

## Short-Term Outcomes of Reinforcement of Staple Line During Revisional Laparoscopic Sleeve Gastrectomy

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### Abstract:

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**Background:** Revisional sleeve gastrectomy has higher complications like bleeding and leakage so staple line reinforcement (SLR) is very important to decrease such dangerous events. **Purpose:** The purpose of this research is to investigate the effectiveness of utilizing barbed suture to strengthen the staple line during revisional laparoscopic sleeve gastrectomy performed following an unsuccessful laparoscopic adjustable gastric band procedure. **Patients and methods:** Patients were arranged into; group (A); 21 cases; underwent Laparoscopic Sleeve Gastrectomy (LSG) with stapler line strengthening by barbed suture and group (B); 21 cases; underwent LSG without strengthening. Patient follow-up period was 6 months. **Results:** There was no mortality. No significant differences between both groups as regard to preoperative data and hospital stay. Group (A) was performed in longer time;  $109 \pm 2.3$  vs.  $78 \pm 1.4$  in group (B). Postoperative leak was reported only in group (B); 2 patients (4.8%) and frequency of bleeding was more in group (B); 4 patients (9.6%) P-value for leak and bleeding was 0.037 & 0.048.

**Conclusions:** Revisional Sleeve gastrectomy by laparoscopy is still safer and minimally invasive procedure. Adding barbed suture reinforcement of the staple line is a weapon to decrease incidence of postoperative leak and bleeding to a great extent.

**Key words:** Revisional Sleeve Gastrectomy, Staple line reinforcement, Outcomes.

### Introduction:

Objective of obesity management is to promote weight loss to reduce health hazards. This weight loss happens by generation of negative energy balance, which is achieved by doing more energy than calories taken (1-3).

Obesity is the outcome of behavioral, environmental, genetic and socio-cultural factors. Modifiable risks of obesity in energy intake include extra calories of high-fat meals and sweets (4). Even though the danger of weight regain (WR) may be

prevalent when individuals achieve their nadir weight, bariatric surgery (BS) is regarded the most effective method for the management of obesity (5, 6).

Laparoscopic sleeve gastrectomy, is a surgical procedure reducing stomach to 15% of its size, leaving a tube or a sleeve. This method significantly reduced complications of weight reduction procedures with weight loss 30-50% of extra body weight over 6-12 months (7).

WR is linked to a decline in quality of life as well as the recurrence or worsening of

obesity-associated comorbidities such as hypertension and type 2 diabetes mellitus (T2DM), all of which need regular monitoring and the use of suitable treatment strategies (8-10). In addition, revisional bariatric surgery to treat weight return or inadequate weight loss (WR/IWL) may result in a greater risk of complications such as bleeding and leaking, as well as an increased risk of death, as compared to first bariatric surgery (11-14).

The use of staple line reinforcement as a potential approach for reducing leakage and bleeding has been investigated. This includes reinforcing the line with additional stitches or using bovine pericardium or synthetic polymers to strengthen the tissue. However, there is not enough information to conclusively state whether staple line reinforcement is useful (4, 15).

In their 2014 evaluation of staple line reinforcement (16), proposed that a sample size of approximately 10,000 LSG operations be necessary to identify a statistically significant difference between the normally low leak rates associated with reinforcing choices. This was mentioned in the context of establishing if a statistically significant difference exists between the normally low leaks rates associated with reinforcing choices (16). Recommendations were established from

facts and expertise based on a pooled data of 12,799 LSG cases with 1.1 percent leakage in practice recommendations created by consensus voting and published in the International Sleeve Gastrectomy Expert Panel Consensus Statement. These rules were developed using data from a large data collection. The Expert Panel reached an agreement on most of the issues pertaining to strengthening the staple line, including the finding that staple-line reinforcement reduces the amount of bleeding that occurs. There was a lack of agreement on whether or not reinforcement helps minimize leakage and whether or not regular reinforcement should be undertaken (17, 18).

The purpose of this research is to investigate whether or not revisional surgery may benefit from the use of barbed suture to fortify the staple line of laparoscopic sleeve gastrectomy.

