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Effect of Laparoscopic Single Anastomosis Duodeno-ileal Bypass-Sleeve Gastrectomy versus Laparoscopic Sleeve Gastrectomy on Hypertension Hyperlipidemia and LDH-Cholesterol

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Authors' contributions

This work was carried out in collaboration among all authors. Author MSA designed the study, performed the statistical analysis and wrote the protocol. Author MAK wrote the first draft of the manuscript. Author AEHA managed the analyses of the study. Author ISAEE managed the literature searches. All authors read and approved the final manuscript.

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ABSTRACT

Background: Reports on outcomes of LSG with patients followed for more than 15 years are evolving—a fact that will produce long-term efficacy SADI-S was started in 2007 as a shorter, safer and equally effective modified version of biliopancreatic diversion with duodenal switch]. As the name suggests, SADI-S combines two bariatric procedures – LSG and duodeno-ileal bypass. This makes it a first option for patients after ineffective sleeve gastrectomy. In an attempt to simplify the effective BPD-DS procedure- the same way Rutledge simplified RYGB by doing one loop end-to-side anastomosis – and to preserve its principles, the single an astomos is duodeno-ileal bypass with sleeve gastrectomy (SADI-S) was first introduced in 2007 by Sánchez-Pernaute and Torres as they did Sleeve gastrectomy followed by 1-loop duodenoileostomy, with 250 cm between an astomos is and ileocecal valve. Anastomosis performed in antecolic and isoperistaltic manner.

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Purpose to assess the effect of Laparoscopic Single Anastomosis Duodeno-ileal bypass-Sleeve Gastrectomy versus Laparoscopic Sleeve Gastrectomy on hypertension hyperlipidemia LDH and cholesterol. In addition to operative time (OR) and long of stay (LOS) in days.

Patients and Methods: The interventions were led at Beni-suef University Hospital between January 2018 and December 2019, after the patients fitted both the inclusions and exclusions criteria. This study consisted of 36 patients which were randomized into 2 groups. Group (A): 18 patients assigned for Single Anastomosis Duodeno-ileal bypass – Sleeve Gastrectomy [SADI-S].Group (B): 18 patients assigned for Sleeve Gastrectomy.

Results: Four patients (22.2%) were suffering from HTN in SADI-S group and 3(16.7%) hypertensive patients in Sleeve gastrectomy group. At 12 months postoperative, only one patient in sleeve group needed low dose of anti-hypertensive drug to have their BP controlled.

Conclusion: Single Anastomosis Duodeno-ileal bypass – Sleeve Gastrectomy (SADI-S) is more effective than laparoscopic sleeve gastrectomy (LSG) regarding controlling blood pressure and hyperlipidemia also. SADI-Stook more operative time and longer hospital stay than LSG. There was an improvement regarding the postoperative levels of LDL-Cholesterol in both groups with no statistically significant difference between them. mostly due to small size of the study.

Keywords: SADI; sleeve; hypertension.

1. INTRODUCTION

Although most research has concentrated on the glucometabolic effects of metabolic surgery, there has been a growing interest in exploring the potential blood pressure–reducing properties of these procedures. Indeed, systematic reviews and meta-analyses based primarily on observational data have asked that metabolic surgery may help in controlling hypertension [1]. A systematic review (136 studies, 22 094 patients) found an overall 63% cure of hypertension, with procedure-specific percentages of 68%, 43%, and 83% for RYGB, AGB, and BPDDS, respectively [2].

Laparoscopic sleeve gastrectomy (LSG) is one of the most common and effective bariatric surgical procedures worldwide. The effect of LSG is mostly dependent on the restrictive policy, which makes it more easy to failure [3]. Failure of bariatric procedures is common and occurs in 6% to 23% of cases [4]. Inadequate weight loss can be defined as an initial loss of less than 50% of excess weight loss (EWL), or relapse of body mass index (BMI) > 35 kg/m^2 [5]. Patient's noncompliance usually is evident, especially regarding dietary restrictions [6]. In the case of weight loss failure, there are no hard recommendations on the choice of the redo procedure. One of the most novel options, relatively simple to perform following LSG, is single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) [7].

SADI-S was started in 2007 as a shorter, safer and equally effective modified version of biliopancreaticdiversion with duodenal switch. As the name suggests, SADI-S combines two bariatric procedures – LSG and duodeno-ileal bypass. This makes it a first option for patients after ineffective sleeve gastrectomy [8].

SADI-S compared with duodenal switch DS eliminates the Roux-en-Y gastric bypass by creating an omega loop, and because of pylorus preservation, no need for bile diversion as the natural barrier remains in place. Pylorus provides control of solid stool emptying, reducing the chances of dumping syndrome and assisting in the maintenance of a physiologically based rate of gastric emptying [9]. SADI-S benefits over DS included reduction of the operative risk by eliminating one anastomosis with potentially similar weight loss and health benefits [10].

