to other bariatric procedures; it is seemingly very effective even in severe diabetes and the only hope for lower BMI diabetics at present

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