

Clipping versus Suturing in Prevention of Staple Line Bleeding in Laparoscopic Sleeve Gastrectomy

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Abstract

Background: Laparoscopic Sleeve Gastrectomy (LSG) has evolved rapidly as a single stage procedure for patients with morbidobesity and now it represents the most famous bariatric operation in the world with favourable therapeutic results and low risk complications. Leakage and bleeding represent the main postoperative complications. Although postoperative leakage is a major concern for bariatric surgeons, staple line bleeding (SLB) still represents an important issue that needs more focus and special attention as its incidence is between 0-10%.

Aim of Study: We aim to compare between clipping and suturing the staple line and its impact on staple line bleeding primarily and other complications secondary.

Material and Methods: It's retrospective study on 410 patients, divided into 2 groups; group A: 220 patients underwent clipping of the suture line, group B: 190 patients underwent suturing. The primary outcome variable was postoperative bleeding (POB). Other outcome variables included hospitalisation period, complications, readmission and mortality within 30 days.

Results: No significant difference between both groups as regard preoperative data. The operative time was significantly different between both; in the clipping group it ranged from 22-50min, in the suturing group from 30-60min. Also the blood loss from the staple line was significantly different; in the clipping group: 50-200cc, suturing group 70-250cc.

Number of cases with POB was significantly different being more in the suturing group (12 cases=6.3%). Leakage and other complications were insignificantly different, however leakage occurred in three cases in the clipping group and one in the other.

Conclusion: We assume that clipping achieve better bleeding control with much less operative time but may carry a little more risk of leakage. We look forward to do wider studies comparing with combined use of both, how and where to use each.

Key Words: *Clipping versus Suturing – Laparoscopic Sleeve Gastrectomy.*

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Introduction

LAPAROSCOPIC Sleeve Gastrectomy (LSG) has evolved rapidly as a single stage procedure for patients with morbidobesity and now it represents the most famous bariatric operation in the world with favourable therapeutic results and low risk complications. Leakage and bleeding represent the main postoperative complications of concern that may lead to devastating results and affect negatively the patients' recovery, hospitalization period and the medical finances. However, fortunately, their risk is low and accepted in presence of good instruments and technical skills. Although similar basic principles of the LSG, technical differences is present between surgeons. There are continuous debates about the importance and means of staple line reinforcement (SLR) after LSG [1].

Although postoperative leakage is a major concern for bariatric surgeons, staple line bleeding (SLB) still represents an important issue that needs more focus and special attention as its incidence is between 0-10%. The stomach has rich blood supply coming from the gastroepiploic vessels, left and right gastric arteries and short gastric arteries. Blood loss during LSG may result from either failure of the energy devices to adequately seal the small branches of the gastroepiploic and short gastric vessels or failure of the staplers to achieve adequate hemostasis of the staple line. The latter may result from improper choice of cartridge size and type in relation to tissue thickness or technical errors in the staplers or misfiring or patient factors like abnormal bleeding tendency [2].

Different techniques have been adopted to minimize SLB and include suturing, buttressing material, and human fibrin sealant. There is no adequate data in literature that favour one technique over the other [2].

The ideal SLR method should be feasible and low cost with minimal risk of complications and doesn't prolong the operative time. Thus, optimization of SLR deserves more research and work up [1].

In this study we aim to compare between clipping and suturing the staple line and its impact on SLB primarily and other complications secondary. Although most surgeons use both sutures and clips in the operation but here we aim to adopt one of them in the staple line particularly; The pros and cons to achieve better outcome than the random use of them.

Material and Methods

This study is retrospective, we selected all patients (410 patients) from Ain Shams University Hospitals in the period between June 2018-June 2021.

Inclusion criteria:

- Patients underwent laparoscopic sleeve gastrectomy in the period between June 2018-June 2021.
- ASA classification: I or II.

