

COMPARATIVE STUDY OF STAPLER ANASTOMOSIS OVER HAND SEWN ANASTOMOSIS IN ELECTIVE GASTROINTESTINAL SURGERIES

P. B. Nichkaode, Mayank Kulshrestha, M. A. Akhtar, Gopal Gurjar, Rahul Zamad.

1. Associate Professor, Department of General Surgery. N.K.P Salve Institute of medical Sciences & Lata Mangeshkar Hospital Nagpur.
2. Junior Resident, Department of General Surgery, N.K.P Salve Institute of medical Sciences & Lata Mangeshkar Hospital Nagpur.
3. Professor & HOD, Department of General Surgery, N.K.P Salve Institute of medical Sciences & Lata Mangeshkar Hospital Nagpur.
4. Lecturer, Department of General Surgery, N.K.P Salve Institute of medical Sciences & Lata Mangeshkar Hospital Nagpur.
5. Junior Resident, Department of General Surgery, N.K.P Salve Institute of medical Sciences & Lata Mangeshkar Hospital Nagpur.

CORRESPONDING AUTHOR:

Dr. P. B. Nichkaode,
71- Old Subhedar Layout,
Sharda Square,
Nagpur- 440024.
E-mail: dsnh@rediffmail.com

ABSTRACT: Anastomosis in Gastrointestinal surgery is a very commonly performed procedure , since the era of Sushruta, various methods of intestinal anastomosis were followed- recent advancement is the use of stapler as a device for GI anastomosis. Because of the use of staplers technical failures is a rarity, anastomosis is more consistent, and can be used at difficult locations.

MATERIALS AND METHODS: A total of 50 cases which met the inclusion and exclusion criteria were included in this hospital based prospective comparative study. The study population included all patients who underwent elective gastrointestinal surgeries. **STUDY FACTORS:** The subjects were allocated into two groups according to the type of anastomosis, hand sewn and stapler. Both hand sewn and stapled anastomosis were further divided into three sub-groups according to the site of anastomosis viz esophageal, gastrojejunal and colorectal. **OUTCOME FACTORS:** Anastomotic Integrity, Duration of operation, Return of Bowel activity, Hospital stay. **RESULTS:** A total of 50 patients with malignant or benign condition of bowel and esophagus, requiring anastomosis were allocated in study group of GI staplers and control group of conventional Hand sewn technique. Out of 50 cases there were 13 esophageal anastomosis, 19 gastrojejunostomies and 18 colorectal anastomosis **CONCLUSION:** In our present study, we found that stapling technique can significantly reduce the time for anastomotic procedure, less tissue trauma due to less tissue handling, there is early restoration of gastrointestinal function, early resumption of oral feeding and reduced duration of hospital stay which helps ultimately in early return to routine work, importantly staplers can be used at places where hand sewn anastomosis is technically difficult. Technique related complications do not show significant differences which suggests that one can use staplers with same safety and accuracy as sutures

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INTRODUCTION: Intestinal Anastomosis dates back to 1000 B.C., the era of Sushruta “The Great Indian Surgeon” he described the use of black ants during the suturing of intestinal anastomosis .⁽¹⁾ Lembert then described his seromuscular suture technique in 1826 which became the mainstay of gastrointestinal anastomosis in the second half of the century. Currently the single layer extramucosal anastomosis is popular, as advocated by Matheson of Aberdeen, as it probably causes the least tissue necrosis or luminal narrowing.⁽²⁾ The evolution of mechanical sutures by means of stapler use has become a real technological advancement , as it has represented the concept of a new product with the combination of new functions that have resulted in improvements and effective gains of quality or productivity in the handicraft suture process that has been done by surgeons for centuries.⁽³⁾ Surgical stapling devices were first introduced by Hüttl in 1908; however, they did not gain popularity because instruments were cumbersome and unreliable. The development of reliable, disposable instruments over the past 30 years has changed surgical practice dramatically. With modern devices, technical failures are rare, the staple lines are of more consistent quality, and anastomosis in difficult locations are easier to construct.⁽⁴⁾ The effect of minimizing the operative trauma has certainly been the main attribute in the use of staplers. We are presenting this study in an attempt to compare the outcome of hand sewn and stapler anastomosis in elective gastrointestinal surgeries.

