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A Study of the Safety and Efficacy of Staplers in Gastrointestinal Surgeries in Adults

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Abstract
Purpose

1 *To study the immediate and delayed complications of stapling devices within one year of the surgeries.*
2 *To study the safety of stapling devices in elective and emergency surgeries.*
3 *To study the efficacy of stapling devices in elective and emergency surgeries.*

Method: *Patients were selected for anastomosis using stapled or hand sewn randomly and the outcomes were evaluated and significant associations were determined using statistical tests and these associations were compared to different similar studies done aroun the globe*

Conclusion: *Stapled anastomosis were found to be superior in terms of reduced operative time , reduced blood loss and reduced time to start oral diet and these finding were compared and found to corroborate with similar studies done previously although further study and trials need to be done for further analysis*

Keywords: *Stapler selection, mechanical stapler , hand sewn, anastomosis.*

Introduction

Staplers were originally developed to address the perceived problem of patency (security against leaks of blood or bowel contents) in anastomoses in particular. Leaks from poor suturing of bowel anastomoses were in the past and till date are a significant cause of post-surgical mortality[(1)].

A surgical stapling device is a type of technical equipment that is used in the various invasive procedures to mechanically connect organs and soft tissues. The most widely used stapling devices are those that connect soft tissue with metal staples. Initially, the staples were made of tantalum, but later they were made of an alloy of CoCrNiMo (40% cobalt, 20% chromium, 16% nickel, 7% molybdenum and 17% filler[(3)]. The stapling devices used in surgical practice are of many forms, each designed for a particular purpose. They can contain single or multiple staplers[(2)] and can be used for inserting linear, circular and oval sutures with longitudinal, transverse and inclined stitches. Immediate, sectional and consecutive stapling is used for inserting one-layered and two-layered buried suture. Stapling devices may have a blade to dissect soft tissue along with an appliance for fixation of soft tissue, a lever and spiral or wedge-shaped drives for the stapling mechanism. The stapling device has three main parts for insertion of the simplest suture: a matrix with two craters, a

magazine with a slot for setting up and directing the staples and a pusher.

Advances in laparoscopic surgery in recent years also owe much to the continuous refinement of stapling devices designed to be used with laparoscopic devices.

There is a wide range of linear, side-to-side and end-to-end stapling devices that provide predictable suture lines with minimal tissue necrosis and are entirely disposable but relatively expensive. Their cost is offset by the saving of operative time and increased range of surgery made possible.

Patients and Methods

1. The study was conducted in a tertiary level medical institution located in Mumbai.
2. The study was included all stapled anastomoses performed in elective and emergency gastrointestinal surgeries, which were compared with prospective and retrospective data on gastrointestinal surgeries conducted in the same institution by hand sewn technique..

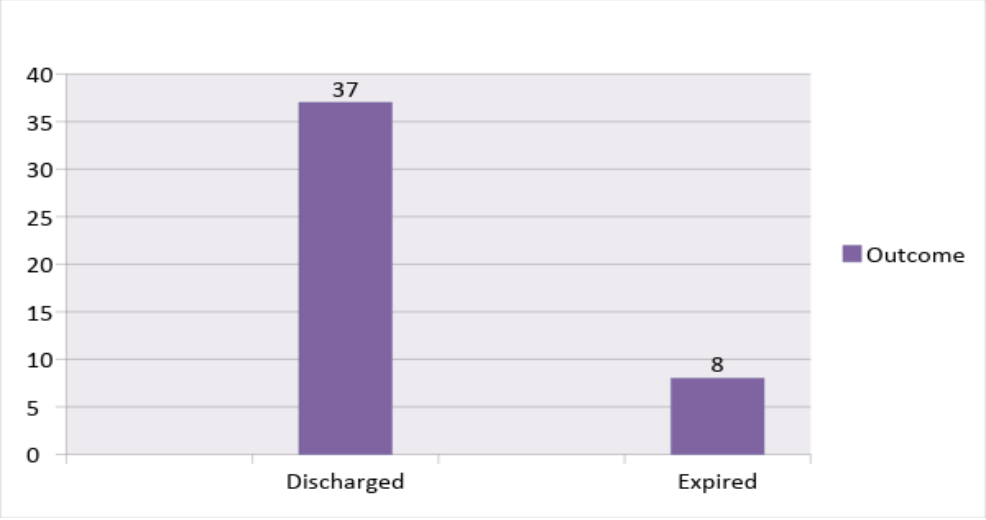
Inclusion Criteria

1. All elective gastrointestinal surgeries.
2. All emergency gastrointestinal surgeries.
3. Laparoscopic gastrointestinal surgeries.
4. Patients of age 13 years and older.

