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Comparison of Staplers vs Sutures gastrojejunostomy in terms of anastomotic time and leakage

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A B S T R A C T

Objective: To compare the outcome of use of staplers versus sutures in gastrojejunostomy in terms of mean anastomotic time and anastomotic leakage.

Methodology: This randomized controlled trial was conducted in surgical unit - I. Services hospital Lahore from 01-10-2014 to 31-12-2015. After approval from ethical committee, Non purposive convenient sampling technique was used.60 patients were selected for study and equally divided in two equal groups. In Group A, sutured gastrojejunostomy and in Group B, stapled gastrojejunostomy was performed. Anastomotic time (minutes) and anastomotic leakage were noted in both groups. Anastomotic time was calculated from start of anastomosis till completion. SPSS version 20 was used for data analysis. Hypothesis was tested by student T test and chi square test was used to show association between different variables. P value less than 0.05 was considered as significant.

Results: In this study 63.33 % (N=38) patients were females and 36.66 % (N=22) were males. Anastomotic time was calculated to be 24.8 ± 2.78 min in Group A (Sutured) and 14.87 ± 2.98 min in Group B (Stapled) with a p-value of 0.00001 which is highly significant. 10% (N=03) patients had anastomotic leakage in Group A (Sutured) as compared to 3.33 % (N=01) patients in Group B (Stapled) with P value = 0.3 which is statistically insignificant.

Conclusion: Stapled gastrojejunostomy is better due to reduced mean anastomotic time. Although there is decreased frequency of anastomotic leakage than sutured gastrojejunostomy but it is not statistically significant.

Key Words: Anastomotic Leakage, Sutured Gastrojejunostomy, Stapled Gastrojejunostomy.

Introduction

In elective gastric surgeries, gastrojejunostomy is the most common anastomosis being done in both benign and malignant conditions. Various sutured and stapled techniques are being used. The recently stapled technique of intestinal anastomosis is popular and being claimed to hold better results with fewer complications like leakage and short anastomotic time. However, local studies are not available and yet there remains debate that which technique is better.

Intestinal anastomosis operation is very commonly performed procedure.[1] It has been performed with regularity for last 200 years.[2] Gastrointestinal

anastomosis is conventionally being performed using a hand-sewn technique. Matherson from Aberdeen Scotland was in favor of single layer anastomosis of the intestine because of less tissue necrosis or luminal narrowing associated with it. [3]

Despite refinements in the field of gastrointestinal surgery, dehiscence and anastomotic leakage are still frequent and serious problems associated with high morbidity and mortality. Stricture formation, hemorrhage, intra-abdominal abscess, wound infection and re-operation are other problems associated with gastrointestinal anastomosis. [4-7] A successful anastomosis should not be under tension and must have good blood flow while ensuring patency of distal intestine. [2]

The techniques of anastomosis commonly used are by hand sewn and use of staplers have been validated. Both have potential benefits and advantages. [6,8,9,10] Possible benefits of stapled anastomosis are minimal tissue handling, decreased blood loss and inflammation, with early return of motility and recovery. Surgeons are now commonly performing anastomosis by staplers owing to short operative time and learning curve. [6, 8, 9] Stapler technique is criticized in view of its apparent expense, and disquiet exists in relation to the possibility of stricture formation.

Various perceptions existing in use of stapling devices are based on untoward fears regarding the technical and cost effectiveness of the device. International studies are available but no local study is available. Our study will look into the outcomes of use of these devices in terms of anastomotic leakage and operative time in comparison to the standard hand sewn techniques in patients undergoing gastrojejunostomy to produce magnitudes for the local population.

Methodology

This randomized controlled trial was conducted at Surgical unit-I Services hospital Lahore from 01-10-2014 to 31-12-2015. The sample size was calculated 60 (30 each) cases using 95 % confidence level, 80% power of test with an expected mean time to appear as 25 ± 6.9 minutes in suture group and 14 ± 5.9 minutes in stapled group.

Non probability, purposive sampling technique was carried out. Every patient regardless of gender from 18 years to 70 years old undergoing gastrojejunostomy in both benign and malignant conditions (pyloric obstruction, corrosive intake, periampullary mass assessed by nausea, vomiting and barium meal and upper G I endoscopy) in elective theatres were included in the study. While patients having peritonitis (tachycardia, abdominal tenderness, rigidity), pregnancy (assessed by urine pregnancy test), immunocompromised patients (diabetes, hepatitis C, AIDS) and Non-compliant patients, were excluded from the study.