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### **Patients and methods:**

Within the department of surgery at Benha University and Benha teaching hospitals, this present research comprised a total of 42 morbidly obese individuals who had a BMI of more than 35 kg/m<sup>2</sup>. Patients were randomly allocated by using simple random allocation method, where 42 cards were prepared by the principal investigator and were put in closed envelopes and mixed together.

After local ethical committee of Benha University and obtaining written fully informed patients consent, Patients were enrolled; From September 2020 till December 2021; Follow-up period was 6 months. All procedures in this study were done according to the Declaration of Helsinki and its updates.

Patients were arranged into 2 groups; group (A); 21 cases; underwent Laparoscopic Sleeve Gastrectomy (LSG) with stapler line strengthening by barbed suture and group (B); 21 cases; underwent LSG without strengthening.

Patients included in the current study were morbidly obese patients after failed laparoscopic adjustable gastric band, BMI >35 kg/m<sup>2</sup> with co- morbidities, or BMI >41 kg/m<sup>2</sup> without comorbidities, Age 18-55 years old, any gender. But Patients excluded from this study were cancer patients at any stage, ASA<sub>4</sub>, current alcohol or drug addiction, severe psychological illness, Contraindications for laparoscopic surgery or BMI >55 kg/m<sup>2</sup>.

All cases in this study were evaluated by clinical history, physical examination including vital signs, Height and weight obtained for BMI calculation and laboratory investigations by routine blood tests for fitness, respiratory functions, Echocardiography, thyroid and growth hormone levels assessment, upper gastrointestinal tract (GIT) endoscopy, X-

ray chest, other potential imaging and psychological consultation.

### ***Operative procedure:***

#### **Group A (Reinforced stable line):**

The night before each operation, 2.5 IU of Fondaparinox (Arixtra) was administered to each patient, and each surgery was performed under general anesthesia. The patient is positioned supine for the examination. The night before each operation, 2.5 IU of Fondaparinox (Arixtra) was administered to each patient, and each surgery was performed under general anesthesia. The patient is positioned supine for the examination then CO<sub>2</sub> pneumo-peritoneum is then established to 15-mmHg pressure by veress needle. The preferred method of entry to the abdominal cavity is optical entry (12-mm trocar loaded with the 10-mm 0-degree scope). A total of 4 trocars 12-mm are passed obliquely through the abdominal wall, including right and left upper quadrant trocars, epigastric and a supra umbilical trocars just to the left of the midline. While a 5<sup>th</sup> 5-mm trocar is inserted in the left lumbar region at the anterior axillary line.

First, the patient's gastric band is removed, and then, around 10 centimeters from the pylorus, a window is created by dissecting the junction of the greater curvature and the larger omentum. Beginning four centimeters proximal to the pyloric ring

and continuing all the way up to the angle of His, the (Harmonic scalpel) is used to divide the gastroepiploic, short gastric, and posterior fundic veins (Harmonic; Ethicon Endosurgery, Cincinnati, OH, USA).

After the conclusion of the dissection, the anesthesiologists will insert a 36 Fr bougie into the stomach via the oral cavity. The surgeon will then guide the bougie down the lesser curvature and into the pyloric antrum and duodenal bulb. Greater curvature transection often starts between 4 and 6 centimeters proximal to the pylorus. After firing, a green or gold cartilage measuring 60 millimeters is positioned across the antrum via the right mid epigastric port. After that, consecutive firings of the stapler are positioned about one to two centimeters from the border of the lesser curvature in the direction of the gastro-esophageal junction till the left crus.

After the full transection, the staple line is invaginated all the way through with running sero-muscular stitches using unidirectional absorbable v-lock 2/0 sutures (Covidien, Mansfield, MA, USA). These threads begin at the angle of His and continue all the way down to the pylorus.

The stomach that has been transected is then extracted via one of the twelve-millimeter port locations. In order to rule out the possibility of macroscopic leaks in the suture line, the integrity of the staple

line is examined using methylene blue while the pylorus is compressed using a surgical grasper. At long last, the drain is placed, and all of the trocar sites are sealed.