Exclusion criteria:

- Extremes of age (above 60 and below 18 years).
- Previous bariatric surgery.
- Presence of blood disease or anticoagulation.
- No concurrent procedures (hernia or cholecystectomy....).

The Patients are divided into 2 groups; group A: 220 patients underwent Clipping of the suture line at the bleeding points & angles of staples, group B: 190 patients underwent suturing of the bleeding points.

Preoperative data included age, sex and body mass index (BMI). Clinical data included comorbid conditions, history of drug intake, certain disorders and interventions. Intraoperative variables included blood loss from staple line, timing of the operation, conversion to open surgery.

The primary outcome variable was post operative bleeding (POB), defined as blood in the drain more than 300cc, Hb drop below 8mg/dl or the need to transfuse blood within three days of operation or any unplanned intervention (including re-exploration or interventional radiology procedures) due to bleeding (3) or hematoma in the surgical bed (by ultrasound) associated with tachycardia (20 beat/min above baseline). We adopted this definition of POB to distinguish those with clinically

significant bleeding events. Other outcome variables included postoperative hospitalisation period, postoperative complications, readmission and mortality within 30 days of operation.

Technique: Sleeve gastrectomy is done by same technique and same type of stapler (Covidien TM, Endo GIATM, Auto Suture TM) and loading unit in both groups: Creation of pneumoperitoneum was done using a small stab at the umbilical scar then insertion of four ports was done: 5-mm epigastric incision (for liver retractor). 5-mm left hypochondrial (left working port). 12-mm right hypochondrial (right working port). 10-mm port supraumbilical for the camera man. Dissection of the greater curvature from the greater omentum from 2cm proximal to pylorus to angle of His was done using ultrasonic harmonic scalpel or Ligasure. Insertion of 36-Fr Bougie inside stomach through mouth was done. The Stapler was introduced using at first green reload 60-4.8mm, and then we used another green one if needed, and stapling was continued using gold and blue reloads 60-3.8mm and 3.5, respectively, till the end but in group (A) clipping of Suture line at the bleeding points & angles of staples by Titanium Clips/Cartridge (Medium-Large) (Figs. 1,2), in group (B): Suturing of the bleeding points by 3/zero vicryl (Figs. 3,4).

None of the patients received anticoagulation before operation, but they all start prophylactic dose 12 hours after.

The choice between both was related to the surgeon's preference in each case.

Follow-up:

- Vital data/6hrs for 24 hrs.
- CBC on the next day.
- U.S after one week or if any vital unstability or HB drop.
- The patient is discharged then follow-up every week for one month, so follow-up period is at least one month.

Results

Statistical analysis:

The data were analyzed using Statistical package for Social Science (SPSS) version 22.0. The quantitative data were expressed as mean \pm standard deviation (SD). Whereas, the qualitative data were expressed as frequency and percentage.

The following tests were used:

Independent-samples *t*-test of significance was used to compare between two means. Chi-square

(X^2) test of significance was used in order to compare proportions between two qualitative parameters. Mann Whitney U test: For two-group comparisons in non-parametric data. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p -value was considered significant as the following: p -value <0.05 was considered significant. p -value <0.001 was considered as highly significant. p -value >0.05 was considered non-significant.

As shown in Table (1), there is no significant difference between both groups as regard demographic data, comorbidities or ASA classification.

The operative time showed high significant difference between both groups (Table 2); in the clips group it ranged from 22-50min, in the suturing group ranged from 30-60min (Fig. 5).

Also the blood loss from the staple line was highly significantly different (Table 2); in the clips group ranged from (50-200cc) and the suture group (70-250cc) (Fig. 6).

None of the patients in both groups was converted to open.

As it is shown in Table (3), there is highly significant difference in the overall drains output volume between both groups, however when analysing the difference according to the nature of the drains' contents (blood, gastric & serosanguinous) we find that there is no significant difference in the number of patients between each, but the number of cases with bloody drains was more in the suture group (14 cases=7.4%) while the cases with gastric content were more in the clips group (3 cases=1.4%).