2. PATIENTS AND METHODS

2.1 Randomization

The participant patients were randomized according to computer generated random numeric table.

2.2 Allocation Concealment

The random allocation sequences were concealed in sealed opaque envelope then patients were assigned randomly into:

- Group (A): 18 patients assigned for Single Anastomosis Duodeno-ileal bypass – Sleeve Gastrectomy [SADI-S].

- Group (B): 18 patients assigned for Sleeve Gastrectomy.

2.3 Study Sample

The study consisted of 36 patients which were randomized into 2 groups. Patients were enrolled in the study after giving written informed consent.

- Group (A): 18 patients assigned for Single Anastomosis Duodeno-ileal bypass – Sleeve Gastrectomy [SADI-S].
- Group (B): 18 patients assigned for Sleeve Gastrectomy.

2.3.1 Inclusion criteria

- Patients who had BMIs of 40 Kg/m^2 or more, or between 35 Kg/m^2 and 40 Kg/m^2 with obesity related comorbidities that could be improved if they lose weight.
- Age (18-65) years old.
- Patients were generally fit for anesthesia and surgery.

2.3.2 Exclusion criteria

- Previous gastric or duodenal surgery.
- Endocrine disorders excluding diabetes mellitus.
- Psychiatric illness.
- Recent diagnosis of malignancy.
- Heavy smokers and alcoholics.

Outcome: Systemic hypertension remission was defined with blood pressure maintained below 140/90 without antihypertensive medications for > 3 months after surgery.

2.4 Operative Details

Laparoscopic sleeve gastrectomy group.

2.4.1 Surgical technique

2.4.1.1 Positioning

Patients were placed in supine, legs spread (French position), in a steep Fowler (reverse Trendelenburg) position, and the table was slightly tilted right side down for an adequate visualization of the gastroesophageal (GE) junction. The patient was secured to the table. Additionally, above knee elastic stockings was employed to prevent venous thromboembolism

- Pneumoperitoneum was created by direct Veress needle at Palmer's point.
- A 15 mmHg CO_2 abdominal pressure was set for all the procedure with 5-6 trocars set up.
- The first trocar (10-12 mm) was placed 2-3 cm to the left of the midline 15-18 cm caudal from the xiphoid for the placement of a 10 mm/30 degrees lens.
  - Both sides of the camera 5- 10 cm away at the same line were placed two 12 mm trocars for both working hands of the surgeon.
  - The assistant placed a 5 trocar lateral in the left side of the patient (anterior axillary line) 2-3 cm from the last costal bone.
  - Another 5/10 mm trocar was placed at the xiphoid to liver retraction.
- A 10-mm, 30° scope is used. The left lobe of the liver is retracted to expose the entire GE junction and the lesser curve.
- The procedure started by cutting the small branches of the gastroepiploic arcade and opening the lesser sac. Then, dissection was carried out along the greater curve, staying very close to it, dividing the branches of both gastroepiploic arteries, until short gastric vessels were divided using an advanced bipolar cutting device or the ultrasonic scalpel. The assistant retracted the omentum laterally during the maneuver and kept repositioning the instrument superiorly to improve exposure of the vessels and avoid bleeding. The remainder of the gastrocolic ligament (without gastroepiploic vessels transection) was severed distally up to 2 cm proximal to the pylorus. The objective of cutting the omentum right by the edge of the greater curve is to minimize the amount of fat attached to the stomach, to make its extraction from the abdomen easier at the end of the operation. The stomach was then lifted to expose its posterior aspect, and all lesser sac attachments of the stomach were freed. This allowed the appropriate positioning of the mechanical suture.

- The gastrophrenic ligament was divided and the angle of Hiss was exposed to determine the presence of a hiatal hernia, adding the full exposure of the left crus to complete the dissection.
- Stomach division started 4 cm proximal to the pylorus, to preserve a part of the gastric emptying mechanism of the antrum. Prior to the creation of the sleeve, the anesthetist introduced a 36-Fr bougie to guide the stapling and maintain an adequate lumen of the gastric sleeve. The bougie was placed prior to stapling, guiding it to reach the pylorus, and positioned close to the lesser curve. Care was taken not to divide the stomach too close to the incisura angularis to avoid kinking or stenosis at this level. Green (4.8 mm) stapler cartridge was used for the first two firings and blue for the rest. In any case, all of them were 60 mm in length.
- Dividing fundus as close as the GE junction as possible, without actually compromising the esophagus 0.5 cm away from the GE junction.
- Additionally, the perigastric fat was mobilized, permitting better identification of the esophagogastric junction,
- The anesthetist removed the bougie under direct vision to check the final shape of the sleeve. The stomach was removed through one of the 12-mm ports. The integrity of the staple line was tested with the instillation of 50–100 ml of methylene blue in saline solution. Drain was inserted at the operative bed.

