

# Diabetes and Obesity Control Following Duodenal Ileal Interposition with BMI-Adjusted Sleeve Gastrectomy-10years Data from a Single Surgeon Experience

Surendra Ugale<sup>1\*</sup>, Akshan Ugale<sup>2</sup>, Ayushka Ugale<sup>3</sup> and Trilok Ram<sup>4</sup>

<sup>1</sup>Department of Advanced Laparoscopy, Bariatric & Metabolic Surgery, Kirloskar & Virinchi Hospitals, Hyderabad, India

<sup>2</sup>Surgeon, Kirloskar Hospital, Hyderabad, India

<sup>3</sup>Surgeon, Kirloskar & Virinchi Hospitals, Hyderabad, India

<sup>4</sup>Nutritionist, Dept of Bariatric & Metabolic Surgery, Virinchi Hospital, Hyderabad, India

## Abstract

**Background:** Type-2 Diabetes Mellitus (T2DM) keeps afflicting more people worldwide. Not having much success through medical treatment, we have been using the surgical option of Laparoscopic Duodenal Ileal Interposition (DII) with Sleeve Gastrectomy (SG) [D-IISG], since 2010, which offers good metabolic improvement and weight reduction without causing significant malabsorption. The objective of this study was to evaluate the results of this procedure over 10 years, for control of type 2 diabetes along with any accompanying obesity, while maintaining nutritional stability.

**Methods:** Retrospective study and analysis of prospectively collected data of 154 patients that underwent laparoscopic DII with BMI-adjusted SG (DII+SG) was done.

The DII & SG was performed in 154 patients from March 2010 to December 2019 by a single surgeon and team. Participants had a mean age of 46.9 years (range 22-72), mean duration of diabetes was 11.64 years (range 1-40) and mean preoperative BMI was 30.4 kg/m<sup>2</sup> (range 20-51). All patients had poorly controlled type 2 diabetes mellitus [(mean HbA1c- 9.47% (range 6.2-14.4)] despite use of Oral Hypoglycemic Agents (OHA) and/or Insulin; or good control with fluctuations and very high doses of medication. Mean fasting C-peptide was 2.69ng/ml and 68.5% were on insulin. Remission of diabetes (HbA1c ≤ 6.5% without OHAs/Insulin) and weight maintenance were the main outcomes studied with nutritional status.

**Results:** With a follow up of 87% at 1 year, 57% and 45% at 7 and 8 years respectively, postoperative glycemic parameters (FBS, PLBS, HbA1C) improved in all patients (p<0.05) at all intervals.

With a mean follow up of 66 months (range 12-120 months), 70.9% had remission of diabetes at 1 year, 75 and 73% at 5 and 7 years respectively, which declined to 62.5% by end of 8 years.

Mean weight loss was 23.5% (18-28 %), (p<0.05). At 1 year, the mean fall in HbA1c(29.7%) was more than the reduction in BMI(23%) Percentage of total weight loss was 21.3% at 5 years with mean BMI of 25.6, whereas %TWL at 10 years was 16.5% with mean BMI of 27. Patients exhibited good nutritional stability even at 10 years.

**Conclusion:** Duodenal Ileal Interposition with sleeve gastrectomy is a very effective option for long term control of diabetes and obesity with nutritional stability.

**Keywords:** Glycemic control; Ileal interposition; Low BMI; Nutritional stability, Type-2 Diabetes; 10 year results

\*Corresponding author: Surendra Ugale, Department of Advanced Laparoscopy, Bariatric & Metabolic Surgery, Kirloskar & Virinchi Hospitals, Hyderabad, India, Tel: +91-9573200951; E-mail: surenugale@gmail.com

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## Introduction

The global search for better medical, technological and surgical options, to combat Type-2 Diabetes Mellitus (T2DM), goes on. Medical options have had limited success and the morbidity and man-days lost, due to complications of DM, keep increasing year after year. Since 2010, we have been performing Laparoscopic Duodenal Ileal Interposition with BMI-adjusted Sleeve Gastrectomy (DII+SG), as presented by the pioneer, Aureo DePaula from Goiania, Brazil [1]. This has been considered by some as the “Ferrari of all Metabolic procedures” as it requires greater effort, to create a BMI-adjusted Sleeve with ileal interposition, with minimal (50 cms) bowel exclusion, to reduce any possibility of malabsorption [2].