Table (1): Pre-operative demographic data.

	Clips (n=220)	Suture (n=190)	t/ X^2	p - value
Age (years)	32.96±6.7	31.6±10.98	1.4t	0.14
BMI	39.9±6.2	40.8±4.6	1.6t	0.1
Sex:				
Male	65 (70.5%)	63 (33.2%)	0.46 x^2	0.496
Female	155 (29.5%)	127 (66.8)		
Comorbidities	80 (36.4%)	70 (36.8%)	0.0 x^2	1
Diabetes mellitus (DM)	39 (17.7%)	36 (18.9%)	0.036 x^2	0.849
Hypertension (HTN)	34 (15.5%)	35 (18.4%)	0.45 x^2	0.504
DM AND HTN	9 (4.1%)	7 (3.7%)	0.002 x^2	0.97
Hyperlipidemia	11 (5%)	4 (2.1%)	1.6 x^2	0.196
Other comorbidity:				
Knee osteoarthritis	1 (0.5%)	0 (0%)	1.4 x^2	0.695
OSA	3 (1.4%)	2 (1.1%)		
Renal stone	1 (0.5%)	2 (1.1%)		
ASA classification:				
ASA I	141 (64.1%)	136 (71.6%)	2.3 x^2	0.13
ASA II	79 (35.9%)	54 (28.4%)		

Data expressed as mean ± SD, percentage.
 t = Student t -test.
 X^2 = Chi square.

OSA = Obstructive sleep apnea.
 ASA = American Society of Anaesthesiologists.

Table (2): Intraoperative data.

	Clips (n=220)	Suture (n=190)	t	p - value
Operative time (min)	30.6±4.8	44.4±8.8	19.2	<0.001
Blood loss from staple line (CC)	72.9±21.98	158.0±47.8	22.5	<0.001

Data expressed as mean ± SD.
 t = Student t test.

Table (3): Show the Postoperative data and complications.

	Clips (n=220)	Suture (n=190)	t/z/X ²	P- value
Hospital stay (day)	1.85±1.08	1.74±0.89	1.1 ^t	0.26
Drain output average (cc):	50 (25-50) (25-400)	100 (75-150) (50-500)	12.5 ^Z	<0.001
Blood	11 (5%)	14 (7.4%)	0.6x ²	1.7x ² 0.43
Gastric	3 (1.4%)	1 (0.5%)	0.12x ²	0.72
Serousanguinous	206 (93.6%)	175 (92.1%)	0.16x ²	0.68
Hb level (mg/dl)	12.38±0.77	10.96± 1.08	15.05x ²	<0.001
Hematoma	9 (4.1%)	18 (9.5%)	3.97x ²	0.046
Blood transfusion	2 (0.9%)	4 (2.1%)	0.35x ²	0.553
Bleeding	4 (1.8%)	12 (6.3%)	4.37x ²	0.037
Leakage	3 (1.4%)	1 (0.5%)	0.127x ²	0.722
<i>Vital stability:</i>				
Fever	3 (1.4%)	3 (1.6%)	5.009x ²	0.171
Fever and tachycardia	4 (1.8%)	5 (2.6%)		
Tachycardia	4 (1.8%)	11 (5.8%)		
Sepsis	3 (1.4%)	3 (1.6%)	0.0x ²	1
<i>Other complications:</i>				
Chest infection	1 (0.5%)	0 (0%)	3.76x ²	0.44
Intra-abdominal sepsis	1 (0.5%)	0 (0%)		
Port site infection	1 (0.5%)	0 (0%)		
Re-exploration	0 (0%)	1 (0.5%)		
Readmissions	5 (2.3%)	5 (2.6%)	0.0x ²	1

Data expressed as mean ± SD.
Median (IQR) (range), percentage.

t = Student t-test.
Z = Mann-Whitney test.
X² = Chi square.



Fig. (1): The clips used in group A.