#### Group B (Non reinforced stable line):

All steps of laparoscopic sleeve gastrectomy were done as in (Group A) without staple line strengthening. Figure (1)

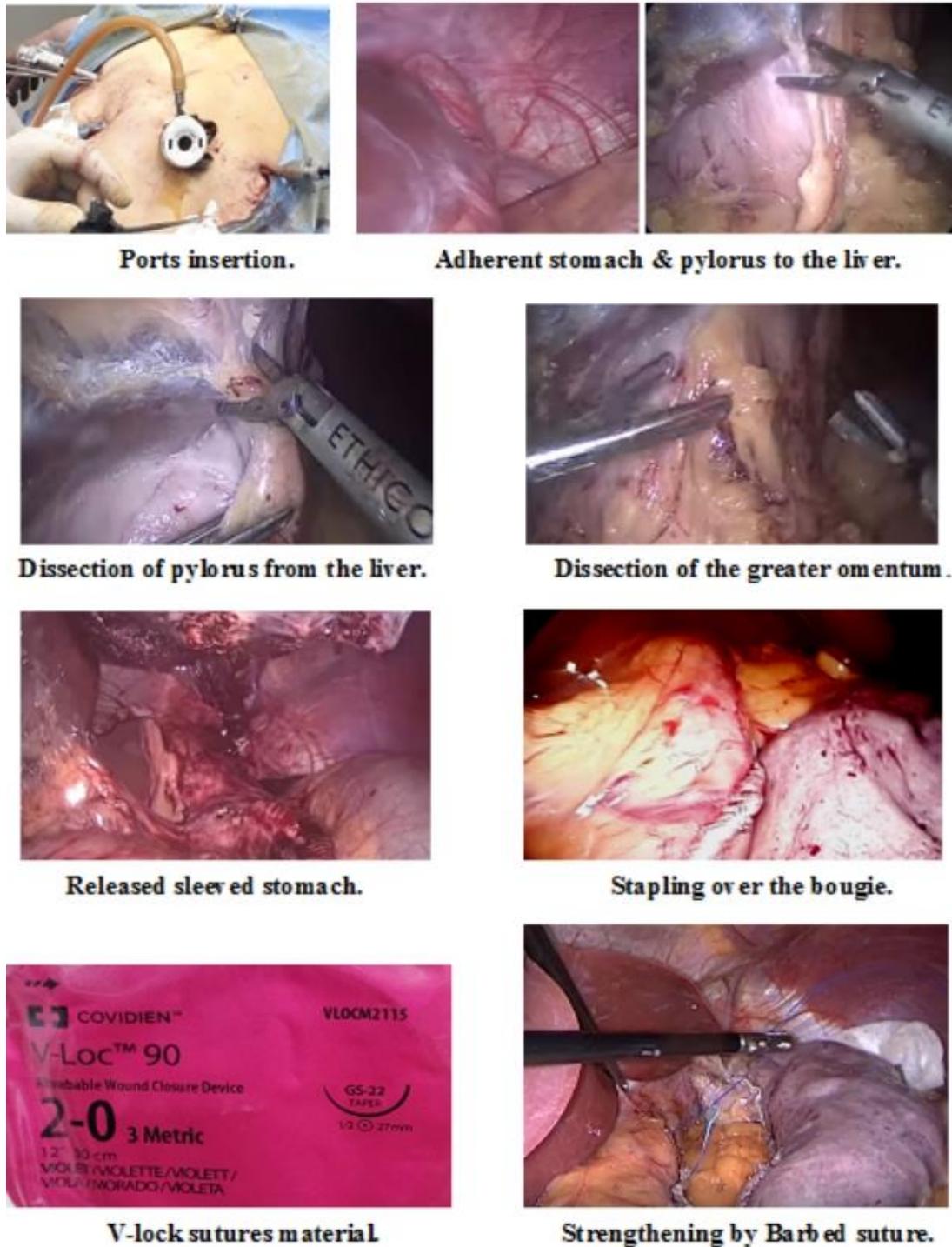
#### ***Postoperative Follow-up:***

Close follow up was done for reporting of post-operative leakage or bleeding, post-operative hospital stays and Duration of surgery. Concomitant medications or procedure were recorded. Weight was measured. Nutritional counselling was performed. Reporting of any changes of patient co-morbidities was done. All events of the patient was recorded as applicable on the day of surgery, 1 week after surgery and monthly to the 6<sup>th</sup> month postoperatively.

