Comparative Study between Duodeno-jejunal Bypass and Ileal Transposition (DJB &IT) in Management of Type II Diabetes Mellitus (DM) in Obese Patients with BMI 30-35

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ABSTRACT

Background: *The prevalence of obesity and T2DM has increased dramatically worldwide, becoming a serious global public health problem. Bariatric surgery should be considered as an alternative line for treating patients with a BMI of 30–35 kg/m2 when DM cannot be controlled by medical regimen.With the exception of omentectomy, which has proven to be totally ineffective, the newly developed operations specifically designed for T2DM treatment ' duodeno-jejunal bypass and ileal transposition (DJB &IT) were inspired by the two known hypothesis (hindgut & foregut theory).* ***Patients and methods:*** *A prospective randomized control trial study at Ain-shams university hospital using the closed envelop method was held at Ain Shams university hospitals, from February 2014 up to July2016 upon 40 obese patients with BMI between 30-35sufferring from type II DM comparing duodeno-jejunal bypass and ileal transposition regarding their effect on glycemic control.* ***Results****: In this study, the 20 patients who had DJB, the mean FBG decreased from 257 mg/dl to 106 mg/dl, and the 2H-PP value also decreased from 335 mg/dl to 161 mg/dl with improvement of HbA1c from 9 gm% to 5.7 gm%. The S. insulin level increased from 9.8 miu/ml to 12.4 miu/ml , with associated increased C-Peptide from 0.9 ng/ml to 1.2ng/ml.In the 20 patients who had ITthe FBG decreased from 265 mg/dl to 92 mg/dl, and the 2H-PP value also decreased from 347 mg/dl to 143 mg/dl with improvement of HbA1c from 8.8gm% to 5.4gm%. The S. insulin level increased from 9.6miu/ml to13.6 miu/ml, with associated increased C-Peptide from 0.9ng/ml to 1.4ng/ml.* ***Conclusion:*** *These data provide preliminary evidence about the benefits of metabolic surgery on the glycemic control of T2DM obese subjects with a BMI of < 35 kg/m2.However, more randomized controlled trials are needed to investigate the effects of surgery in T2DM remission in pre-obese patients.*

INTRODUCTION

It has been estimated that 190 million people worldwide have diabetes mellitus (DM) and it is likely that they will increase to 324 million by 2025. This epidemic is taking place both in developed and developing countries and the combination of DM, obesity, and metabolic syndrome is now recognized as one of the major threats to human health in the 21st century .[1]

The effect of purely restrictive procedures in improving glucose control is directly proportional to the degree of weight loss .[2]

Two hypotheses have been proposed to explain the early effects of bariatric surgery on T2DM, the hindgut and the foregut hypotheses .[3]

Rubino and Marescaux have developed an experimental animal model with duodenal exclusion. A surgery with only two anastomoses performed on rats of the Goto-Kakizaki species, the most widely used animal model of non-obese T2DM. A duodeno-jejunal bypass and a simple entero-enteric anastomosis were performed, preserving the gastric volume. [4]

The continual advances in our knowledge of the pathogenesis and hormonal disorders of morbid obesity lead to the development of new technical options. In Europe, multinational studies are being assembled to look at a procedure called ileal transposition (IT), First described by Koopmans andSclafani in 1981. [5]

This procedure has actually been proposed as beingpotentially useful in treating glucose intolerance related toobesity because of the potential for increasing GLP-1 secretion. [6]

PATIENTS AND METHODS

This prospective randomized control trial (RCT) was held at Ain Shams university hospitals during the period between February 2014 and July 2016,using the closed envelop method, upon 40

obese patients with BMI between 30-35, who suffered from type II DM, comparing the duodeno-jejunal bypass to the ileal transposition regarding their effect on glycemic control. The preoperative assessment included thorough clinical examination with laboratory and radiological work up. It was done in the outpatient department.

Inclusion criteria: Age (18 -65) years, of both genders &BMI: 30-35 &Uncontrolled DM type II (HbA1c> 6.4gm%, FBS>126 mg/dl, 2 hs PPS>200 mg/dl).

Exclusion criteria:Type 1 DM and suspected mixed type DM &Patients unfit for general anesthesia (coexisting severe hepatic, pulmonary, renal, cardiovascular, neurological diseases) &Pregnancy (or positive pregnancy test) & Secondary DM &BMI under 30 or more than 35.