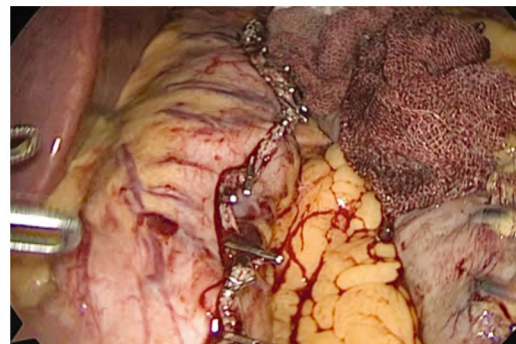


Fig. (2): Clipping along the suture line.

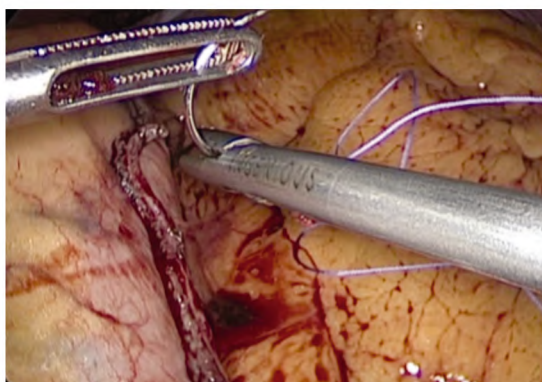


Fig. (3): Suturing the bleeding points.

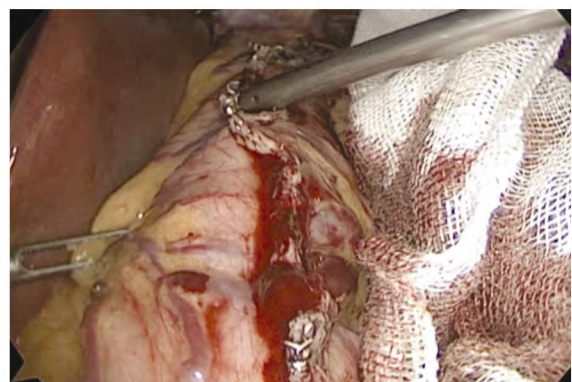


Fig. (4): Bleeding point in the suture line.

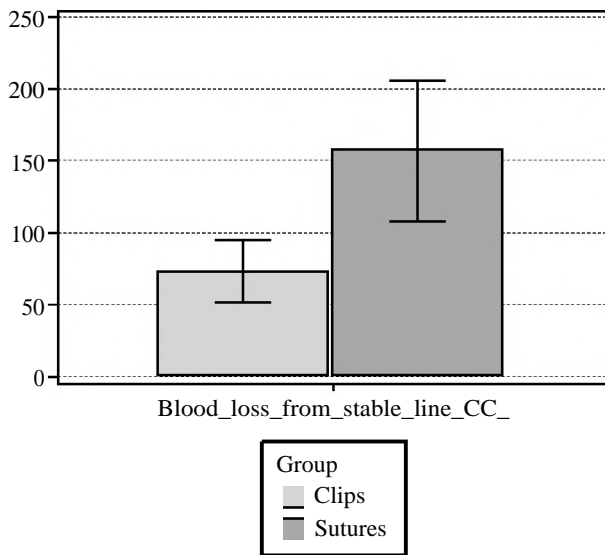


Fig. (5): Blood loss from stable line (CC).

