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Research Article

10 Year Data on Efficacy of Diabetes and Weight Control by Ileal Interposition with Sleeve - Sleeve Plus Procedure Without any Bowel Exclusion

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Abstract

Background: Type-2 diabetes mellitus (T2DM) keeps increasing worldwide. Of the many options available surgically to treat diabetes, the Sleeve Plus group appears to have good results. One such procedure, the Jejunal Ileal Interposition with sleeve gastrectomy (J-IISG) has been assessed here for its long term outcomes up to 10 years, on diabetes and weight control, a big advantage being that there is no bowel exclusion (no bypass).

Methods: Retrospective study and analysis of prospectively collected data of 72 patients who underwent J-IISG, for T2DM, since 2008, having mean age of 46.5 years, mean Body Mass Index (BMI) of 34.5 kg/m2, duration of diabetes mellitus (DM) being 9 years, fasting C-peptide of 3.18ng/ml and mean glycosylated hemoglobin (HbA1c, A1c) of 8.9%. 54% of patients were on insulin.

Results: Follow-up at 10 years was 63.8%, with remission of diabetes of 67% up to 3 years, 57% at 5 years, and 43% of patients at 10 years maintained A1c ≤ 6.5%. 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: Jejunal ileal interposition with sleeve gastrectomy is a very good option to achieve good long term results with nutritional stability, without bypassing any bowel.

Keywords: *Type-2 Diabetes; Low BMI; Glycemic Control; Ileal Interposition; Nutritional Stability; 10 Year Results*

Introduction

The world continues to search for better medical, technological and surgical options, to combat Type-2 Diabetes Mellitus (T2DM), as the disease burden keeps increasing year after year. Since 2008, we have been performing Laparoscopic Jejunal Ileal Interposition with Sleeve Gastrectomy (J-IISG), as proposed by the pioneer, Aureo DePaula from Goiania, Brazil [1]. This can be considered as one of the "Sleeve Plus" procedures, as the ileal interposition is done in addition to the Sleeve Gastrectomy (SG), without any bowel exclusion, to overcome any possibility of malabsorption [2].

Methods

72 patients underwent this procedure, after an ethical committee approval and informed consent, since 2008. 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 an IISG 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 LADA (Latent Auto-immune Diabetes of Adult). The baseline parameters of these patients are outlined in table 1.

Baseline Parameters	Mean	Range
Age (years)	46.5	30 - 65
BMI (Kg/m^2)	34.52	23.5-53.5
Weight (kg)	94.67	57-145
Duration of DM (years)	9.03	1 to 25
Number of OHAs	1.51	0 - 3
Fasting C-peptide	3.18	0.89 - 8.37
HbA1c	8.92	5.2 - 15.8

Table 1: *Baseline parameters with median/mean values and ranges. BMI: Body Mass Index; OHA: Oral Hypoglycemic Agents; HbA1c: Glycosylated Hemoglobin.*

Most of the patients had severe, uncontrolled diabetes, with 54% on insulin treatment.

4.8% had fasting C-peptide < 1, while 43.5% had < 3n g/ml; duration was ≥ 10 years in 41.4% and HbA1c ≥ 10% in 29.2%, all indicating severe disease.

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 25% were in mild category, 63.3% in moderate and 11.7% in severe.

DRS Scores	% of patients
Mild 7 - 8	25.00
Moderate 9 - 11	63.33
Severe > 11	11.67

Table a

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.

Procedure details

With a six-port laparoscopic technique, a variable sleeve gastrectomy was performed using a 38 - 50 French calibration tube. The endo-GIA stapler with 60-mm cartridges was used for gastric resection and the staple line was reinforced by inverting 3-0 polydioxanone sutures. Non-obese patients were subjected to only fundectomy, leaving a good volume of residual stomach.

A distal ileal segment of 170 cm in length was created by dividing the ileum at two points -- 30 cm and 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, using a white 45 mm cartridge and 1-layer, continuous intracorporeal suturing with 3-0 polydioxanone. The mesenteric gap was closed with interrupted 3-0 polypropylene sutures, to prevent any internal herniation.

The jejunum was transected between 20 - 50 cms from DJ flexure (20 cms for BMI < 30; 50cms for those with higher BMI, to create a greater "ileal brake" effect) [4]. The proximal end of the jejunal transection was anastomosed to the proximal end of the ileal segment, in an isoperistaltic, similar manner, creating a jejuno-ileal anastomosis, followed by closure of that mesenteric space. The distal end of the ileal segment was anastomosed to the distal end of the jejunal transection, in a similar fashion, creating an ileo-jejunal anastomosis, and mesenteric gap was closed [5] (Figure 1).