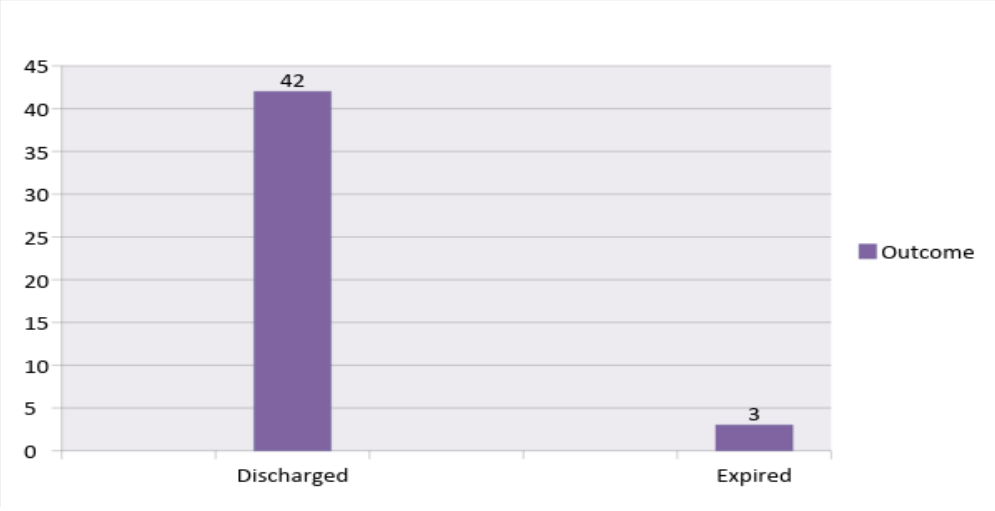
Exclusion Criteria

1. Patients younger than 13 years.
2. Pregnant patients.
3. Redo anastomosis.

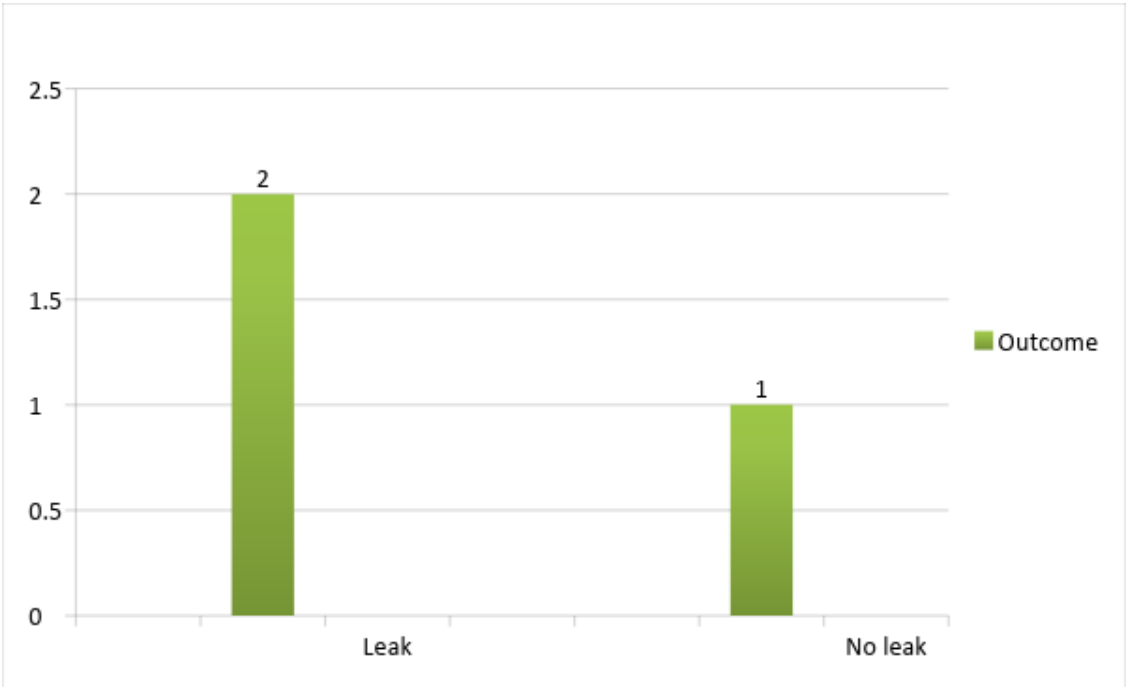
Results



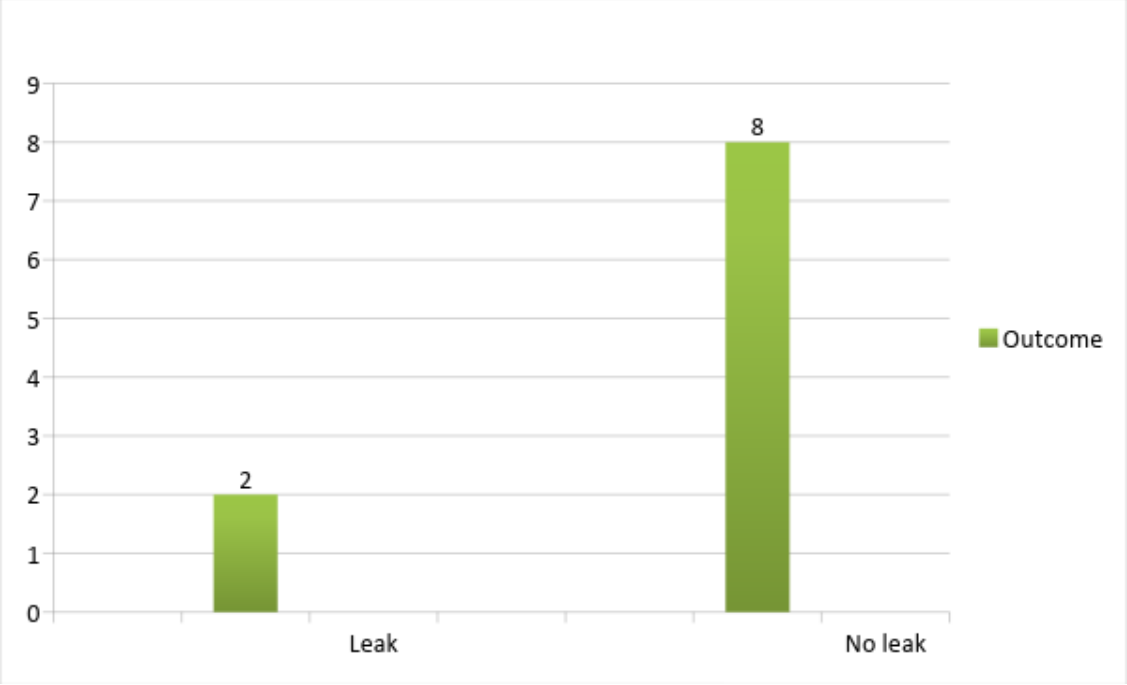
Graph showing no. of patients operated by hand sewn anastomosis