## Methods

154 patients underwent this procedure, after an ethical committee approval and written informed consent, since 2010. These were all diabetics who underwent detailed history-taking, clinical examination and laboratory investigations to check all systems for fitness for anesthesia and surgery.

Decision to perform a DII+SG was done after ensuring adequate pancreatic function with C-peptide and serum insulin in fasting state and 1 hour after glucose meal stimulation. GAD and Islet cell antibodies were checked when necessary, to rule out Type-1 diabetes or Latent Auto-Immune Diabetes of Adult (LADA). The baseline parameters of these patients are outlined in Table 1.

Most of the patients had severe, uncontrolled diabetes, with 68.5% on insulin treatment.

6.67% had fasting C-peptide<1, while majority of patients (68%) had<3ng/ml; duration was ≥ 10 years in nearly 60% and HbA1c ≥ 10% in 35%, all indicating severe disease. (Tables 1.a, 1.b)

Baseline Parameters	IISG-D	
	Mean	Range
Age (years)	46.9	22-72
BMI (Kg/m <sup>2</sup> )	30.4	20-51.1
Weight (kg)	83.56	45.1-150
Duration of DM (years)	11.64	1 to 40
Number of OHAs	1.53	0-4
Fasting C-peptide	2.69	0.5-10
HbA1c	9.47	6.2-14.4

**Table 1:** Baseline parameters; Body Mass Index (BMI); Oral Hypoglycemic Agents (OHA); glycosylated hemoglobin (HbA1c).

Fasting C-Peptide ng/ml				
No. of patients <1	%	No of patients <3	%	Total number
9	6.67	92	68.15	135

**Table 1.a**

Duration of DM-years			HbA1c %		
No. of patients ≥ 10	%	Total Number	No. of patients ≥ 10	%	Total Number
92	59.74	154	54	35.06	154

**Table 1.b**

This is a single surgeon experience with Indian diabetics; the severity of diabetes (DM) was also established using the DRS scoring system [3], which showed that only 14% were in mild category, with 86% having a greater severity of DM (69% moderate and 17% severe). Table 1.c

DRS IISG-D	%
Mild 7-8	13.95
Moderate 9-11	68.99
Severe >11	17.05

**Table 1.c:** DRS score indicating severity of diabetes in this cohort.

**Remission of diabetes** has been considered if HbA1c ≤ 6.5%, without any medication for 1 year, as physicians in clinical practice here use this benchmark. The result is considered as “good glycemic control” if HbA1c<7% without any medication; physicians usually prescribe medication only if HbA1c is>7%.

**Inclusion criteria-** Patients with T2DM>1 year duration; Age 20-70 years usually, with rare exceptions in very fit individuals ; Stable weight for the last 3 months (variation in weight<3%); BMI ≥ 20kg/m<sup>2</sup>; Inadequate glycemic control with HbA1c>7% on optimum dosage of insulin and/or OHA; stimulated C-peptide level>1ng/ml.

**Exclusion Criteria-** Type-1 DM; Undetectable fasting C-peptide; Positive urine ketones, pregnancy; Coexisting severe hepatic, pulmonary, renal, cardiovascular, neurological and psychiatric diseases and obesity due to organic illness; addiction to alcohol or illicit drugs.

**Preoperative Evaluation-** Subjects had mean age of 46.9 years (range 22-72), mean duration of diabetes 11.64 years (range 1 to 40)

and mean preoperative BMI of 30.4 kg/m<sup>2</sup> (range 20-51). All patients had poorly controlled T2DM with a mean HbA1c-9.47% (range 6.2-14.4) despite use of OHA and/or Insulin.

Preoperative evaluation included assessment of serum insulin, basal and 1hr post meal C-peptide.