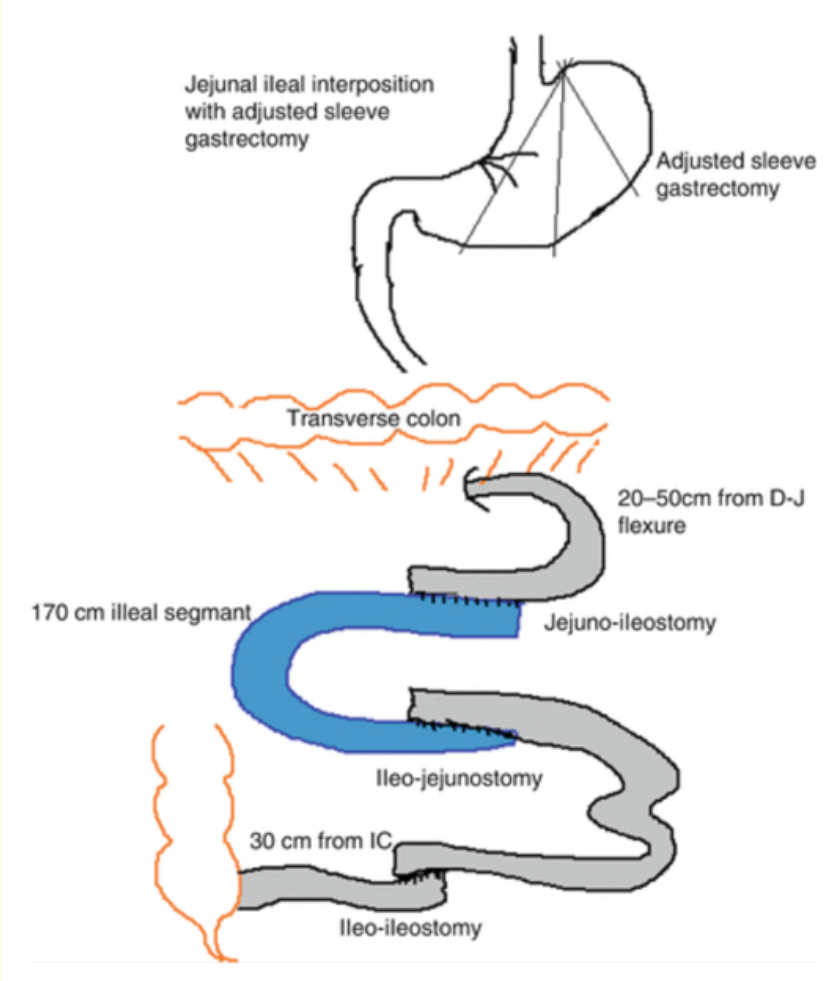

Figure 1: *"IISG for T2DM and Metabolic Syndrome", Chapter-58, Springerlink.*

Results

We had 93% follow-up at 1 year, 68.6% at 3 yr, 69% at 5 yrs; 59% at 8 yrs and 63.8% at 10 yrs. Follow up is encouraged every 3-monthly in 1st year, 6-monthly in 2 - 3 years, then annually, for life.

	Total	Follow up	%
Year 1	72	67	93.06
Year 3	67	46	68.66
Year 5	65	45	69.23
Year 7	55	34	61.82
Year 8	49	29	59.18
Year 10	36	23	63.89

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

Remission of diabetes was 65.7% at 1 year, which was maintained at 3 years, declining to 57.8% at 5 years and only 30% at 10 years; HbA1c of ≤ 6.5% with only OHAs is 2.2% at 5 years and 13% at 10 years, which is a great achievement of this procedure, as 43% of patients have HbA1c ≤ 6.5 at 10 years.

Excellent long term control of glycemia, with A1c ≤ 7% over 10 years in all patients, and nearly 50% of those needing insulin initially, did not require insulin, even at 10 years.