According to those criteria patients were divided randomly using the closed envelops method: Group (A): included 20 patients; all had duodeno-jejunal bypass Only 11 cases were done by laparoscopy and Group (B): included 20 patients; all had ileal transposition Only 10 cases were done by laparoscopy.

Operative technique:

All cases were done by the same surgical team and under general anesthesia.

Laparoscopic DJbypass (Fig. 1):

Insufflation of the abdomen: either by closed or open methods, followed by insertion of the ports as follows: 10mm supra-umbilical port for the camera, sub-xiphoid 5mm port for liver retraction, two 12mm ports are placed subcostally on both sides in midclavicular lines, another right side caudal 10 mm port is inserted around 3-4 fingers caudal and lateral to the 12mm port.

Formal exploration of the whole abdomen is done followed by identification of the stomach, insertion of NGT to evacuate stomach if needed.

Dissection of the posterior wall of duodenum must be medial to the common bile duct (CBD) to avoid technical injuries to pancreatic parenchyma and the gastroduodenal artery, and to maintain good blood supply to the duodenum.Mobilization and transection of the first part of the duodenum using the Endo GIAlinear stapler (*Ethicon Endo-surgery, Cincinnati, OH, USA*) using 60mm blue cartridge.Identification of the DJ flexure is done then grasping the jejunum with atraumatic grasper and Babcock, about 50 cm from (DJ) flexure, followed by transection of the loop with the linear stapler with enlarging of the mesenteric window, forming two closed ends (*proximal &distal*). The distal limb is brought up to be anastomosed with the duodenum side to side by a linear stapler 45mm cartridge, with a hand-sewn closure of the staple entry site. The proximal limb is then anastomosed side to side to the jejunum using a 60mm blue cartridge 150 cm away from the previous anastomosis. Closure of the staple entry site by hand-sewing technique with absorbable 3/0 Vicryl continuous suturing is also done followed by placing of an intra-abdominal drain.

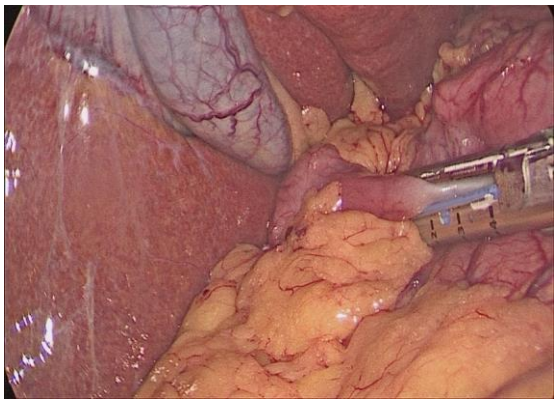


Fig 1: Division of the first part of the duodenum

Laparoscopic Ileal transposition (Fig. 2-a,b)

Insertion of ports: an umbilical port (10mm): At the umbilicus used for the camera, an epigastric 10mm port. Two right sided ports are placed, the first (12 mm) in the right midclavicular line 10 cm caudal to costal margin, and the other (5 mm) is placed in the anterior axillary line about 5 cm above level of umbilicus. Another 10mm port is placed just below the level of umbilicus, at the left anterior axillary line.

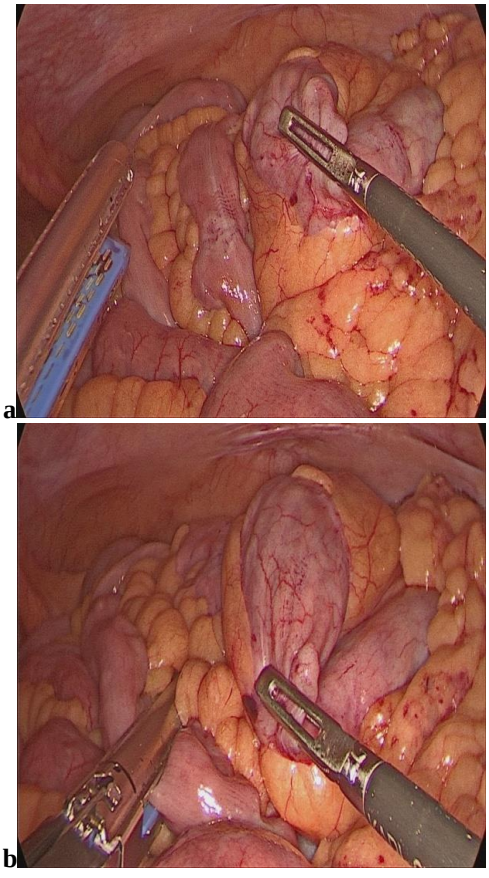
Formal exploration of the whole abdomen, followed by Identification of the caecum.