## Outcomes

**Primary outcome measure-** Remission of T2DM, defined as HbA1c ≤ 6.5% without requiring oral or parenteral hypoglycemic agents, for 1 year.

**Secondary outcomes measures-** Improvement in glycemic parameters (HbA1c, Fasting blood sugar [FBS], Post Lunch Blood Sugar [PLBS]), maintenance of weight and BMI, nutritional parameters.

## Procedure Details

With a six-port laparoscopic technique, a BMI-adjusted sleeve gastrectomy was performed using a 36-50 French calibrator. The endo-GIA stapler with 60-mm cartridges was used for gastric resection and the staple line was reinforced by imbricating 3-0 polydioxanone sutures. Non-obese patients were subjected to mainly fundectomy, leaving a good volume of residual stomach. The devascularization of the greater curvature of the stomach was continued onto the duodenum, 3-4 cm beyond the pylorus, as far as the gastro-duodenal artery. The duodenum was transected, distal stump was reinforced with 3-0 polydioxanone continuous suture, and the resulting gastro-duodenal tube was then passed into the inframesocolic space through an opening created at the root of mesocolon.

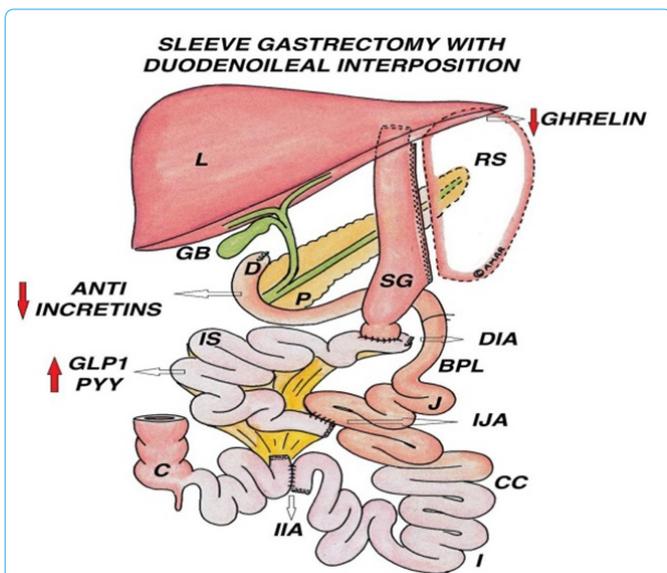
A distal ileal segment of 100-170 cm in length (depending on total small bowel length) was created by dividing the ileum at two points, 30 cm and usually 200 cm from the ileocecal valve preserving its mesenteric pedicle. Continuity of small bowel was restored by a stapled side to side ileo-ileal anastomosis.

The gastro-duodenal tube was anastomosed to the proximal end of the ileal segment end to side in an iso-peristaltic manner in 1 or 2 layers using intracorporeal hand suturing with 3-0 polydioxanone. The distal end of the ileal segment was anastomosed to the jejunum 50 cm from the ligament of Treitz with a stapled side to side anastomosis. All anastomoses were performed using 45-mm linear staplers with white cartridges, and 3-0 polydioxanone enterotomy suture closure [4].

The linear defect in the distal ileal mesentery, the circular defect in the transverse mesocolon and the two arched defects in ileo-jejunal mesentery and the gastro-ileal anastomosis are closed using 3-0 polypropylene sutures to prevent internal herniation [5] (Figure 1). The 10 and 12 mm trocar openings were closed with 1-0 polydioxanone sutures using a suture-passer instrument, after removing the gastric specimen; if necessary, a flat Penrose drain was placed along the sleeve and the duodenal stump.

## Postoperative follow up

Medication was adjusted according to the plasma glucose (measured 3 hourly, with insulin used according to sliding scale) and blood pressure levels. The patients were kept on a liquid diet, started 24-36 hrs after surgery, for 5-7 days, followed by semisolid diet for another 7 days, and finally a solid diet. The patients were discharged between 3-5<sup>th</sup> postoperative day with vitamin supplements. Follow up is



**Figure 1:** DII+SG (ref-Chapter “Metabolic Surgery for Diabetes and Hyperlipidemia”, 3<sup>rd</sup> Ed. 2019, Surgical Gastroenterology, Editor Sanjiv Haribhakti, Paras Medical Publisher).

encouraged every 3-monthly in 1<sup>st</sup> year, 6-monthly in 2<sup>nd</sup> and 3<sup>rd</sup> years, then annually for life, for clinical and laboratory evaluation.