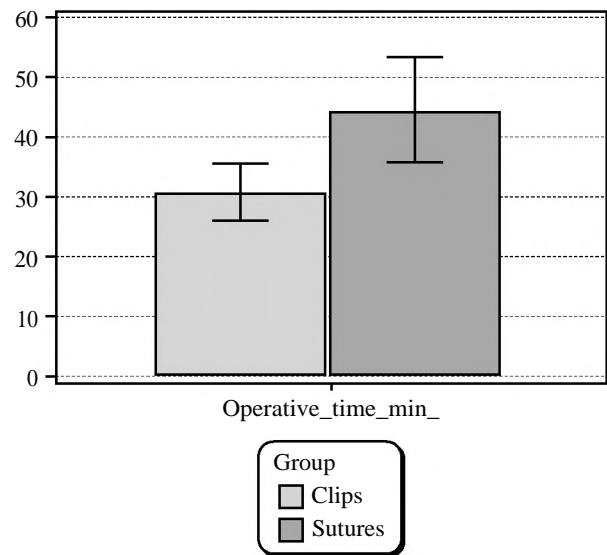


Fig. (6): Show operative time in both groups (minutes).

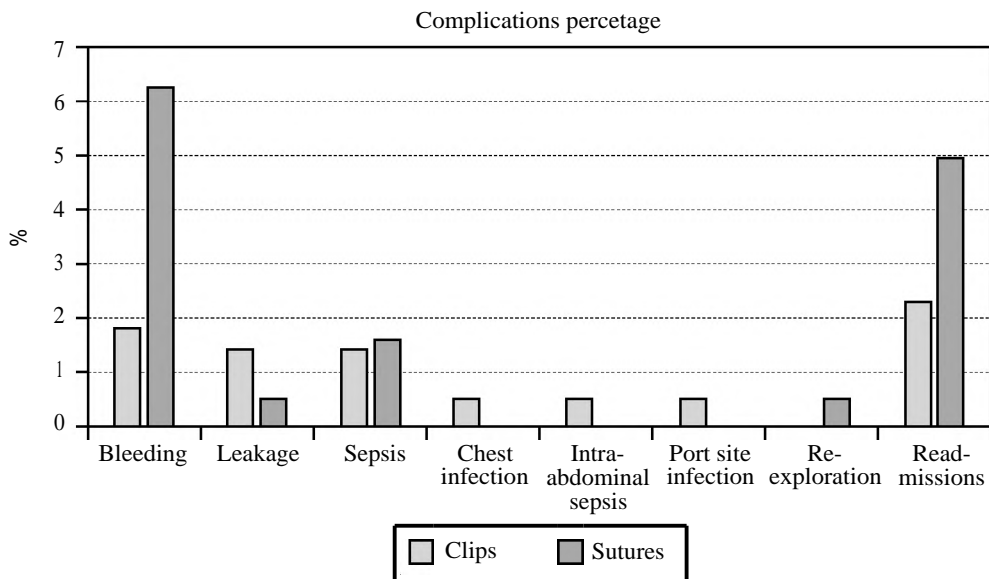


Fig. (7): Show the postoperative complications in both groups.

Hb level (24hr postoperative) and finding hematoma is Ultrasound also showed significant difference, presented by more Hb drop and more hematoma in the suture group. The overall cases diagnosed as bleeding according to our previous definition were significantly different being more in the suture group (12 cases=6.3%). As a result, the blood transfusion was more in the suture group (4 cases=2.1 %) but the difference is non-significant. It's to be noticed that not all cases that had bloody content in the drains or hematoma in ultrasound were diagnosed as 'bleeding', we were strict to the our definition of bleeding.

Leakage and other complications were insignificantly different, however leakage was more in the clips group (3 cases=1.4%) and in the suture groups only one case (Fig. 7). One of the cases in clipping group showed 2 adjacent clips just at the site of leakage in the gastrograffin study.

The case that needed re-exploration in group B was done laparoscopic and a bleeder along the suture line near the antrum was found and secured by a suture.

There was no cases of gastric twist and no perioperative mortality in both groups.

Discussion

The importance of that topic is aroused from the point that there is no similar articles, to the best of our knowledge, comparing both techniques, and in same time the SLB is an issue that do matter all bariatric surgeons, however both are feasible to some degree with some differences.

In our study the demographic data; including age, sex, co-morbidities, all showed insignificant differences. However, some studies showed that comorbidities, like hypertension, may increase the risk of SLB [4,5].