Formation of the transposed ileal loop:Grasping the terminal ileum with a traumatic grasper and Babcock starting at the ileo-cecal junction. Then Measuring about 30 cm proximal to the ileo-cecal junction with opening of a mesenteric window at this point, using harmonic scalpel (*Ethicon Endo-surgery, Cincinnati, OH, USA*) followed by division of the ileum by the linear stapler blue load 60mm forming two closed ends (*proximal &distal*).Enlarging this window by harmonic scalpel to allow free movement of the ileal loop, the distal end is marked by a

metallic clip to identify it for iso-peristaltic anastomosis later. Measuring about 100 cm proximally using atraumatic instruments is done followed by division of the ileum by the same previously mentioned technique, with widening of this window.The jejunum is then divided at 20-50 cm from DJ flexure by the linear stapler forming two closed ends.Restoration of the GIT continuity is then achieved by three anastomoses, all are done side to side by the linear stapler 45 mm using the blue cartridges, with closure of the staple entry site with Vicyl 3/0 continuous sutures, the anastomoses are:

A) Proximal jejunoileal anastomosis.
B) Distal jejunoileal anastomosis
C) Ileo-ileal anastomosis.

The transposed ileal loop is put in the original peristaltic direction (isoperistaltic), application of intra-abdominal drain is then followed by closure.



a

b

Fig 2: a) Identification of ileocecal junction, b) Ileal division

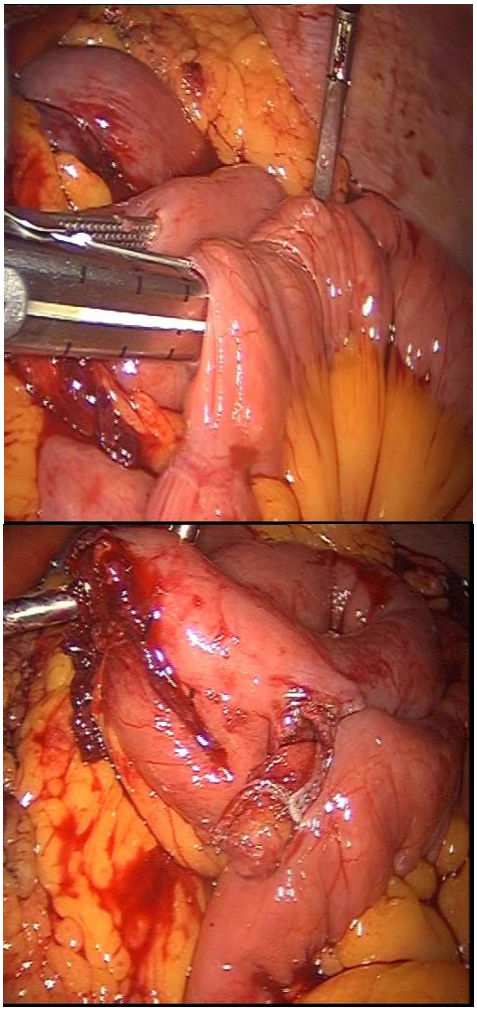


Fig 3: Ileo-jejunal anastomosis via side to side stapling

Outcome measures:

1. *Primary outcome measures:* The primary endpoint is to assess the control of T2DM in both operations.
2. *Secondary outcome measures:* The secondary endpoints arethe associated co-morbidities improvement namely hypertension, along with comparing both operations regarding operative time, safety and complications.

All patients at discharge were instructed to follow up with us, at our outpatient clinic once weekly in the first month, then at 3, 6 and 12 months later. However, all patients were instructed to seek our advice whenever they notice anything abnormality, as they could contact us anytime where they were given our phone numbers. Most of patients were instructed to have

at least 8 hourly glucose level monitory at home with recording of the results, but some patients were non-compliant towards that step.