#### ***Statistical analysis:***

The version 25 of SPSS was used to conduct the statistical analysis (IBM, Armonk, New York, United States). Means and standard deviations were calculated using the numerical data that was collected. The registrar transcribed the categorical data into numbers and percentages. When comparing the two groups' numerical data, the independent t-test was used, whilst comparisons of the

groups' categorical data were conducted using either the Chi-square test



**Figure (1):** Steps of reinforced stable line of LSG.

or Fisher's exact test, depending on the circumstances. A multivariate linear regression analysis with control for all

other characteristics was performed to determine the impact of utilizing reinforced staple line on the total amount

of time needed for surgery. Calculations were made to determine the regression coefficient as well as the confidence intervals for 95 percent. Each and every p-value was a two-sided statistic. P values lower than 0.05 were used to indicate statistical significance.

**Results:**

This prospective randomized interventional study was conducted on 42 cases in the department of surgery at Benha University and Benha teaching hospitals. All patients completed their follow up and there was no mortality.

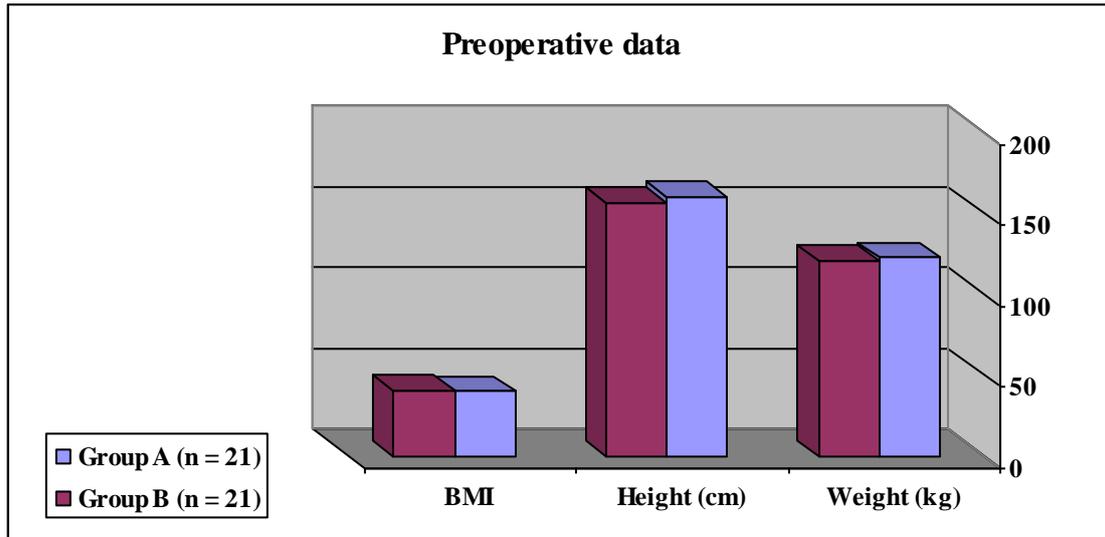
**Table (1):** Preoperative data between both groups:

|                               |                      | <b>Group A<br/>(n = 21)</b> | <b>Group B<br/>(n = 21)</b> | <b>P value</b> |
|-------------------------------|----------------------|-----------------------------|-----------------------------|----------------|
| <b>Gender</b>                 | <i>Males</i> n (%)   | 8 (38.1)                    | 7 (33.3)                    | 0.675          |
|                               | <i>Females</i> n (%) | 13 (61.9)                   | 14 (66.7)                   |                |
| <b>Age (years)</b>            | <i>Mean ±SD</i>      | 31 ± 5.8                    | 39 ± 2.6                    | 0.691          |
| <b>Weight (kg)</b>            | <i>Mean ±SD</i>      | 123 ±19.2                   | 121.2 ±21.3                 | 0.352          |
| <b>Height (cm)</b>            | <i>Mean ± SD</i>     | 161 ± 9.2                   | 157 ± 10.3                  | 0.541          |
| <b>BMI (Kg/m<sup>2</sup>)</b> | <i>Mean ±SD</i>      | 39.84 ± 4.03                | 40.62 ± 3.09                | 0.749          |

Chi-square test was used for gender & Independent t-test was used for others.