Materials and Methods: The present study was carried out in the Department of Surgery, N.K.P.Salve Institute of Medical Sciences and Lata Mangeshkar Hospital, Nagpur from October 2010 to October 2012.

A total of 50 cases which met the inclusion and exclusion criteria were included in this hospital based prospective comparative study. The study population included all patients who underwent elective gastrointestinal surgeries.

INCLUSION CRITERIA: Patients Of Elective Gastro-Intestinal Surgeries Who Underwent Bowel Anastomosis.

EXCLUSION CRITERIA: Ediatric age group (< 12 years), gastro-intestinal anastomosis done in emergency setting, pancreatico-duodenectomies with triple bypass, biliary-enteric anastomosis, patients refusing to join the study or left the hospital before final evaluation, patients with prior chemo-radiation and patients unfit for anaesthesia were excluded from the study.

STUDY FACTORS: The subjects were allocated into two groups according to the type of anastomosis, hand sewn and stapler. The allocation to the groups was at random decided by affordability of stapler by the patient and need for use of stapler. Both hand sewn and stapled anastomosis were further divided into three sub-groups according to the site of anastomosis viz esophageal, gastrojejunal and colorectal.

Anastomotic techniques

All the hand sewn anastomosis were performed by an experienced surgeon who did almost more than 100 gastrointestinal anastomosis with either single layer or double layer / interrupted or continuous technique of anastomosis using 3-0 / 2-0 polyglactin (vicryl). In the double layered technique, 3-0 silk was used for outer seromuscular layer. A full standard exploration was done as per the pathology under necessary anaesthesia decided by anaesthesiologist. Staplers Used in

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Anastomosis are Linear cutting staplers (TLC 55, 75), Linear anastomosing staplers (TCR 55, 75), Circular anastomosing staplers (CDH 25, 29)

OUTCOME FACTORS: Both hand sewn and stapler anastomosis in all 3 groups were compared on following parameters:

- 1. ANASTOMOTIC INTEGRITY:** Anastomotic integrity was based on the presence or absence of anastomotic leak. There are two types of Anastomotic Leak (Clinical and Radiological). Clinical leak is defined as “anastomotic dehiscence confirmed by re-operation, development of an entero-cutaneous fistula, appearance of bowel contents from drains or systemic sepsis in association with peritonitis”. In patients undergoing esophageal or colo-rectal anastomosis, anastomotic integrity was also assessed by contrast radiography in the period between 4 and 14 days after operation. Radiological leak was defined as “any extravasation of contrast medium from the anastomosis in the absence of any criteria for clinical leak.”
- 2. DURATION OF OPERATION (IN MINUTES):** Duration of operation was counted from the time of starting of incision to closure.
- 3. Return of gastrointestinal function:** Assessed by the day of return of bowel sounds after surgery
- 4. HOSPITAL STAY (IN DAYS):** Post operative hospital stay was taken into account.

STATISTICAL METHODS: The basic parameters of two categories like age, gender, weight, presence or absence of co-morbid conditions, haemoglobin, Serum proteins, malignant or benign condition are compared to assess the comparability of the two groups (hand sewn and stapler). The Outcome factors in two categories in all three groups are compared. For continuous variables student' t \square test was used. For categorical variables chi-square test was used. Data collection was done using a prepared proforma.

RESULT: A total of 50 patients with malignant or benign condition of bowel and esophagus, requiring anastomosis were allocated in study group of GI staplers and control group of conventional Hand sewn technique. Out of 50 cases there were 13 esophageal anastomosis, 19 gastrojejunostomies and 18 colorectal anastomosis.