During the follow-up visits, the following was done: Taking history from patients, with special concern about symptoms of hyperglycemia, hypoglycemia and diabetes associated conditions, Measuring fasting, 2 hours postprandial blood glucose, and HbA1c, Measuring the arterial blood pressure, Possible addition, stoppage, increasing, or decreasing doses of insulin, oral hypoglycemics and antihypertensive drugs according to needs and in addition to FBG, 2 H-PP, and HbA1c at 12 months; both serum insulin and C-peptide levels were measured.

Ethical considerations:

Our study was approved by the ethical committee in our faculty and all the patients participating in this study were well informed about the technique of the operation, the possible benefits and complications, and are allowed to participate without any pressure, with obtained written consent containing all the required data, and patients allowed to contact us easily and at anytime using the mobile phone, and were allowed to present to us whenever an incident occurs.

Conflict of interests:

There is no conflict of interests regarding the authors of this study and the study itself.

RESULTS

The data from those patients as regards preoperative glycemic state, operative time, intraoperative complications, postoperative complications, hospital stay and, resolution (or improvement) of diabetes mellitus were revised, and coded.The data were introduced to a personal computer using Statistical package for Social Science (*SPSS 15.0.1 for windows; SPSS Inc, Chicago, IL, 2001*), tabulated and statistically processed.

***Preoperative parameters:**

Demographic Data:The age of patients included in group A (DJB) ranged from 34 years to 51 years, with a mean age of 44±2.7 years. While the age of the patients ingroup B (IT) ranged from 38 years to 52 years, with a mean age of 45±1.98years.

In group A (DJB),male to female ratio was 40 % (8 male patients) to 60 % (12 female patients).In group B (IT),male to female ratio was 50 % (10 male patients) to 50 % (10 female patients). Chart (1)

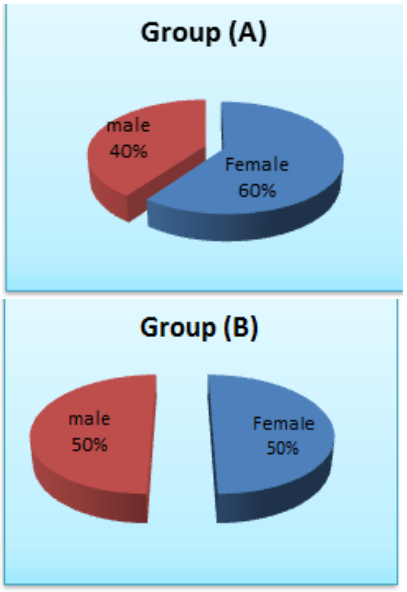


Chart (1): A&B, Percentage of gender included in both groups.

Diabetic profile:

Duration since discovery of T2DM it was ranged from (6 months-9 years), in group (A) with a mean duration of 5±2.8 years. While in group (B) it was ranged from 3 months to 10 years, with a mean duration of 5.5±2.61 years.

The medication used by patients included in group A (DJB) was oral hypoglycemics only in 8 patients (40%), insulin only in 4 patients (20%) and combination of both of them in the other 8 patients (40%). While in group B (IT), oral hypoglycemics were used by 50% of patients (n=10), insulin only in 20% (n=4) and combination of both of them in 40% of included subjects (n=6). Chart (2) &table (1):

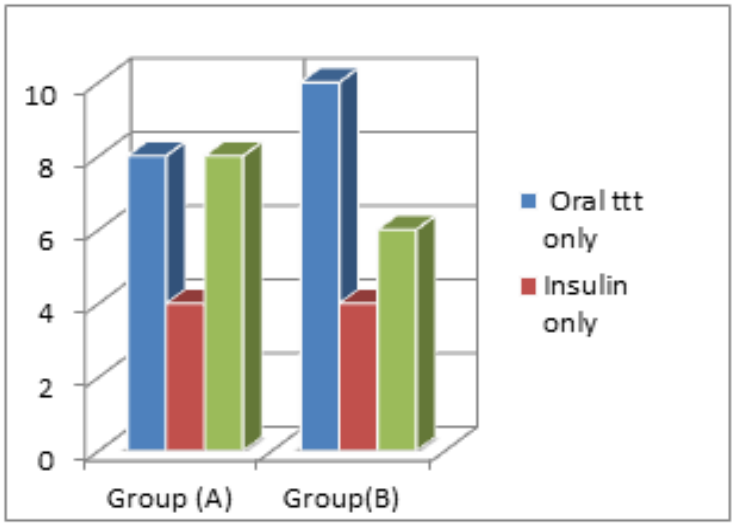


Chart (2): Preoperative antidiabetic medication

So as the chart states, 55% of our patients included in the study on insulin, either alone or in combination with oral hypoglycemic drugs.