2.4.1.2 Laparoscopic single anastomosis duodeno-ileal bypass–sleevegastrectomy group

For the sleeve gastrectomy part of the procedure (with the operating table under Anti- trendlenburg position and the surgeon positioned between the legs of the patient):

- Devascularization of the greater curvature of the stomach with a Harmonic scalpel™ or a Bipolar Ligasure device™
- The stomach was then tubularized over a suitable sized oral bougie with linear staplers ,commencing 5-6 cm proximal to the pylorus

Then, For the Single Anastomosis Duodeno-ileal bypass part:

- The dissection of the greater curvature of the stomach was prolonged through the first portion of the duodenum down to the gastroduodenal artery.
- The first part of duodenum was divided with a linear blue cartridge stapler, then the table was changed to the horizontal position and the surgeon moved to the left-hand side of the patient.
- The ileocecal valve was identified and 250 cm was measured upwards.
- The selected ileal loop was ascended ante-colically without division of the greater omentum, and stapled iso-peristaltic end-to-side duodeno-ileal anastomosis was completed using a 35 mm blue cartridge.

3. RESULTS

Table 1. Preoperative and postoperative hypertension

		SADI-S group		LSG group		P value
		No.	%	No	%	
Hypertension	Yes	4	22.2%	3	16.7%	0.7
	No	14	77.8%	15	83.3%	
Anti-hypertensive drugs after 6 months	Increase	----	----	----	-------	0.25
	Decrease	1	25%	2	66.7%	
	Discontinue	3	75%	1	33.3%	
	Restart	----	-------	-----	------	
Anti-hypertensive drugs after 12 months	Increase	----	-----	------	------	0.3
	Decrease	…	,,,,,	1	33.3%	
	Discontinue	4	100%	2	66.7%	
	Restart	-----	----	----	-----	

Table 2. Preoperative and postoperative hyperlipidemia

		SADI-S group		LSG group		P value
		No.	%	No	%	
Preoperative Hyperlipidemia	Yes	12	66.7%	11	61.1%	0.73
	No	6	33.3%	7	38.9%	
Hyperlipidemia (6 months)	Improved	9	75%	7	63.6%	0.55
	Not	3	25%	4	36.4%%	
Hyperlipidemia (12months)	Improved	11	91.7%	8	72.7%	0.8
	Not	1	8.3%	3	27.3%	

Table 3. LDL-cholesterol in both groups at follow up

	Group A (SADI-S) Mean (SD)	Group B (LSG) Mean (SD)	Test of significance	P-value
Preoperative LDL-Cholesterol (mg/dl)	134.56(34.55)	125(26.3)	Independent-samples t test t (34) = .93	0.36
LDL-Cholesterol after 3 months	108.56(33.16)	106(22.52)	Independent-samples t test t (34) = 0.18	0.86
LDL-Cholesterol after 6 months	99.39(23.9)	100.44(23.3)	Independent-samples Mann-Whitney U test	0.89
LDL-Cholesterol after 12 months	89.22(16.96)	96.94(22.73)	Independent-samples Mann-Whitney U test	0.31

There was an improvement regarding the postoperative levels of LDL-Cholesterol in both groups with no statistically significant difference between them

Table 4. Operative time in both groups

	Group A (SADI-S) Mean (SD)	Group B (LSG) Mean (SD)	Test of significance	P-value
Operative time (minutes)	189.9(31.4)	97.5(35.2)	Independent-samples t test t (34) = 8.3	≤0.005**

Table 5. Hospital stay in both groups

	(SADI-S) Mean (SD)	(LSG) Mean (SD)	Test of significance	P-value
Hospital stay (days)	2.9(1)	1.8(0.42)	Independent-samples Mann-Whitney U test	≤0.001**

4. DISCUSSION

Obesity has presented an exponential increase in the last few years, becoming a serious public health matter [11]. Increased body mass index exhibit different comorbidities, including hypertension, which are tightly related to the high cardiovascular risk of this population [12]. In the United States, half of the patients with increased blood pressure display obesity. Moreover, a third of obese subjects have high blood pressure levels, compared to the 20% observed in subjects with a normal body mass index [13]. Furthermore, the intervention strategy for increased blood pressure in patients with obesity implies various challenges concerning the effect of the pharmacological treatment. In this respect, obesity leads to a resistance to antihypertensive medication together with disturbances in volume distribution and hepatic and renal clearance. This implies that patients with high blood pressure and obesity in general require a more "aggressive" antihypertensive treatment in order to achieve desirable blood pressure levels [14].