Graph showing patients operated with stapled anastomosis and their ourcomes



Graph showing those patients expired having undergone stapled anastomosis-
Patients with leak
Patients with no leak



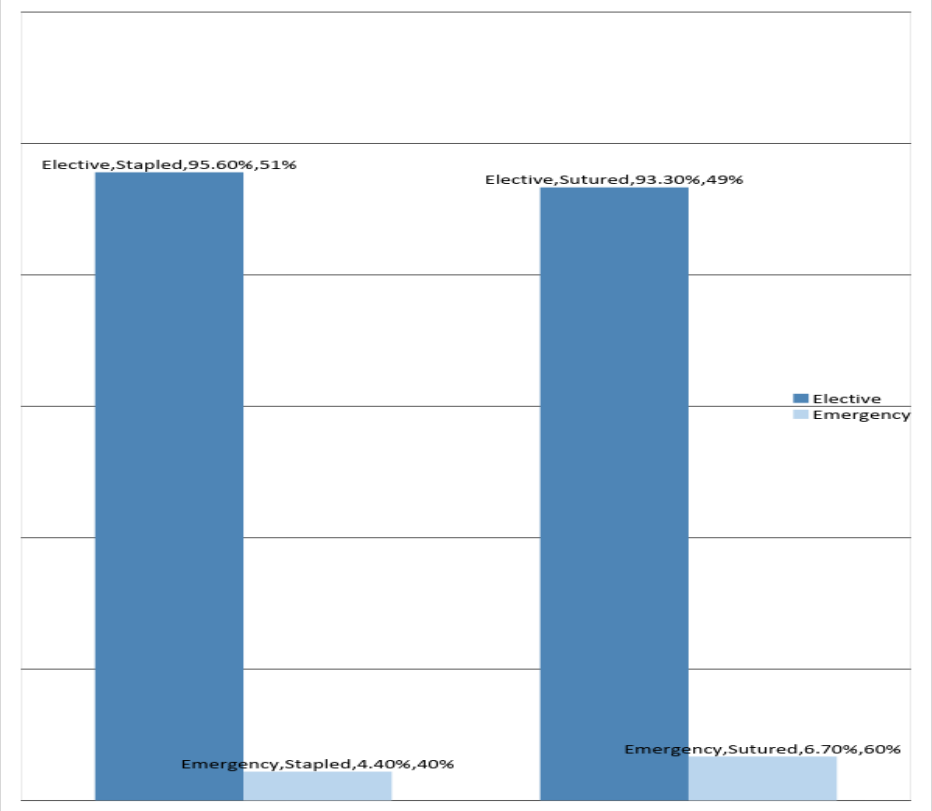
Graph showing those patients expired having undergone hand sewn anastomosis