Meanwhile, there is significant difference in the operative time, which is expected as the laparoscopic suturing is technically demanding and needs skills and special training with learning curve, and for sure will take more time than clipping. The longer operative time will be reflected negatively on the outcome. Procter et al., analyzed a database of 299,359 surgical procedures across 173 hospitals, found that operative time is independently associated with increased risk of infection complications and length of hospital stay [6]. And also will increase the overall cost of the operation as well.

According to the study done by Dapri et al., on different methods of SLR; No staple line reinforcement could statistically decrease the time of gastric resection or the mean operative time [7].

Also the intraoperative SLB is more in the suture group, this is probably due to the liberal use of The clips in any suspicions point & in the angles of the staple line, whereas suturing was probably used in definite bleeding points and bleeding points were left relatively more time before being secured due to the relatively longer suturing time (20-50sec) than clipping.

But none of our cases in both groups converted open.

As for the main concern, POB was significantly higher in group B and its related events as well (Hb drop, hematoma formation, blood transfusion and tachycardia) this may be explained by the possibility of POB from the angles of stapling of points not evident intraoperative, the feasibility of clipping may encourage the surgeon to clip any suspicious points as mentioned above. But it is to be noticed that there is no solid grantee that the source of POB is the staple line, we assume that but not confirmed unless the patient underwent exploration. This is considered a drawback in this study and all similar studies.

In the same time leakage was more in group A (1.4%) than in group B (0.5%), may be due to excessive clipping that may cause ischemia in some points in the suture line evidenced by the case that had 2 adjacent clips at site of leakage in the Gastrograftin study, However the difference was insignificant. All cases were managed conservatively. The case in group B underwent gastric stent by endoscope.

In a relevant study about SLB, Zafar et al., selected all patients (98,142 patients) who underwent LSG from the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP). There were 623 (0.63%) patients had POB and 181 (0.18%) needed re-exploration. POB in the group that hadn't any SLR was 0.80%, in the BUTTRESS group 0.57%, in the OVERSEW group 0.68%, and in the COMBINATION group 0.55%. On further multivariable analyses, all methods of SLR in that study had less POB compared with the first group (3).

In a similar analysis of an older version of MBSAQIP, Berger et al., assumed that POB was less in buttressing group compared with no SLR. In their study, they stated that the bleeding rate with buttressing (either alone or with oversewing) was less than oversewing alone [8].

Musella et al., reported that using fibrin sealant decreased bleeding significantly in comparison with no reinforcement [9].

D'Ugo et al., conducted a multicenter study on 1162 patients who underwent LSG and found lowerrate of POB inpatients who had SLR with either-bovine pericardium, oversewing, Orthrombin matrix, syntheticpolyester, glycolide / trimethylenecopolymer. Nevertheless, there was novariations in the results of the different methods used

[10].

However, there is other studies that prove that there is no benefit with SLR to prevent occurrence of POB after LSG. Carandina et al., reported that usage offibrin glue coverage or oversewing with imbricating absorbable for SLR didn't add much benefit in comparison with the group with no SLR [11]. There is a large meta-analysis study derived from seven randomized controlled trials that show no significant difference in blood loss when using staple line oversewing technique during LSG [12].

Such studies demonstrate that the effect of SLR in preventing POB is doubtful with different results between studies. Albanopoulos et al., did a randomized study that showed no significant difference

between suturing and buttressing with Seamguard® (Gore, Arizona) in the POB rate [13]. While Dapri et al., randomized a controlled study comparing 3 different methods showed that the least bleeding was found in buttressing (32ml) followed by no intervention group (49ml) and suturing group (62ml) [7]. In a recent systematic review it was found that the incidence of bleeding is 0-6.7% without reinforcement and 0-8% with reinforcement [14] and in a meta-analysis considered with different methods of SLR did not find a statistically significant decrease in staple line bleeding [15]. These inconsistent outcomes make it difficult for the surgeons to select a specific technique for reinforcement of the suture line.