Outcomes measures were recorded prospectively.

## Results

We had 87% follow-up at 1 year, 52%, 57% and 45% at 5, 7 and 8 years respectively.

Mean follow up was 66 months (range 12-120 months) (Table 2).

	Total	Follow-up	%
Year 1	154	134	87.01
Year 3	132	78	59.09
Year 5	84	44	52.38
Year 7	45	26	57.78
Year 8	35	16	45.71
Year 10	6	2	33.33

**Table 2:** Rates of follow-up.

Postoperative glycemic parameters (FBS, PLBS, HbA1c) improved in all patients ( $p < 0.05$ ) at all intervals (Table 3).

The mean FBS and PPBS were well controlled for 5 years; our data shows these worsening from 7-10 years.

#Levels of FBS / PPBS over 8/10 years

70.9% had remission of diabetes at 1 year, 75 and 73% at 5 and 7 years respectively, which declined to 62.5% at end of 8 years.

Excellent long term control of glycemia, in 82-84% of patients upto 8 years, with mean A1c  $< 7\%$  over 10 years, and  $> 80\%$  of those needing insulin initially, did not require insulin, at 8 years.

### Reduction in BMI at 5 yrs is 19.7% while HbA1c reduction is

At 5 years mean fall in HbA1c (34.5%) was more than reduction in BMI (19.7%).

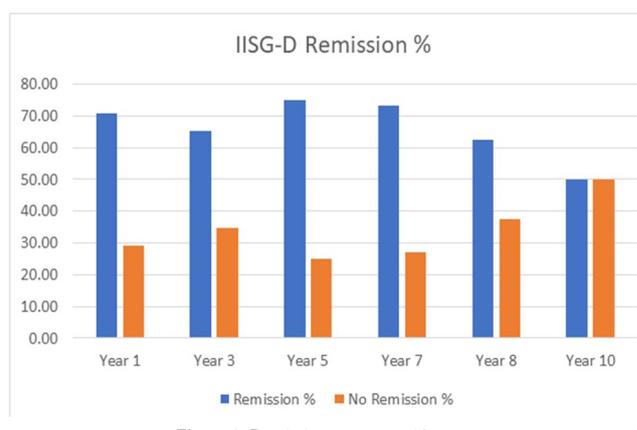
At 8 years, A1c reduction of 30.7% was again  $>>>$  than BMI 17.4% (Tables 4-6, Figure 2).

	FBS mg/dl	PPBS mg/dl	HbA1c %	"p" value
Preoperative	188	249	9.47	
1-year	102	117	6.26	
3-year	123.55	138.28	6.35	
5-year	116.04	138.16	6.20	
7-year	141.95	160.06	6.47	
8-year	146.58	166.38	6.56	
10-year	153.24	173.94	6.56	

**Table 3:** Glucose control over 10 years; mean values of FBS=Fasting blood sugar, and PPBS= Post-prandial blood sugar.

	HbA1c Mean	Remission %	HbA1c $< 7$ , no Meds Glycemic Control %	Total No. of patients
Pre-op	9.47			
Year 1	6.26	70.90	82	134
Year 3	6.35	65.38	74.4	78
Year 5	6.20	75.00	84.09	44
Year 7	6.47	73.08	76.92	26
Year 8	6.56	62.50	83.33	16
Year 10	6.56	50.00	50.00	2

**Table 4:** Remission rates for D-IISG upto 10 years with mean values of HbA1c.



**Figure 2:** Remission rates upto 10 years.

Excellent long term control of glycemia, with A1c between 6.2-6.56% over this 10 year period. This was accompanied by very effective weight maintainance, with mean BMI between 22-25.8kg/m<sup>2</sup> throughout the 10 year period, having 20% TWL at 5 and 8 years. This long term success was achieved with a negligible bowel exclusion of only 50cms of jejunum, as compared to BPD-DS, where 350-700cms of small bowel could be excluded (Tables 6.a-9).