Association between –

Surgery- emergency or elective

Surgery- Emergency or elective		Group		Total
		Stapled	Hand sewn	
Emergency	No.	2	3	5
	%	4.4%	6.7%	5.6%
Elective	No.	43	42	85
	%	95.6%	93.3%	94.4%
Total	No.	45	45	90
	%	100.0 %	100.0 %	100.0 %

Chi-square Tests	Value	df	p-value	Association is-
Pearson Chi-Square	0.212	1	0.645	Not significant
Continuity correction	0.000	1	1.000	Not significant

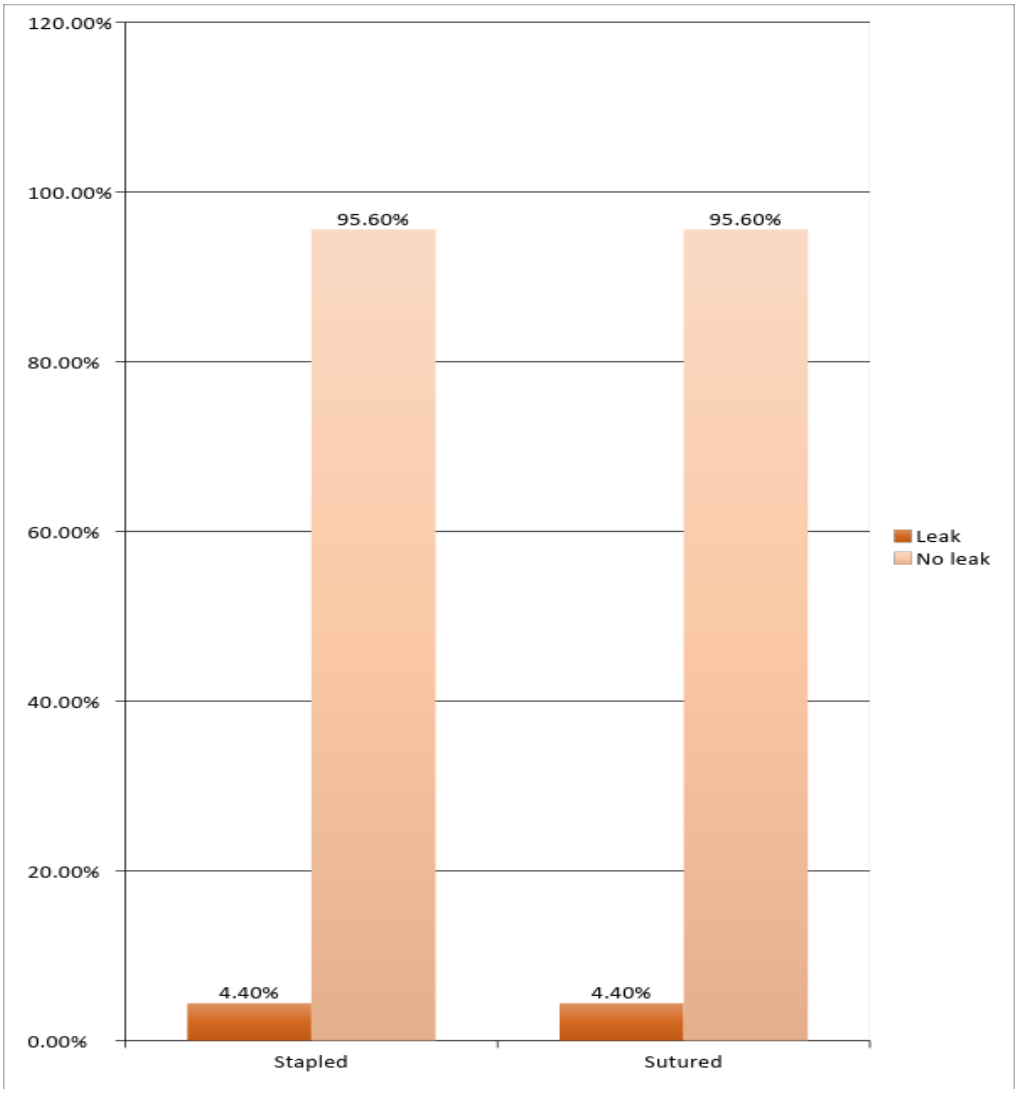


Association between –

Anastomotic Leak Group

Anastomotic Leak		Group		Total
		Stapled	Hand sewn	
YES	No.	2	2	4
	%	4.4%	4.4%	4.4%
NO	No.	43	43	86
	%	95.6 %	95.6%	95.6%
Total	No.	45	45	90
	%	100.0 %	100.0 %	100.0 %

Chi-square Tests	Value	df	p-value	Association is-
Pearson Chi-Square	0.000	1	1.000	Not Significant
Continuity Correction	0.000	1	1.000	Not Significant