There was no significant difference between both groups regarding preoperative demographic data; P-value was non-significant. Tab. (1), Graph (1)

Upon review operative time; group (A) was performed in longer time with Mean ± SD; 109 ± 2.3 but group (B) was performed in shorter time Mean ± SD; 78 ± 1.4 and there was statistical significance between both groups; P-value was <0.001. Hospital stay was Mean ± SD; 2 ± 1 in group (A) and 3 ± 1 in group (B) and showed no significant difference between both groups. P-value was 0.213. Tab. (2), Graph (2).

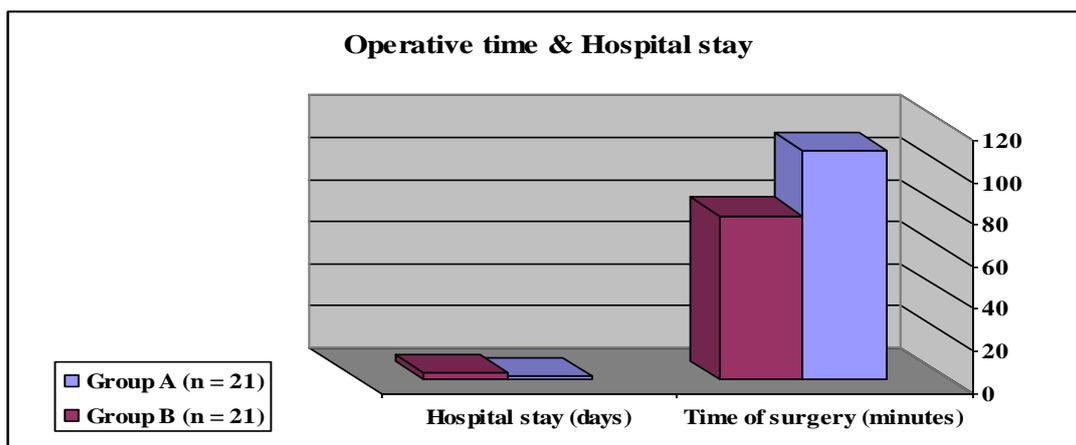


Graph (1): Preoperative data between both groups.

Table (2): Operative time & Hospital stay in both groups:

|                              |           | Group A<br>(n = 21) | Group B<br>(n = 21) | P value |
|------------------------------|-----------|---------------------|---------------------|---------|
| Time of surgery<br>(minutes) | Mean ± SD | 109 ± 2.3           | 78 ± 1.4            | <0.001  |
|                              | Mean ±SD  | 2 ± 1               | 3 ± 1               | 0.213   |

Independent t-test was used.



Graph (2): Operative time & Hospital stay in both groups.

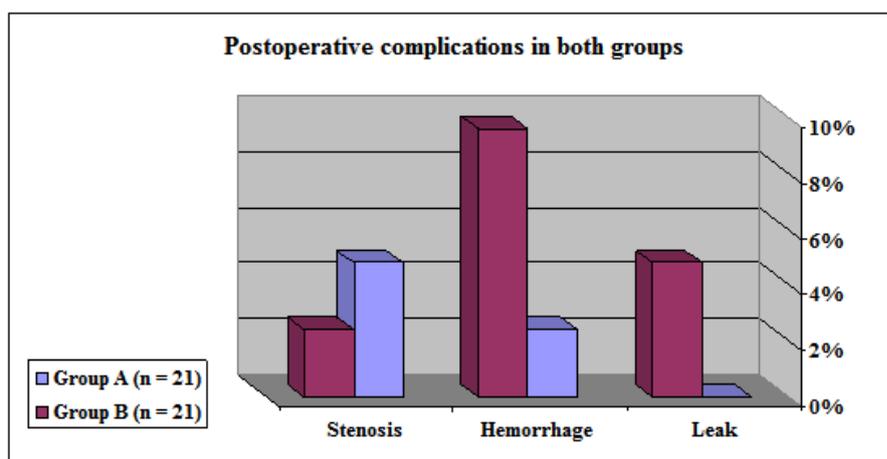
In the present study; the postoperative leak was reported only in group (B); 2 patients (4.8%); these two patients were managed endoscopically by mega stent. Frequency of bleeding was more in group (B); 4 patients (9.6%); two of them were managed laparoscopy and stapling of

bleeding points and the other two were managed conservatively). On the other side; patient with bleeding in group (A) was treated conservatively. Regarding postoperative stenosis; there was no significance between both groups. Tab. (3), Graph (3).