Mean anastomotic time was the number of minutes required from start of anastomosis to complete anastomosis.

Anastomotic leakage was determined by clinical/radiological examination assessed on 5th postoperative day i.e. Signs of peritonitis (tachycardia [Heart rate > 100 BPM], abdominal tenderness, rigidity), the appearance of gastrointestinal contents from drains, Formation of enterocutaneous fistula, Intra-abdominal collection on USG. Our hypothesis was that use of staplers in gastrojejunostomy decreases the mean operative time and anastomotic leakage.

Ethical approval from ethical committee was taken. Informed consent was obtained from all 60 patients fulfilling the inclusion criteria and undergoing gastrojejunostomy in surgical unit -I Services Hospital Lahore. All patients were divided in two groups using random tables. Group A comprised Sutured gastrojejunostomy and Group B comprising Stapled Gastrojejunostomy. The single surgical team performed the procedure. In sutured group we used double layered continuous technique with VICRYL 2/0 suture. The appropriate loop of intestine was plicated with two stay sutures, and electrocautery was used to make the gastrotomy and enterotomy sites. The operative site was isolated with laparotomy sponges. The jejunotomy site was placed on the antimesenteric border, and the gastrotomy site was positioned on the posterior and inferior aspect of the antrum. Both viscera were entered and enteric contents suctioned. The two enterotomies were gently spread with a hemostat. In stapled technique gastrointestinal anastomosis (GIA) linear staplers of 80mm length with cartridge of double rows of staples with size 4.8mm were used. The larger end was inserted through the gastrotomy and the smaller piece was placed through the jejunotomy. By using the two stay sutures, the stomach and small intestine are aligned. The staple line should correlate with the antimesenteric border of the small intestine and the most inferior and posterior aspect of the stomach. After the GIA stapler was deployed, the anastomosis was visually inspected with the aid of a suction catheter to ensure hemostasis. Interrupted 3-0 Vicryl sutures are used as needed to ensure hemostasis. The nasogastric tube was taped into position before the

anastomosis is completed. The enterostomy was closed with a TA (transverse anastomosis) stapler. The enterostomy was reoriented at an angle to avoid intersecting three staple lines. (The junction of the three staple lines theoretically functions as an "angle of sorrow" with decreased blood supply and increased risk of ischemia.) Generally, four Allis clamps are used to approximate the serosal edges of the enterostomy. The distal remnant previously grasped by the Allis clamps does not require excision. Although it may be aesthetically displeasing, this remnant necroses without sequelae. Amputating this remnant with a scalpel against the edge of the TA stapler results in oozing, requiring more electrocautery or interrupted sutures. The rent in the mesocolon was closed**. Gastrojejunostomy was performed in retro colic fashion in benign corrosive intake and pyloric obstruction. However, it was done in ante colic fashion in malignant cases. The length of anastomosis was kept to 8 cm in both groups. Per - operatively mean anastomotic time was noted by staff nurse and paramedical staff. Post operatively anastomotic leakage was also noted. All data was recorded over Performa. Statistical analysis for p values of numerical data was done using SPSS 20. Age and operative time were described in terms of mean and standard deviation. Frequency and percentage were calculated for gender and anastomotic leakage. Student's t - test was performed to testify the outcomes (i.e. mean anastomotic time) in either groups. Significance for anastomotic leakage was described by chi square test in groups A and B. P–value ≤ 0.05 was considered as significant. Data stratified for age and gender. T-test was applied to compare mean operative time in stratified data. Chi - square test was applied to compare anastomotic leakage in stratified data. P-value ≤ 0.05 was considered as significant.

Results

Age distribution of the patients was computed , most of the patients were between 20 – 30 years of age (33.33 % n = 20) , 13.33 % (n= 08) were between 31 – 40 years , 6.67 % (n = 04) were between 41 – 50 years , 23.33 % (n = 14) were between 51 – 60 years and 23.33 % (n = 14) > 60 years . Mean and SD was calculated as 44.77 + 18.18 & 41.77 + 18.36 for Group A (SUTURED) & Group B (STAPLED) respectively.