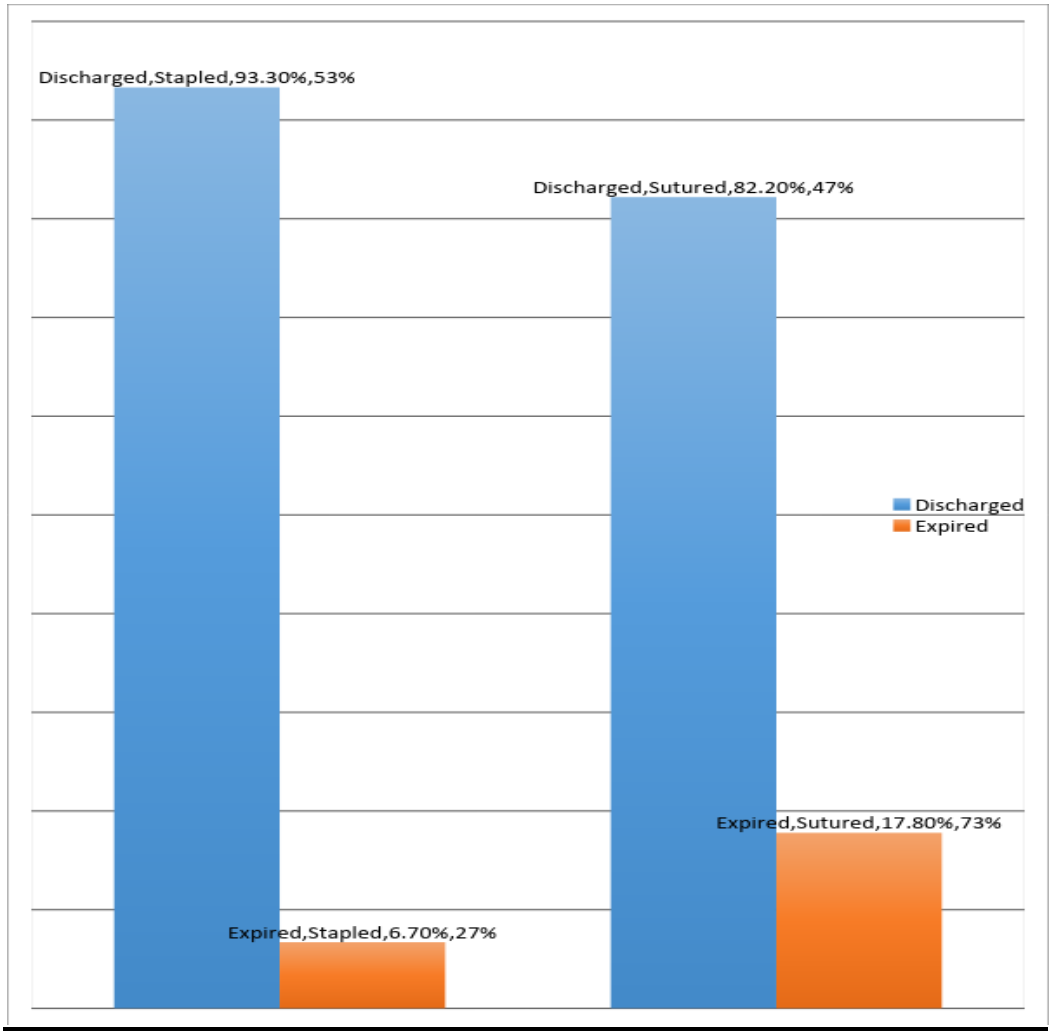
Association between –
Outcome Group

Outcome		Group		Total
		Stapled	Hand sewn	
Expired	No.	3	8	11
	%	6.7%	17.8%	12.2%
Discharged	No.	42	37	79
	%	93.3 %	82.2%	87.8%
Total	No.	45	45	90
	%	100.0%	100.0 %	100.0 %

Chi-square Tests	Value	df	p-value	Association is-
Pearson Chi-Square	2.589	1	0.108	Not Significant
Continuity Correction	1.657	1	0.198	Not Significant