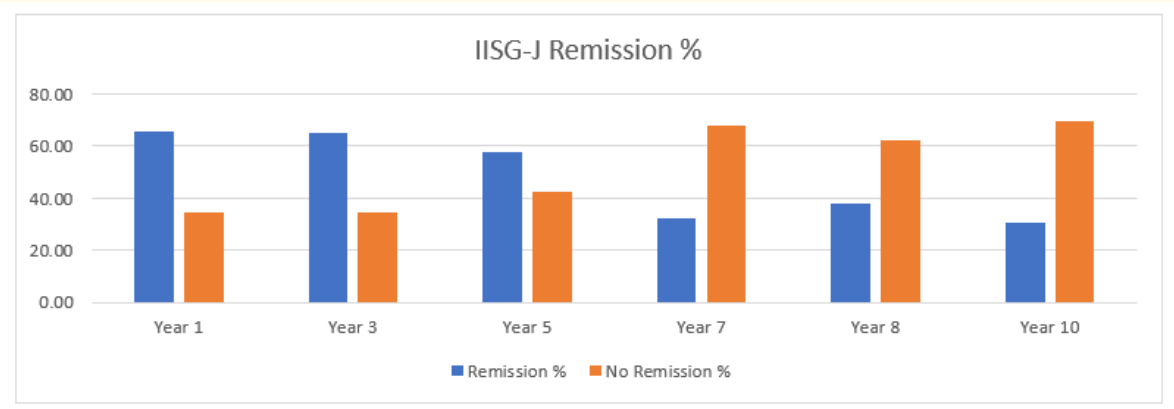

***Figure 2:** Remission rates compared with patients who have no remission.*

	Remission %	No Remission %	Total No. of patients with data
Year 1	65.67	34.33	67
Year 3	65.22	34.78	46
Year 5	57.78	42.22	45
Year 7	32.35	67.65	34
Year 8	37.93	62.07	29
Year 10	30.43	69.57	23

***Table 3**: Remission rates for J-IISG upto 10 years.*

	FBS (Mean)	PPBS (Mean)	Se. Triglycerides	Se. Cholesterol
Preop	174	233	171.53	174.66
1-yr	107	129	143.15	154.44
3-yr	119	134	156.60	146.43
5-yr	119.2	146	131.72	144.72
7-yr	149	173	129.90	145.70
8-yr	154	187	139.35	157.78
10-yr	156	181	210.50	190.45

Table 4: *Glucose and lipid control over 10 years; FBS: Fasting Blood Sugar; PPBS: Post-Prandial Blood Sugar.*

The mean FBS and PPBS were well controlled for 5 years; our data shows these worsening from 7 - 10 years. The control of triglycerides and cholesterol was not very significant, though these were very well controlled for 8 years, before worsening at the 10-year mark.

				Remission						
BMI	**No.**	**%**	**Duration DM**	**year 1**	**Year 3**	**Year 5**	**Year 7**	**Year 8**	**Year 10**	**HbA1c Mean**
<25	7	9.72	7.28	57.14	0.00	33.33	0.00	0.00	0.00	8.59
25-29.9	15	20.83	9.13	50.00	55.56	55.56	12.50	25.00	12.50	9.27
< 30	22	30.56	8.54	52.38	41.67	50.00	9.09	20.00	11.11	9.05
30-34.9	21	29.17	9.88	61.90	73.68	55.56	36.36	45.45	42.86	9.28
<35	43	59.72	9.19	57.14	61.29	53.33	22.73	33.33	25.00	9.16
35-49.9	26	36.11	8.82	82.61	76.92	76.92	40.00	42.86	33.33	8.58
>50	2	2.78	5.00	0.00	0.00	0.00	100.00	-	-	9.3

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

	BMI (Mean)	HbA1c (Mean)	Needing insulin (%)	No. of OHA (Mean)
Pre-op	34.52	8.94	54.24	1.51
1-yr	25.37	6.42	20.45	0.24
3-yr	25.66	6.46	29.63	0.38
5-yr	25.63	6.66	25.93	0.47
7-yr	27.25	6.73	26.47	0.64
8-yr	27.37	7.25	30.00	0.66
10-yr	27.12	7.07	29.17	0.70

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

Patients had good weight maintenance even at 10 years, with percentage of total weight loss (%TWL) of 21.3% at 5 years and mean BMI of 25.6, whereas % TWL at 10 years was 16.5% with mean BMI of 27.

TWL % at 5yr	BMI Mean at 5 yr	TWL % at 10yr	BMI Mean at 10y
21.29	25.63	16.5	27.12

BMI group	C-Peptide F	C-Peptide PP	Se. Insulin F	3-Yr HbA1c	5-Yr HbA1c
20.00-24.99	2.36	4.12	49.98	7.53	6.86
25.00-29.99	2.63	4.84	66.45	6.77	6.73
30.00-34.99	3.71	7.15	30.58	6.42	7.04
35.00-39.99	3.4	4.39	37.53	6.07	6.66
40.00-44.99	2.93	5.61	40.82	6.01	6.46
45.00-49.99	3.75	7.9	28.81	6.15	6.16
50.00-54.99	1.7	3.8	6.1	-	-

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 BMI ≤ 8 or even up to A1c < 11%.*

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 up to 10 years.*

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].

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 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 ≤ 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 < 35 kg/m^2. Yet the results were comparable with those whose BMI > 35, up to 10 years; such long term data could lay the grounds for establishing new guidelines, allowing surgical intervention, for poorly controlled diabetes, without any BMI restrictions [7,8].

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 27k g/m^2.

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 up to 10 years (Table 10); supplements were used routinely for 1st year, and later only if any deficiency was found during follow-up checks [10].

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.*

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.

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