The duodenal switch procedure has a profound impact on BMI and ample literature exists comparing it to other bariatric procedures. Furthermore, the duodenal switch has shown more rapid prolonged weight loss and comorbidity improvement when compared to these other procedures especially in the super-

obese patient population [15]. This procedure combines restriction, malabsorption, and hormonal changes to achieve weight loss and comorbidity improvement [16]. Several iterations of duodenal switch exist and it has evolved over time. Scopinaro et al. fashioned the way with his initial experience in humans by performing a distal gastrectomy and a long Roux-en-Y construction with a gastroileal anastomosis [17]. Two more recent alterations of the procedure exist including the traditional duodenal switch with a vertical sleeve gastrectomy and a Roux-en-Y duodenoileal construction, and a duodenal switch consisting of a sleeve gastrectomy with a single anastomosis duodenoilealbillroth II construction (SADI-S) [18]. In our study the mean operative time was 189.9± 31.4 min in SADI- S group and 97.5± 35.2 min in LSG group with p-value of ≤0.005. There is a statistical difference as SADI-S took more time. This may be explained by: The duodenal dissection took some more time to avoid injury of the duodenum, the gastroduodenal artery or even the common bile duct. The duodeno-ileal anastomosis took more time as, the duodenoileostomy was fashioned as end to side anastomosis to avoid stapling the pyloric ring in case of side to side anastomosis. Similarly Lin et al. [19] reported a mean operation time (min) 95.8 ± 27.8 in LSG. Unlike Topart et al. [20] who reported a mean operative time in SADI-S 100.8 minutes (range 69.9-181.7), while Gebelli et al. [21] reported a mean Surgical time 115 min (80-180) in SADI-S.

In our study the mean hospital stay was 2.9 days ± 1 in SADI-S group and 1.8 days ± 0.42 in LSG group with statistical significance between both groups (P-value ≤0.001).On the other hand studies reported a longer hospital stay. Moon et al. [22] reported a mean hospital stay of 4.1 ± 2.7 days in SADI-S. Also Nelson et al. [23] reported a mean length of hospital stay of 4.3± 2.6 days (range, 3-24). Six patients had a prolonged hospital stay (longer than five days) due to decreased oral intake (n=3), atelectasis (n=1), postoperative bleeding (n=1), and duodeno- ileal obstruction with perforation of the small bowel (n=1). While in LSG, Lin et al. [19] reported length of postoperative hospital stay (days) 3.9 ± 1.4 [19]. Our study shows shorter hospital stay which could be because of patients' smooth recovery as we had no intra-operative or early post-operative complications.

Four patients (22.2%) were suffering from HTN in SADI-S group and 3(16.7%) hypertensive patients in LSG group. At 12 months postoperative, only one patient in sleeve group needed low dose of anti-hypertensive drug to have their BP controlled. Patients showed more improvement in SADI-S group than LSG group regarding hypertension, which may be attributed to weight loss and improvement of T2DM, but wasn't statistically significant. Shoar et al. [24] reported similar results resolution rate of 96.3% for hypertension at 12 months postoperative.

However Nelson et al. [23] reported that out of 33 patients (47.8%) with HTN at the time of surgery, 14 (42.4%) had their HTN resolved at six months after SADI-S. On the other hand Noel et al. [25] reported that 59.4% of patients with HTN at the time of surgery, had their HTN resolved at 8 years after LSG. Moreover, Felsenreich et al. [26] reported that 29% of patients with HTN at the time of surgery had their HTN resolved at 5 year after LSG.

Twelve (66.7%) patients were suffering from hyperlipidemia in OADS/SADI-S group and eleven (61.1%) patients in Sleeve group. At 12 months postoperative, only one patient in OADS group and three patients in Sleeve group did not have their blood HDL and cholesterol levels well controlled, with improvement rate of 90.9% and 72.7% in OADS/SADI-S and LSG respectively, but wasn't statistically significant between both groups.

Similarly Sanchez-Pernaute et al. [27,28] stated that lipidic profile has improved significantly after surgery as 100% of the patients had normal cholesterol levels at 12 months after surgery and only 16% of the patients maintained hypertriglyceridemia. However Shoar et al. [24] reported a resolution rate of 68.3% for hyperlipidemia.

On the other hand Neagoe et al. [28] reported a 51% improvement of hyperlipidemia after LSG at 12 month postoperative.

The same argument with controlling T2DM can also explain the improvement of the lipid profile.

5. CONCLUSION

SADI-S/OADS is more effective than LSG regarding controlling blood pressure and hyperlipidemia also .SADI-S/OADS took more operative time and longer hospital stay than LSG. There was an improvement regarding the postoperative levels of LDL-Cholesterol in both groups with no statistically significant difference

between them this is mostly because of the sample of the study.

CONSENT AND ETHICAL APPROVAL

Approval taken from the ethical committee from our faculty and a written consent was taken to carry out the study.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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