A retrospective study was done on 914 patients at a single center that uses a novel technique for SLR, starting from proximal end with inverted suture of the proximal part then oversewing of the distal part of staple line with omentum, this study compared 384 patients underwent this hybrid method with 530 patients underwent running sutures, this new technique resulted in less operative time with significant lower POB and there was 2 cases of leakage in the running suture group only [1].

Though debates regarding to reinforce or not to reinforce the staple line are still continuous, the latter study demonstrated the importance of reinforcement as 39.2% patients developed active staple line bleeding after gastric resection. The hemostasis could be difficult if the bleeding was from arterial origin or due to high blood pressure. Studies by D'Ugo and Taha have shown the incidence of POB ranged from 9% to 13.7% without SLR, which was significantly more than oversewing group (1.4% and 2.0%). The main obstacle in running suture technique is the inadequate hemostasis as the pressure on perpendicular vessels at staple line may be insufficient [1].

In a study comparing oversewing with no SLR, there was no cases of POB or stricture in both groups and the oversewing group had no cases of leak meanwhile the other group had two cases of leak. The overall surgical complication rate was 5%. The Mean operative time in Group A (139 ± 10 minutes) was significantly more than in Group B (117 ± 19 minutes) ($p=0.02$). Nevertheless, they recommended sufficient stapler compression time and accurate meticulous technique rather than using expensive buttressing materials or unnecessary oversewing [16].

Conclusion:

Sleeve gastrectomy is simple, but not easy. Staple line reinforcement will still be a negotiable

issue for bariatric surgeons. We assume that clipping achieve better bleeding control but may carry a little more risk of leakage than suturing. We look forward to do wider studies comparing with combined use of both and how and where to use each of them.

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استخدام الكلبسات مقابل الخياطة في منع النزيف من خط التدبيس في عملية تكميم المعدة بالمنظار

تهدف الدراسة للمقارنة بين استخدام الكلبسات في إيقاف النزيف الحاصل في خط التدبيس في عملية تكميم المعدة وبين الخياطة وهي دراسة مرجعية (بأثر رجعي) تشمل ٤١٠ من المرضى في مجموعتين، الأولى وتشمل ٢٢٠ مريضاً الذين تم فيهم استخدام الكلبسات، والثانية وتشمل ١٩٠ مريضاً استخدمت فيهم طريقة الخياطة.

وتتمت المقارنة بين النتائج وأهمها النزيف بعد العملية، والنتائج الأخرى وهي فترة الإقامة في المستشفى، والمضاعفات، ومعاودة الحجز في المستشفى، والوفيات خلال الشهر الأول بعد إجراء العملية.

وكانت النتائج كالآتي:

لم يوجد اختلاف ذو قيمة بين المجموعتين في بيانات المرضى قبل العملية وأما مدة العملية فكانت أقل بصورة واضحة في المجموعة التي استخدمت فيها الكلبسات (٢٢-٥٠) عن مجموعة الخياطة (٣٠-٦٠).

وكذلك كانت كمية الدم المفقود أثناء العملية مختلفة بين المجموعتين حيث تراوحت في مجموعة الكلبسات بين (٥٠-٢٠٠مل) وفي مجموعة الخياطة ما بين (٧٠-٢٥٠مل).

وأما بالنسبة للنزيف بعد العملية فكانت النسبة أعلى في مجموعة الخياطة بصورة واضحة حيث حدث نزيف في ١٢ حالة (٦.٣٪) بينما لم يحدث في مجموعة الكلبسات إلا في أربع حالات فقط (١.٨٪).

وأما التسريب وما سوى ذلك من مضاعفات فلم يكن هناك فرق ذو قيمة بين المجموعتين.

التصور أن استخدام الكلبسات يقلل من وقت العملية والنزيف الذي يمكن أن يحدث بعد العملية إذا قورن بطريقة الخياطة.