Basic features of two groups: In order to assess the comparability and avoid biases the two groups (hand sewn and stapler) were compared on the basis of age, gender, co-morbid conditions, weight, haemoglobin, serum proteins and malignant or benign condition.

The mean age (in years) of patients in Hand Sewn group was 49.04 ± 15.15 with a range of 27 – 80 years whereas in the Stapler group mean age was 52.50 ± 19.01 with a range of 22 – 86 years. Majority of patients in both groups were in the range of 51 – 65 years. The mean weight (in kg) of patients in the hand sewn group was 47.32 ± 10.86 with a range of 31 – 71 kg. In the stapler group mean weight was 50.84 ± 11.20 with a range of 35 – 82 kg. Majority of patients in both groups had a weight in the range of 41 – 50 kg. The mean haemoglobin (in gm%) of patients in hand sewn group was 10.61 ± 1.70 with a range of 7.20 – 15 . In the stapler group it was 10.24 ± 1.25 with a range of 8.90 – 14.50. The mean Serum proteins (in gm%) of patients in the hand sewn group was 6.35 ± 0.71 with a range of 5.10 – 7.50 whereas in the stapler group it was 6.42 ± 0.66 with a range of 5 – 7.40. Majority of patients in both groups had Serum proteins in the range of 6.1 – 7.

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Both the groups showed equivalence in gender distribution with 52% males and 48% females in both groups. According to the presence or absence of co-morbid conditions both the groups were similar. In the Hand Sewn group, 32% of the patients had some or the other co-morbid condition whereas in the Stapler group, 20% of the patients had presence of a co-morbid condition. In the hand sewn group 72% of patients were operated for malignant condition and 28% were operated for benign condition. In the stapler group 80% were operated for malignant condition whereas the remaining 20% were operated for benign condition. The two groups showed that they were quite comparable on basic features, hence biases and confounders were taken care of.

OUTCOME: The outcome was measured for the three sub-groups which were made on the basis of site and type of anastomosis. Group 1 - Esophageal, Group 2 - Gastro-jejunal and Group 3 - Colo-rectal / colo-anal.

- 1. ANASTOMOTIC LEAK:** In esophageal anastomosis, leak was noticed in one patient in hand sewn as well as stapler anastomosis. For gastrojejunostomy no anastomotic leak was noticed in either hand sewn or stapler group. However in colo-rectal anastomosis three patients in the hand sewn group had an anastomotic leak whereas none of the patients in the stapler group suffered from leak. On statistical evaluation this difference came out to be significant.

Anastomotic Leak	Hand Sewn		Stapler		χ ² -value	p-value
	Present	Absent	Present	Absent		
Group 1	1(4%)	5(20%)	1(4%)	6(24%)	0.05	0.81*
Group 2	0(0%)	10(40%)	0(0%)	9(36%)	NA	
Group 3	3(12%)	6(24%)	0(0%)	9(36%)	14.40	0.0001**
Total	4(16%)	21(84%)	1(4%)	24(96%)		

Leaks were classified as either clinical or radiological. No clinical leak was found in esophageal anastomosis. One patient in hand sewn and stapler anastomosis who had anastomotic leak were radiological. In colorectal anastomosis three patients undergoing hand sewn anastomosis had clinical leak but there was no evidence of a radiological leak. In the stapler group none of the patients suffered from a leak, either clinical or radiological.

2. DURATION OF OPERATION

Duration of operation	Hand Sewn		Stapler		t-value	p-value
	Mean	SD	Mean	SD		
Group 1	265.33	12.75	198.14	16.31	8.32	0.000*
Group 2	179.60	19.65	152.88	17.67	3.11	0.006*
Group 3	225.55	35.09	175.22	14.68	3.96	0.002*

*- Significant, $p < 0.05$

Stapling led to a significant decrease in the total operating time for esophageal anastomosis, gastrojejunostomies as well as colorectal anastomosis as evident from the table above.