Gender distribution of the patients showed 63.33 % (n = 38) female patients and 36.66 % (n = 22) male patients. Group A (Sutured) contain 33.33 % (n = 10) male & 66.67 % (n = 20) female patients while Group B

(Stapled) contain 40 % (n = 12) male & 60 % (n = 18) female patients.

Mean Anastomotic time was significantly shorter in Group B (Stapled) [14.87 + 2.98 min] than in Group A (Sutured) [24.8 + 2.78 min] with a p-value of 0.00001 which is highly significant.

In Group A (Sutured), 10% % (n = 03) patient had anastomotic leakage while in Group B (Stapled), 3.33 % (n = 01) patient had anastomotic leakage. The two groups were compared with each other for any significant difference. Chi-square test was applied. Calculated P-value was 0.3 and hence not significant (P-value>0.05).

Age and gender stratification for anastomotic time and leakage are presented in tables I-IV

Table I: Age Stratification for Anastomotic Time between Two Groups

Age		Group	No. Of Pts (n)	Means	Standard Deviation	P Value
≤40	Anastomotic Time	A	12	24.08	2.64	<0.00001
		B	16	15.25	2.77	
>40	Anastomotic Time	A	18	25.28	2.84	<0.00001
		B	14	14.43	3.25	

Table II: Gender Stratification for Anastomotic time between two Groups

Gender		Group	No. Of Pts	Means	Standard Deviation	P Value
Male	Anastomotic Time	A	10	24.9	3.03	<0.00001
		B	12	13.75	3.04	
Female	Anastomotic Time	A	20	24.75	2.73	<0.00001
		B	18	15.61	2.77	

Table III: Age Stratification for Anastomotic Leakage between Two Groups

Age		Group A	Group B	P value
≤40yrs	Anastomotic leakage present	01	00	P value =0.2
	No anastomotic leakage	11	16	
>40 yrs	Anastomotic leakage present	02	01	P value=0.7
	No anastomotic leakage	16	13	

Table IV: Gender Stratification for Anastomotic Leakage between Two Groups

Sex		Group A	Group B	P value
Female	Anastomotic leakage present	00	00	P value =0
	No anastomotic leakage	20	18	
Male	Anastomotic leakage present	03	01	P value=0.19
	No anastomotic leakage	07	11	

Discussion

Restoration of continuity of gut is known as anastomosis which is commonly performed procedure in both elective and emergency abdominal surgeries. Various methods of anastomosis have been in practice. Lembert described his seromuscular technique in 1826. This technique became mainstay in second half of century. It was Halsted who noted that strength bearing layer is submucosa. He advocated single layer anastomosis that did not incorporate mucosa. Connell also used single layered interrupted method but incorporating all layers of bowel. Later Kocher introduced two layered methods in which first layer was completed with catgut in continuous manner and second layer with continuous or interrupted inverting seromuscular sutures with silk. Nowadays single layer extra mucosal sero submucosal interrupted sutures technique has become widely accepted owing to approximately 2% leakage rate.   Currently better results in many surgical procedures are partly due to newer techniques, anesthesia developments, advance investigations, and antibiotics. These also encourage surgeons to take the next step for prevention of anastomotic leak. Other influential factors affecting surgical success includes transfusion of blood, inotropic support in the perioperative period, hypoalbuminemia, male sex, cardiovascular disease and tumor location are also independent risk factors to affect anastomotic leakage. [13-14] Good nutritional status of the patient [15], a sufficient blood flow , minimum or no tension at anastomotic site , and adequate luminal patency are important the other way.[16]

The first compression anastomosis device was developed by Felix Denans in 1826. It was just a metallic ring that connected the intestinal ends together. Murphy's button was also steel ring used in 1930 that became the basis of modern devices. Humer Hultl is renowned as the father of surgical stapling. He developed first surgical stapler that was used in gastric resection. Later on, Russians and Americans made new advancements in staplers. The modern developments have led to the dramatic change in surgical practice. Now technical failure is a rarity. The staple lines are of more consistent quality and anastomosis in difficult anatomical locations are now easily performed. A few disadvantages of staplers are also present. These are expensive, furthermore, staplers are not in usual practice of surgeons. There is also possibility of both stricture formation and even tumor recurrence after a colorectal resection for malignant disease. Tissue glue, LASER welding and biofragmentable rings are infrequently used for anastomosis. [17-18]