Table (1): Comparison between both groups as regard Diabetic profile

*Diabetic profile:	**Group A** No. of cases (%)	**Group B** No. of cases (%)
1) Duration:	(6 m-9 y).	(3m-10y).
2) Medication:		
(A) Oral hypoglycemic:	8 patients (40%).	10 patients (50%).
(B) Insulin:	4 patients (20%).	4 patients (20%).
(C) Both of them:	8 patients (40%).	6 patients (30%).
3) Complications:	In 4 patients (20%)	In 3 patients only (15%).

Diabetic complications:

The preoperative diabetic complications present in 4 patients of group (A) in form of peripheral neuropathy, recurrent urinary tract infection, and in one patient only a history of hyperosmolar coma 3 months preoperative with admission for 2 days in internal medicine department. Whereas in group (B) in 4 patients, 1 in the form of multiple folliculitis and carbuncle, another patient had infected diabetic foot, neurotrophic ulcers and Charcot joint, with 2 times admission for wound debridement and 2 case suffered peripheral neuropathy.

***Intra-operative parameters:**

In case of Group A: operative time ranged from (120-230) minutes with a mean time of 170±11.3 minutes; while in case of Group B: operative time ranged from (130-250)minutes with a mean time of 145±12.74 minutes ($p< 0.05$).

So a statistically significant difference could be detected between both groups in the operative time (*which is less in ileal transposition group*).

In our study, we had no mortalities. There are no major intra-operative complications in patients of both groups, except for 2 cases of bleeding in group A who were successfully managed intra-operativelyby hemostatic devices and laparoscopic clips, along with one case of intestinal injury in group B that was managed by intra-operative limited resection using endo-stapler with no further sequelae.

***Post-operative parameters:**

1) Postoperative Hospital stay:

Overall, the mean hospital stay for the group B (IT) was higher than the group A (DJB) (*7.4 versus 6.3 days*) ($p > 0.1$) which was statistically non-significant.

2) Postoperative glycemic control:

(A): At 3 months (table: 2):

The laboratory parameters of glycemic control including FBG,2H.PP, and HbA1c improved markedly in both groups after 3 months, reaching lower values in IT group as follows:

Table (2): Comparison between both groups regarding parameters at (3) Months postop.

	Group A Range & mean value	**Group B** Range & mean value	**P**
F.B.G	(82- 150) mg%, with a mean value 119 mg%	(74- 132) mg%, with a mean value 103 mg%	<0.05 S
2H.PP	(145- 220) mg%, with a mean value 198 mg%	(135- 205) mg%, with a mean value 170 mg%	<0.05 S
HbA1c	(5.8- 6.4) %, with a mean value 6.2 gm%	(5.1- 6.7) %, with a mean value 5.9 gm%	>0.05 NS

(B): At 6 months (table: 3):

All parameters of glycemic control showed mild changes in both groups at 6 months, reaching also lower values in IT group also.

Table (3): Comparison between both groups regarding parameters at (6) Months postop.

	Group A Range & mean value	**Group B** Range & mean value	**P**
F.B.G	(70- 136) mg%, with a mean value 108 mg%	(78- 122) mg%, with a mean value 98 mg%	<0.05 S
2H.PP	(120- 208) mg%, with a mean value 164 mg%	(120- 196) mg%, with a mean value 151 mg%	<0.05 S
HbA1c	(4.8- 6.7) %, with a mean value 5.8 gm%	(5- 6.4) %, with a mean value 5.5 gm%	>0.05 NS

(C): At 12 months (table: 4):

FBG,2H-PP, and HbA1c showed minimal changes in both groups at 12 months, whereas S. insulin& C-peptide showed marked improvement than their pre-operative levels.

Table (4): Comparison between both groups as regard parameters at (12) Months postop.