3. RETURN OF GASTRO-INTESTINAL FUNCTION: Stapled Esophageal anastomosis required a significant less time for return of bowel sounds. Mean time required for return of bowel sounds was 5.83 ± 0.75 days in the hand sewn group compared to 4.85 ± 0.69 days in the stapler group. Similar results were also noted for stapled gastrojejunostomies which required a mean of 3.44 ± 0.52 days for the return of bowel sounds compared to 5.20 ± 0.91 days in hand sewn gastrojejunostomies. For stapled colorectal anastomosis similar pattern was obtained with a mean of 5.66 ± 0.50 days for the return of bowel sounds in hand sewn group which was significantly more than 3.55 ± 0.72 days required in the stapler group.

4. HOSPITAL STAY: In esophageal anastomosis mean post operative hospital stay was 20.66 ± 3.66 days in the hand sewn group compared to 17 ± 3.41 days in the stapler group. This difference however did not show significance on statistical analysis ($p = 0.09$). The mean post operative hospital stay for stapled gastrojejunostomies was 13.33 ± 2.00 days which was significantly less than compared to 17.00 ± 4.24 days required in hand sewn gastrojejunostomies ($p = 0.029$). For colorectal anastomosis favourable results were obtained for stapler technique with a mean post operative hospital stay of 14.33 ± 2.91 days which was significantly less compared to mean post operative hospital stay of 25.55 ± 11.03 days with the hand sewn technique ($p = 0.016$).

DISCUSSION: In the present study, hand sewn and stapler groups were found comparable on the basis of age, gender, presence or absence of co-morbid condition, weight, haemoglobin, Serum proteins, and pathology (malignant or benign). Seo SH et al ⁽⁶⁾ (2012) in a study comparing hand sewn and stapled gastrojejunostomies showed a similarity in the age and gender distribution between two groups. Similar pattern of age and gender distribution was also noted in the study by Hassanen A et al ⁽⁷⁾ (2008) comparing hand sewn and stapled anastomosis of the large bowel, Law S et al ⁽⁸⁾ (1997) in a study comparing hand sewn and stapled esophageal anastomosis and West of Scotland and Highland Anastomosis Study Group ⁽⁹⁾ (1991) in a study comparing suturing and stapling at different gastrointestinal sites. Present study findings goes on parallel lines of the study by Seo SH et al ⁽⁶⁾ (2012) where it was found that in the stapler group 60% of patients had a co-morbid condition compared to 47.5% of patients in the hand sewn group, the difference of which was statistically insignificant. Findings regarding weight, haemoglobin and Serum proteins of the patients are consistent with previous study findings of study by Hassanen A et al ⁽⁷⁾ (2008) and West of Scotland and Highland Anastomosis Study Group ⁽⁹⁾ (1991). The study by West of Scotland and Highland Anastomosis Study Group ⁽⁹⁾ (1991) too revealed similarity in distribution of patients according to malignant or benign condition. For esophageal anastomosis, the leak rate in the present study was similar for hand sewn and stapler group with no statistical significance. These findings are on the parallel lines as in previous studies by Saluja SS et al ⁽¹⁰⁾ (2012), Worrel S et al ⁽¹¹⁾ (2010) and Leuchakiettsak P et al ⁽¹²⁾ (2008). None of the patients undergoing gastrojejunostomy either by hand sewn or stapler technique had an anastomotic leak. This may be attributed to the fact that peritoneal viscera are less likely to leak than extraperitoneal viscera.