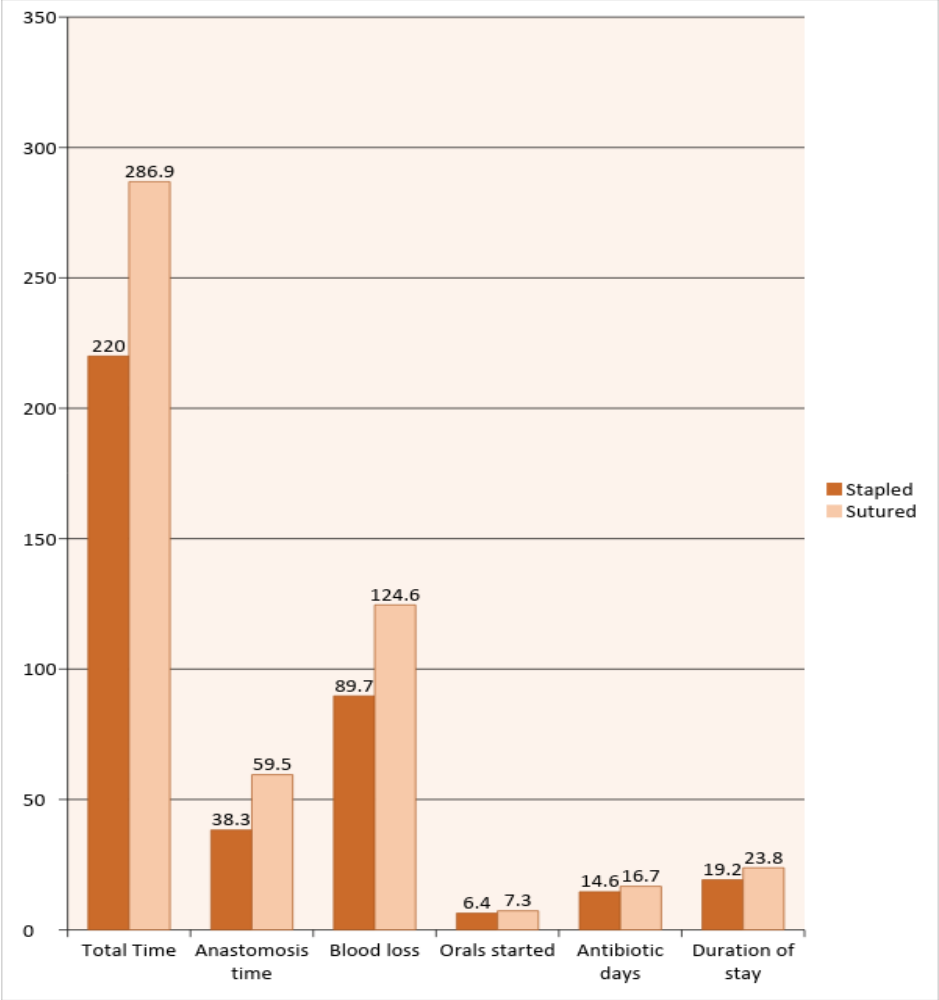
The above table shows the association between outcomes of patients operated with type of anastomosis as stapled or hand sewn. It shows that 3 (6.7%) patients who underwent surgery with stapled anastomosis expired and 42 (93.3%) patients were discharged. While in the hand sewn anastomosis group, 8 (17.8%) patients expired and 37 (87.8%) patients were discharged.