**Table (3):** Postoperative complications in both groups:

|            |       | <u>Group A</u><br><u>(n = 21)</u> | <u>Group B</u><br><u>(n = 21)</u> | <u>P value</u> |
|------------|-------|-----------------------------------|-----------------------------------|----------------|
| Leak       | n (%) | 0 (0.0)                           | 2 (4.8)                           | 0.037          |
| Hemorrhage | n (%) | 1 (2.4)                           | 4 (9.6)                           | 0.048          |
| Stenosis   | n (%) | 2 (4.8)                           | 1 (2.4)                           | 0.059          |

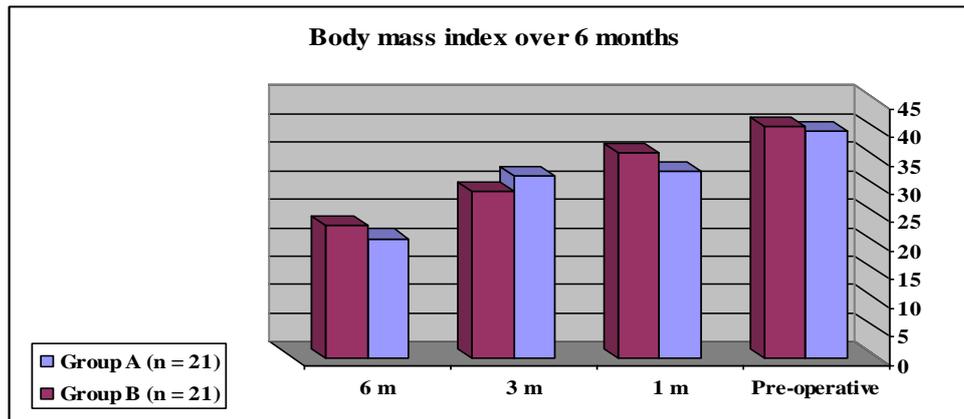
Fisher's exact test was used.



Graph (3): Postoperative complications in both groups.

**Table (4):** Body mass index changes over 6 months in both groups:

| <b>Time</b>          | <b>Group A</b><br><b>(n = 21)</b> | <b>Group B</b><br><b>(n = 21)</b> | <b>Range</b> | <b>P value</b> |
|----------------------|-----------------------------------|-----------------------------------|--------------|----------------|
| <b>Pre-operative</b> | 39.84 ± 4.03                      | 40.62 ± 3.09                      | 33.6 - 45.2  | <0.001         |
| <b>1 month</b>       | 32.84 ± 6.12                      | 36.11 ± 6.11                      | 31.25-40.59  | (HS)           |
| <b>3 months</b>      | 31.98 ± 1.32                      | 29.21 ± 2.32                      | 25.21-33.82  |                |
| <b>6 months</b>      | 21.01 ± 3.13                      | 23.21 ± 3.91                      | 20.89-26.79  |                |



Graph (4): Body mass index changes over 6 months in both groups.

There was high statistically significant reduction in BMI of both groups from pre-operative levels following sleeve gastrectomy over 6 months. Tab. (4), Graph. (4).

**Discussion:**

Obesity is a serious worldwide health problem, associated with increased mortality and morbidities, such as diabetes mellitus, hypertension, osteoarthritis and obstructive sleep apnea syndrome. The surgical management is proven to be the ideal solution of the morbid obesity including several procedures (19, 20).

The most common observed morbidities of LSG are leaks, bleeding and postoperative stenosis. Most haemorrhage reported with LSG comes from line of applied staples after gastric transection (21).

Revisional BS may have higher complications like leak and haemorrhage and even mortality rates compared to primary BS (12-14). So, Staple-line reinforcement has been used with hoping

results in patients underwent laparoscopic BS to reduce leakage, increase staple-line integrity and diminish staple-site bleeding (22).