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These findings are on the lines of previous study by Seo SH et al ⁽⁶⁾ (2012) comparing hand sewn and stapled gastrojejunostomies. For colorectal anastomosis a significantly high anastomotic leak rate was found in the hand sewn group consistent with the findings of previous study by Hassanen A et al ⁽⁷⁾ (2008). In esophageal anastomosis, there was one radiological leak in each group, which goes on the parallel lines of study by West of Scotland and Highland Anastomosis Study Group ⁽⁹⁾ (1991). In colorectal anastomosis, there was a significantly high rate of clinical leak. These findings are in contrast to the findings of previous studies by MacRae HM et al ⁽¹³⁾ (1998), West of Scotland and Highland Anastomosis Study group ⁽⁹⁾ (1991) and Lustosa SA et al ⁽¹⁴⁾ (2002). In esophageal anastomosis there was a significant reduction in the total operating time with the stapling technique. These findings are consistent with the findings of previous studies by Luechakietisak P et al ⁽¹²⁾ (2008), Hsu HH et al ⁽¹⁵⁾ (2004) and Law S et al ⁽⁸⁾ (1997). Similar significant decrease in the total operating time was also noted for stapled gastrojejunostomies which goes along with the findings of previous study by Seo SH et al ⁽⁶⁾ (2012) and Damesha N et al ⁽²⁾ (2008). Colorectal anastomosis too revealed a significant decrease in total operating time with staplers. These findings are consistent with those of previous studies by Beuran M et al ⁽¹⁶⁾ (2010), Damesha N et al ⁽²⁾ (2008) and West of Scotland and Highland Anastomosis Study Group ⁽⁹⁾ (1991). In Stapled gastrojejunostomies, there was early restoration of gastrointestinal function with significantly early return of bowel sounds compared to the hand sewn counterpart. Previous studies by Seo SH et al ⁽⁶⁾ (2012) and Damesha N et al ⁽²⁾ (2008) too revealed early return of bowel sounds with stapling but the difference was statistically insignificant. Similarly early return of bowel sounds was also noted for esophageal and colorectal anastomosis consistent with findings of previous study by Damesha N et al ⁽²⁾ (2008). In the esophageal anastomosis group, no significant difference was found between the hand sewn and stapler groups with respect to post operative hospital stay. These findings are in accordance with the findings of the previous study by Craig SR et al ⁽¹⁷⁾ (1996). Previous studies by Seo SH et al ⁽⁶⁾ (2012) and Damesha N et al ⁽²⁾ (2008) comparing hand sewn and stapled gastrojejunostomies revealed no significant difference in postoperative hospital stay between hand sewn and stapler groups. On the contrary present study reveals a significant decrease in post operative hospital stay with stapled gastrojejunostomies. Stapled colorectal anastomosis led to a considerable decrease in the post operative hospital stay. This is in contrast to the findings of previous study by Damesha N et al ⁽²⁾ (2008) and Fingerhut A et al ⁽¹⁸⁾ (1995).

CONCLUSION: In our present study, we found that stapling technique can significantly reduce the time for anastomotic procedure. With reduced operating time and less tissue trauma due to less tissue handling, there is early restoration of gastrointestinal function, early resumption of oral feeding and reduced duration of hospital stay which helps ultimately in early return to routine work. Technique related complications do not show significant differences which suggest that one can use staplers with same safety and accuracy as sutures. There is no doubt however, that stapling techniques are quicker to perform, particularly in situations where access is difficult such as in low colorectal / coloanal anastomosis. Thus stapling technique can be used safely and effectively as a part of modern Surgeon`s armory and one should be equally expert with stapler gun as with needle holder and suture. This study shows that suturing or stapling are equally safe in large bowel surgery. However it also shows a long term benefit of stapling in colorectal cancer patients in restoring the normal continuity and avoiding the permanent stoma. There is insufficient evidence

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showing that routine drainage after colorectal anastomosis prevents anastomotic leak and other complications. These results suggest that with the use of stapler for low sphincter saving anastomosis, more number of patients will be spared a permanent colostomy. These stapling instruments cannot be used on edematous, friable, avascular bowel or very thick tissue. Operating Surgeon should be a master in surgical technique to handle the situation in case the machine fails or staple is contraindicated. Proper training and precision will prevent their misuse. The defect may be related to stapler design, can be avoided by using less than the full staple line on the initial firing of the stapler or by using alternative device. However, the study had weakness that it is not a randomized control trial and cost analysis is not included in the study.

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