## Discussion

This procedure was favoured instead of the other bypass or sleeve plus procedures, as this has no bowel exclusion and no bypass, yet results in very good long term control of diabetes and weight, even at 10 years. This might prove to be a healthier way to lose weight and get diabetic control [6].

IISG-D	No.	%	Duration DM	Remission %					
				year 1	Year 3	Year 5	Year 7	Year 8	Year 10
<25	25	15.72	12.46	59.09	66.67	50.00	100.00	50.00	100.00
25-29.9	61	38.36	11.21	67.92	59.38	61.11	70.00	50.00	-
< 30	86	54.09	11.57	65.33	60.98	59.09	76.92	50.00	100.00
30-34.9	36	22.64	12.27	74.19	71.43	91.67	57.14	75.00	-
<35	122	76.73	11.78	67.92	64.52	70.59	70.00	58.33	100.00
35-49.9	29	18.24	11.38	84.00	64.29	87.50	75.00	66.67	0.00
>50	3	1.89	15.00	50.00	100.00	100.00	100.00	100.00	-

**Table 5:** Distribution of BMI groups, mean HbA1c and duration of diabetes, and their correlation with remission rates over 10 years.

IISG-D	IISG-D			
	BMI (Mean)	HbA1c (Mean)	Need for insulin (%)	No. of OHA (Mean)
Preop	30.40	9.47	68.57	1.53
1-yr	22.89	6.26	4.29	0.15
3-yr	23.40	6.35	10.00	0.27
5-yr	24.40	6.20	3.85	0.20
7-yr	25.80	6.47	7.41	0.25
8-yr	25.10	6.56	11.76	0.35
10-yr	24.50	6.56	25.00	0.00

**Table 6:** Efficacy of BMI and diabetes control over 10 years.

	BMI	% TWL
Pre-op	30.4	
At 5 years	24.36	19.69
At 8 years	25.14	20.15
At 10 years	24.24	18.51

**Table 6.a:** Mean BMI and percentage of total weight loss at 5, 8 and 10 years.

by the DRS scoring system. Remission of 65.7% at 1 and 3 years, gradually declined to 57% at 5 years and 30% at 10 years, although 43% maintained A1c  $\leq 7$  even at 10 years. Even though 54% were on insulin preoperatively, nearly half of them had diabetic control without insulin at 10 years.

About 10% had BMI<25, 30.5% had BMI<30, with nearly 60% being<35kg/m2. Yet the results were comparable with those whose BMI>35, upto 10 years; such long term data could lay the grounds for

BMI group	No.	%	C-Peptide F	C-Peptide PP	Se. Insulin F	3-Yr HbA1c	5-Yr HbA1c
20.00-24.99	22	75.86	2.46	4.22	16.8	6.28	6.57
25.00-29.99	61	79.22	2.61	4.63	24.08	6.41	6.44
30.00-34.99	39	65.00	2.95	4.63	20.27	6.49	5.9
35.00-39.99	22	68.75	2.74	4.29	27.12	6.26	6.18
40.00-44.99	7	43.75	3.26	5.28	63.83	5.87	5.5
45.00-49.99	0	0.00	-	-	-	-	-
50.00-54.99	3	60.00	1.6	3.2	35.28	5.8	6.3

**Table 7:** Correlation of C-peptide and insulin levels, in different BMI groups, with HbA1c control at 3 and 5 years. [F=Fasting; PP=Postprandial].

HbA1c	No. of patients	% of patients	Pre-OP BMI	Remission	Total	%
<7	11	57.89	34.76	6	6	100.00
7-7.9	11	27.50	40.66	5	6	83.33
8-8.9	17	30.91	33.2	6	10	60.00
9-10.9	24	28.92	32.5	10	16	62.50
11-15	9	20.45	36.1	3	8	37.50

**Table 8:** The poorly controlled patients with high HbA1c, had poorer response, compared to the better controlled patients with A1C  $\leq 8$ , and even upto 11%.