The purpose of this research is to investigate the effectiveness of utilizing barbed suture to strengthen the staple line during revisional laparoscopic sleeve gastrectomy performed following an unsuccessful laparoscopic adjustable gastric band procedure.

The current investigation consisted of 42 cases; the average age was around 35 years old; there were no significant differences between the two groups with regard to age or gender; the P values for these categories were respectively 0.691 and 0.675. These data was similar to results reported by "Konstantinos, et al."; in total, 187 patients underwent LSG; 134 women (71.7%), 53

men (28.3%), 2.5/1 ratio; median age =36 years (range = 16–60)) (23).

By reviewing weight and length in the current study; it was showed no significant difference between both groups. P-value was 0.352 & 0.541. These results were comparable to "Taha et al." study; P-value was 0.512 & 0.303 (24).

Indications of bariatric surgery according to National Institutes of Health guidelines include BMI of 40 kg/m<sup>2</sup> or higher or a BMI between 35 and 40 kg/m<sup>2</sup> with at least two obesity-related comorbidities (25).

Upon review operative time; group (A) was performed in longer time with Mean  $\pm$  SD; 109  $\pm$  2.3 but group (B) was performed in shorter time Mean  $\pm$  SD; 78  $\pm$  1.4 and there was statistical significance between both groups; P-value was <0.001. Hospital stay was Mean  $\pm$  SD; 2  $\pm$  1 in group (A) and 3  $\pm$  1 in group (B) and showed no significant difference; P-value was 0.213. Current study operative time was longer than reported by "Taha et al."; Operative time was shorter during LSG without strengthening staple line (44.3  $\pm$  5.5 min in group (1) vs. 51.3  $\pm$  4.3 min in group (2), p < 0.01) (24).

In the current work, length of hospital stay was around 3 days; P-value was 0.213. These results were in consistent with "Hany and Ibrahim" results; Mean hospital stay (days) was 1.92  $\pm$  0.33 in group (A)

and 1.97  $\pm$  0.42 in group (B) with P-value was 0.068. This short hospital stay is referred to the fact that the laparoscopy is minimal invasive surgery (26).

Revisional laparoscopic surgery on the gastrointestinal tract is associated with a number of risks and complications, some of which include leakage caused by disruption of the staple line, bleeding that necessitates additional surgery, and postoperative strictures that require either endoscopic or surgical intervention (12, 27).

Staple-line leak is a serious complication with rate 2-5%. GIT leak after bariatric surgery has been identified as an independent risk factor associated with perioperative death (28, 29).

The present study had zero leak in group (A) but frequency of leak in group (B) was 2 patients (4.8%); P-value was 0.037. These results were in complete accordance with "Hany and Ibrahim"; Leak was 0 in group (A) and 8 patients (1.7%) in group (B) with P value was 0.008 (26).

There are many causes of such leak; probably due to the increased dissection required by re-operative surgery, with a resulting increased risk of injury and ischemia to the tissues (29, 30).

In the current work, Use of barbed 2/0 decreased leak and haemorrhage to a great extent and these good effects were approved by " Nemecek et al." (31).

Due to the lengthy staple line, postoperative hemorrhage is a frequent complication that may occur following revisional LSG. The risk ranges from 1% to 6% (32). The bleeding rate of the current investigation was similar to the findings of "Taha et al."; bleeding was decreased in reinforced LSG in comparison to non-reinforced LSG (2% in group (A) vs. 9% in group (B),  $p < 0.05$ ) (24). Because frequently oversewing the staple line is related with a decreased risk of leaks and bleeding, those surgeons were found to have greater expertise and a lower overall complication rate than those who did not habitually oversee the staple line

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(33). There are several randomized controlled studies that confirm our results, which revealed that staple line reinforcement in revisional LSG has advantages to minimize staple-line bleeding and leakage. These trials were conducted to demonstrate that our findings are accurate (34, 35).

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## Conclusions:

Revisional Sleeve gastrectomy by laparoscopy is still safer and minimally invasive procedure. Adding v-lock suture reinforcement of the staple line is a weapon to decrease incidence of Procedure leakage and bleeding to a great extent.

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