Sutured gastrojejunostomy took an average of 24.8 minutes anastomotic time with a minimum of 20 minutes and a maximum of 30 minutes. Stapled gastrojejunostomy took an average of 14.87 minutes with a minimum of 10 minutes and a maximum of 19 minutes. Sutured gastrojejunostomy took an average 10 more minutes than stapled gastrojejunostomy and this difference was statistically significant (P value = 0.00001).

The anastomotic time is used as a gauge for the assessment of any gastrointestinal anastomosis. It was also used in this study to determine that if it compared to the mean anastomotic time set by the sutured gastrojejunostomy group when the surgical team was asked to do stapled gastrojejunostomy. The anastomotic time was set as the time taken from the start of anastomosis until the anastomosis was completed. The anastomotic time was measured in minutes and the recorded time was entered in the Performa.

The anastomotic time of the two groups was comparable with a mean anastomotic time difference of ten minutes which is highly significant.

Our study also evaluated the presence or absence of anastomotic leakage as one of the variables. Anastomotic leakage is a great concern while doing any gastrointestinal anastomosis. In this study, anastomotic leakage was determined by clinical/radiological examination i.e., signs of peritonitis (tachycardia, abdominal tenderness, rigidity), the appearance of gastrointestinal contents from drains, formation of enterocutaneous fistula, intra-abdominal collection on USG.

Any two or more of these were fulfilled. It was assessed on 5th postoperative day.

This study showed that only 3.33% of patients with stapled gastrojejunostomy experienced anastomotic

leakage as compared to 10% of patients who had undergone the sutured gastrojejunostomy. The result showed that the sutured group had a higher frequency of leakage than stapled anastomosis.

In literature, there have been described many clinical trials that have shown the comparison between the two techniques.

In 2013, Murthy V studied these two techniques in elective gastric operations in south India. Both groups had no complications owing to the involved technique. It took significantly shorter time (16.80 min) in the stapled technique group than in the sutured group (21.19min).[11] When compared with our study it is slightly less in sutured group and almost equal in stapled group.

Seo SH, et al, performed a clinical trial on 60 patients. In his study he compared the hand sutured method with the circular stapling technique for Billroth-II. He performed laparoscopic-assisted distal gastrectomy for gastric cancer. In his study manual group was comprising 40 patients and circular stapler group was comprising in 20 patients. No significant difference was observed in clinic pathological parameters. However, time for anastomosis in manual group was 15.2 ± 2.2 and 5.7 ± 0.7 in stapler group. It revealed that stapled anastomosis had shorter operation time and anastomosis time as compared to the hand-sewn anastomoses. [18]

Murata Y et al concluded that stapled side to side gastrojejunostomy reduced the operative time and the incidence of delayed gastric emptying also reduced. It was also associated with significantly shorter hospital stay as compared to hand sutured group.[19]

In another study published in 2016, new hand sewn technique was introduced. The time to accomplish the anastomosis by using the new technique was a little shorter than the control group (8 ± 1.6 min *vs.* 9 ± 2.8 min). But the cost of the new technique was significantly lower than the control group (30 ± 6.8 *vs.* 1000 ± 106.2). The new technique also had lower bleeding (0/80 *vs.* 2/70) and leakage (0/80 *vs.* 1/70). No stricture was reported in both groups (0/80 *vs.*0/70). [10] So the field is debatable and further studies required to improve the ways to control anastomotic leak.

In a study performed by Nichkaode et al gastrojejunostomy was performed in 21 patients.11 patients underwent hand sewn and 10 patients underwent stapled anastomosis. He found that there was no anastomotic leak in both groups. However anastomotic time was significantly reduced. Similarly, as a result of shorter operative time, there was early return to normal life. [20]

The field is still debatable regarding financial concerns with the use of staplers. The author suggests further local studies regarding this issue.

Conclusion

Under the provided number of patients, it is concluded that stapled gastrojejunostomy is better in terms of the reduced mean anastomotic time. However anastomotic leakage is comparable so we advocate its usage.

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