Applying the Pearson chi-square test, there is no significant association between outcomes of patients and the type of anastomosis performed.



Comparison of various variables between Stapled and Hand sewn anastomosis groups

Variable	Group				Unpaired t-test applied		
	Stapled		Sutured		t-value	p-value	Difference is
	Mean	SD	Mean	SD			
Total Time	220	127.7	286.9	147.6	-2.299	0.024	Significant
Anastomosis time	38.3	13.8	59.5	25.7	-4.874	0.000	Significant
Blood loss	89.7	37.6	124.6	53.6	-3.587	0.001	Significant
Orals started	6.4	1.9	7.3	2.1	-2.049	0.043	Significant
Antibiotic days	14.6	8.0	16.7	7.8	-1.224	0.224	Not significant
Duration of stay	19.2	9.8	23.8	7.8	-2.465	0.016	Significant



Discussion

This study takes into consideration 45 cases operated with stapled anastomosis and 45 cases operated with hand sewn anastomosis at our institute over two year period. It includes all types of bowel anastomosis like esophago-gastric, small bowel and colorectal. Indication for surgery, age and sex of the patient were excluded from the comparative study. Variables like nature of surgery, hemoglobin, serum albumin, WBC count, sepsis or no sepsis, co morbidity, time for surgery and bowel anastomosis, leak or no leak, blood loss, day of starting orals, wound gape, duration of intravenous antibiotic use and duration of stay in the hospital were compared.

In our series, the mean total time taken for the complete surgery in the stapled anastomosis group was 220 minutes, while the mean total time taken for complete surgery in the hand sewn group was 286.89 minutes.

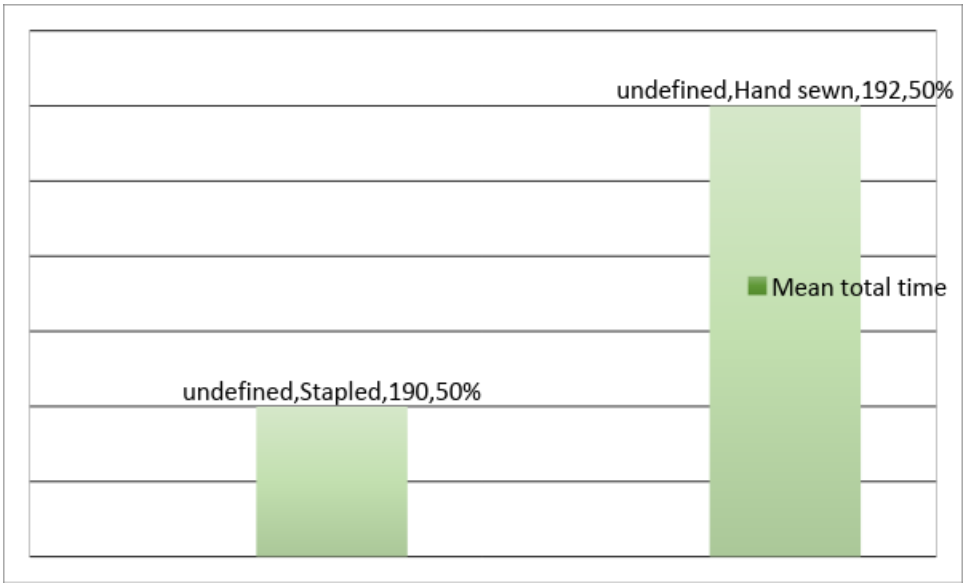
Applying statistics to it, there was a statistically significant association between the total time taken for complete surgery and the type of anastomosis performed.

As shown in the study by Anselmi A et al[7] the mean total time required for stapled anastomosis was 190 minutes and for hand sewn anastomosis was 192 minutes, however the difference was not statistically significant.

Comparative table showing the mean total time for surgery in various studies

Study	Stapled (in min.)	Hand sewn (in min.)
Our study	220	286.89
Anselmi A et al	190	192

Graph Showing the mean total time for surgery in a study done by Anselmi a et al



However in the study by Kusunoki et al[9] there was a significant difference in the operative times between the two groups of patients operated with stapled anastomosis and hand sewn anastomosis.

In our series, the mean total time taken for the anastomosis in the stapled anastomosis group was 38.33 minutes, while the mean total time for anastomosis in the hand sewn group was 59.56 minutes.

Applying statistics to it, there was a statistically significant association.