Reasonably good follow-up of 73% at 5 years and 63% at 10 years, probably offsets the disadvantage of the smaller total number of patients being 72.75% were moderate and severe diabetics as assessed

establishing new guidelines, allowing surgical intervention, for poorly controlled diabetes, without any BMI restrictions [7,8].

Mean HbA1c							
BMI group	Preop	1 yr	3 yr	5 yr	7 yr	8 yr	10 yr
20.00-24.99	8.58	6.76	7.53	6.86	6.65	7.75	7.8
25.00-29.99	9.18	6.68	6.77	6.73	6.87	8.1	7.26
30.00-34.99	9.28	6.42	6.42	7.04	7.17	7.1	7.04
35.00-39.99	9.33	6.04	6.07	6.66	5.86	5.95	6.05
40.00-44.99	8.62	6.38	6.01	6.46	7.18	7.56	7.6
45.00-49.99	7.46	5.81	6.15	6.16	5.06	5.76	6.35
50.00-54.99	9.3	8.1	6.2	6.2	6.2	-	-

**Table 9:** This shows that persons with BMI <35, responded nearly as well as those with >35 with good diabetic control which was maintained upto 10 years.

MEAN	Hb%	Protein	Albumin	Calcium	Vit D3	Vit B12	Iron
Pre Op	12.93	8.25	4.27	9.96	24.42	409.48	69.37
Year 1	12.28	6.8	3.69	8.34	26.25	391.77	77.37
Year 3	12.29	6.71	3.87	8.44	26.43	460.06	71.03
Year 5	12.93	6.78	3.86	8.47	28.33	425.63	59.25
Year 7	13.05	6.57	3.85	8.67	30.56	456.95	60.69
Year 8	12.81	6.77	3.84	8.26	28.25	344.7	52.41
Year 10	11.98	7.01	3.96	8.13	22.46	342.49	54.84

**Table 10:** Nutritional stability over 10 years as shown by mean values of different nutrients; Hb=Hemoglobin; Vit= Vitamin.

Since the majority were having BMI<35, it is not surprising that the %TWL was 21% at 5 years maintaining a good BMI of 25, and 16.5% at 10 years having BMI of 27kg/m<sup>2</sup>. Greater insulin resistance was seen in BMI<30, with higher fasting serum insulin levels, indicating sufficient insulin reserve; no insulinopenia seen at these levels, giving us further confidence to operate on such patients [9].

Better preoperative control and reduction of HbA1c, may favour good results and those with high A1c levels preop had poorer response to surgery. Since there is no bypass of any portion of the gastrointestinal (GI) tract in this procedure, there is no malabsorption expected, which is shown by the good nutritional stability upto 10 years (Table 10); supplements were used routinely for 1st year, and later only if any deficiency was found during follow-up checks [10].

The downside of not doing any bypass of the duodenum and proximal jejunum, is the reduced efficacy of the procedure, as the duodenal anti-incretin factor is not overcome, as seen in the diverted or duodenal ileal interposition [11].

Efficacy of this procedure has been shown by many studies [12-18], along with its safety profile [19-21], its efficacy of comorbidity resolution [22-23] and very importantly, its safety in low BMI diabetics [24-27].

## Conclusion

J-IISG is a very good option for surgical treatment of T2DM, especially with mild and moderate severity of DM and BMI>30, although its efficacy and safety even in low BMI diabetics has been shown here. Having no bowel exclusion is an attractive option especially for the lower BMI diabetics, who do not tolerate malabsorption well, using bypass procedures. These 5 and 10-year results should encourage surgeons to study this procedure in larger number of patients at multiple centers. Being a procedure requiring 3 transections, 3 anastomoses

with closure of all mesenteric gaps, attention to details with good technical skills and initial proctoring of surgeons is important.

## Conflict of Interest

- None of the authors have any conflict of interest.
- No funding was obtained for this study.

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