	Group A Range & mean value	**Group B** Range & mean value	**P**
F.B.G	(76-128) mg%, with a mean value 106 mg%.	(72- 118) mg%, with a mean value 92 mg%.	<0.05 S
2H.PP	(110- 215) mg%, with a mean value 161 mg%.	(108- 204) mg%, with a mean value 143 mg%.	<0.05 S
HbA1c	(4.8-6.6) gm% with a mean value 5.7 gm%.	(5.1- 6.3) gm%, with a mean value 5.4 gm%.	<0.05 S
S. Insulin	(9-21.2) with a mean value 12.4 miu/ml.	(9.6-22.1) with a mean value 13.6 miu/ml.	<0.05 S
C-Peptide	(0.9- 1.7) with a mean value 1.2ng/ml.	(1- 2.1) with a mean value 1.4ng/ml.	<0.05 S

Postoperative complications:

A) Early postoperative complications:

The major early postoperative complications which occurred in our study were in the form of two cases of anastomotic leakage, one in each group: In group (A) Surgical exploration was done which revealed leakage from the duodeno-jejunostomy. Primary closure of the defect was done with an overlay omental patch, with generous lavage of the peritoneal cavity and feeding jejunostomy was inserted distally and we had a case of anastomotic leakage in group (B): on exploration leakage was noticed from the ileoileal anastomosis, generous lavage of the abdomen was done, anastomosis was refashioned. Patient had a smooth postoperative period.Both of the above leakage cases were found in the laparoscopic cases.

We had three cases of surgical site infection, two in group A and one in group B, all were treated successfully conservatively with antibiotics and more frequent dressing (all in the open cases).

B) Late postoperative complications:

We had one case of port site hernia In group (A): that was detected at site of the epigastric port 6months postoperative. Repair with a small piece of mesh was done, another case of subacute adhesive intestinal obstruction in group (B), treated conservatively (*with NGT, no oral intake, and IV fluids*) with good response. Also we had another case of incisional hernia in the open group that was repaired with placement of mesh, with uneventful post-operative course.

DISCUSSION

Discontinuation of antidiabetic medication and remission of T2DM after metabolic surgery were achieved in 86.8% and 64.7% of the patients, with FBG and HbA1c approaching slightly above normal range.[8]

This study focused on the comparison between the 2 operations as regard: Postoperative glycemic control, operative time, safety and complications.

Mean FBG, 2h PP, HbA1c, serum insulin &C-Peptide were calculated from the data available. The criterion for statistical significance was P value (if < 0.05 was considered to be significant (S), if < 0.001 it was highly significant (HS), on the other hand if it was > 0.05 it was considered non-significant (NS)).Data is presented as mean, range and number of patients (n).

Ferzli and his colleagues in 2009, in their prospective study on 7 patients, with mean age 43.3 (33–52), mean duration passed since discovery of T2DM was 10.7 years, 85.7 % (n=6) on insulin therapy. After 12 months of DJB, the mean FBS decreased from 208.8mg/dl to154.8mg/dl, with improvement of mean HbA1c from 9.4% to 8.5%. Also mean BMI decreased from 29.6 to 28.2, with no postoperative complications.[11]

Ramos and his colleagues in 2009, in their prospective study on 20 patients, with mean age 43.0 (29–60), mean duration passed since discovery of T2DM was 5.3 years, not on insulin therapy. All had foregut exclusion via DJB operation, and on follow up for 6 months of patients, the mean FBG decreased from 171.3mg/dL to96.3mg/dl, with improvement of mean HbA1c from 8.8% to 6.8%. Medication stopped by 90% (*n* = 18⁄20). Mean BMI improved from 27.1 to 24.4, with no mortality.[12]

In our study, in the 20 patients whose had DJB, with mean age 44 (34–51), mean duration passed since discovery of T2DM was 5 years, 60% of them were on insulin therapy (*alone or in combination with oral hypoglycemic agents*). On follow up of patients for 12 months, the FBG decreased from 257 mg/dl to 106 mg/dl, and the 2H-PP value also decreased from 335 mg/dl to 161 mg/dl with improvement of HbA1c from 9 gm% to 5.7 gm%. The S. insulin level was increased from 9.8 miu/ml to 12.4miu/ml, with associated increased C-Peptide from 0.9ng/ml to 1.2ng/ml.

We had remission in 55% of patients(n=11), and improvement in 35% (n==7), we had also 2 patients with same laboratory results as the preoperative state however one of them presented three times in the follow up year with simple hyperglycemia (*high glucose levels, with no coma*), and multiple folliculitis.

Reis and his colleagues in 2012 (table: 5) in a statistical meta-analysis done in Brazil, confers a good analysis of 29 studies involving 675 T2DM obese patients, with a BMI of < 35 kg/m2. They compared between 7 metabolic operations (*DJB, IT, RYGB, BPD, adjustable gastric banding, sleeve gastrectomy, mini-gastric bypass*) as regard their effect on the glycemic level.[9]

Table (5): Comparison between outcome data of both operations in Reis et al study.

Operation	DJB	IT
1) Remission:	6.3% (n=3)	58% (n=203)
2) Control:	59.5%(n=28)	29.7% (n=104)
3) Improvement:	29.7 % (n=14)	11.1% (n=39)
4) Same or worse:	4.2% (n=2)	1.1% (n=4)

They stated that T2DM resolution was high (87.71%) in IT operation which is comparable to RYGB (89.56%) and to the mini gastric bypass (88.89%).

DePaula and his colleagues in another large prospective study in 2011on 454 patients, with mean age of 53.6 (27–75). All had IT operation, and its preliminary data which are published after 1 month of follow up of patients, the mean FBS decreased from 198.3mg/dl to 125.8mg/dl (P< 0.01, HS), with improvement of mean HbA1c from 8.8% to 6.8%., with no reported mortality.[10]

In our study, in the 20 patients whose had IT, with mean age 45 (38–52), mean duration passed since discovery of T2DM was 5.5 years, 50% them are on insulin therapy. On follow up of patients for 12 months, the FBG decreased from 265 mg/dl to 92 mg/dl, and the 2H-PP value also decreased from 347 mg/dl to 143 mg/dl with improvement of HbA1c from 8.8gm% to 5.4gm%. The S. insulin level was increased from 9.6miu/ml to13.6 miu/ml, with associated increased C-Peptide from 0.9ng/ml to 1.4ng/ml.

We had remission in 75% of patients (n=15), and improvement in 20% (n==4), we had also 1 patient with same laboratory results as the preoperative state however she developed severe foot infection, and had three times wound debridement with bad response that was followed by below knee amputation of this limb, her duration of illness was 10 years.

On analysis of the results of FBG level of both groups, we found the rapid decrease of FBG occurred within the first 3 months, and it was more apparent and reaching lower levels in patients of group (B).

Also the results of the 2H-PP follows the same pattern of the FBG, indicating that both operations can cause T2DM resolution but favoring the IT operation to be the best option of treatment in patients with uncontrolled T2DM OF BMI <35 kg/m2.

The duration passed since discovery of DM and the preoperative medication are considered to be important determinant of the outcome (resolution or improvement).

Shimizu and his colleagues in 2012 tried to confirm that by the stratification of some studies by mean duration of T2DM preoperative (5 studies < or equal to 8 years, and 7 studies >8 years), the percentage of insulin-dependent patients prior to surgery was 18.2% and 45.9% (*P* <0.01). Remission ofT2DM was achieved in 66 % of the patients with short history (< or equal to 8 years) of T2DM and 52.9% of those with long history (>8 years) of T2DM (*P* = 0.03) .[8]

These data provided preliminary evidence about the benefits of metabolic surgery on the glycemic control of T2DM obese subjects with a BMI of < 35 kg/m2. However, more randomized controlled long term trials are needed to investigate the effects of surgery in T2DM remission in pre-obese patients.

CONCLUSION

In this study, we focused the light on two types of the antidiabetic surgeries (DJB & IT), depending on the theories that tried to explain their effects (foregut theory & hindgut theory).

We tried to compare the effects of the previously mentioned two operations on patients with uncontrolled T2DM with BMI ranging from 30-35. We found that both operations can cause improvement of the glycemic level, with possible remission of T2DM, but IT operation offers a slightly better adjustment of the blood glucose level, and higher percent of remission, along with having a less operative time than DJB. Although long-term follow-up data and verification of its exact mechanisms are required, early operative outcomes were satisfactory in terms of glycemic control and the safety of both procedures

The limitations of our study included study brevity, a report from a single center with a follow up of only 1 year and a relatively small number of patients that lacked a control group. Multicentric studies on a larger number of patients with a longer follow up period would strengthen our observations.

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