In our study, the mean total blood loss during the anastomosis in the stapled anastomosis group was 89.67 ml, while the mean total blood loss during the anastomosis in the hand sewn group was 124.67 ml. This blood loss was expected to come while resection of the bowel, tissue handling and during the anastomosis. In the stapled anastomosis as a result of less tissue handling and therefore less tissue trauma, the amount of blood loss was less compared to hand sewn group.

Applying statistics to it, there was a statistically significant association.

This is similar to the study conducted by Kusunoki et al[9] where the blood loss during the surgeries performed with stapled anastomosis was comparatively less as that in those surgeries done with hand sewn anastomosis.

In our study, the number of anastomotic leaks in the patients operated with stapled anastomosis was 2 (4.4%), whereas the number of patients with anastomotic leaks in the hand sewn group was also 2 (4.4%). Applying statistics to it, there was no statistically significant association between the anastomotic leaks and the type of anastomosis performed.

In the study conducted by Docherty et al[14] the anastomotic leak rate in stapled group was 4.4%, while in hand sewn group it was 4.5%, which is almost same as in stapled group, and the difference was not statistically significant

In the study conducted by Anselmi A et al[7] the anastomotic leak rate in stapled group was 5% while in hand sewn group was 7.4%. However the difference was not statistically significant

Comparative Table Showing the rates of Anastomotic Leaks in Various Studies

Study	Stapled	Hand sewn
Our study	4.4%	4.4%
Docherty et al	4.4%	4.5%
Anselmi A et al	5%	7.4%

In the studies conducted by Cochrane Database of systemic Reviews 2007[10], the leak rates were less in the stapled anastomosis group but in the study performed by Beitler et al[11], Mr. W.G. Everett[28] and Urschel JD et al[12] the leak rates were

comparable in both the study groups which is similar to our study. However there is a study conducted by Brundage SI et al[13] which states that the leaks were more in the stapled anastomosis group. This could probably because the study was carried out on trauma patients requiring bowel surgeries.

In our study the mean day of starting orals in patients with stapled anastomosis was 6.4 days while the same in the hand sewn group was 7.3 days. This could be due to less time required for the complete surgery as well as less tissue handling in the stapled group considering other confounding factors were removed.

In the study by Scher KS et al[8] the day of starting orals in the two groups of patients showed no difference. This again could be because the study groups included patients with only colonic anastomosis.

Comparative Table Showing the Mean Duration of Stay in Various Studies

Study	Stapled (in days)	Hand sewn (in days)
Our study	19.20	23.80
Anselmi A et al	13.2	15.2

Also in the study done by Scher KS et al[8] there was no difference in the length of hospital stay between the two study groups. But in the study by Kusunoki et al[9] the length of hospital stay was significantly less in the stapled anastomosis group from that in the hand sewn group which is similar to that in our study.

In our study 3 patients (6.7%) expired in stapled anastomosis group while 42 patients (93.3%) were discharged. Out of 3 expired patients 2 patients had anastomotic leak while the rest died due to associated comorbidities. In case of hand sewn anastomosis group 8 patients (17.8%) were expired while 37 patients (82.2%) were discharged. Out of 8 expired patients only 2 patients had anastomotic leak while the rest died due to associated comorbidities. However the difference was found to be not significant.

In the study by Docherty et al (14) the outcomes in terms of patient discharged or expired were better in the stapled anastomosis group.

Conclusion

1) The mean total time for surgery amongst the patients operated with stapled anastomosis was 220 minutes; while mean total time for surgery for patients operated with hand sewn anastomosis was 286.9 minutes. Applying unpaired t-test, there is significant association between mean total time for surgery and type of anastomosis performed.
2) The mean total time for anastomosis amongst the patients operated with stapled anastomosis was 38.3 minutes; while mean total time for anastomosis for patients operated with hand sewn anastomosis was 59.5 minutes. Applying unpaired t-test, there is significant association between mean total time for anastomosis and type of anastomosis performed.
3) The mean total blood loss in ml amongst the patients operated with stapled anastomosis was 89.7 ml; while mean total blood loss in ml for patients operated with hand sewn anastomosis was 124.7 ml. Applying unpaired t-test, there is significant association between mean total blood loss and type of anastomosis performed.
4) The mean day of starting orals amongst the patients operated with stapled anastomosis was 6.4; while mean day of starting orals of patients operated with hand sewn anastomosis was 7.3. Applying unpaired t-test, there is significant association between day of starting orals and type of anastomosis performed.
5) The mean duration of stay amongst the patients operated with stapled anastomosis was 19.2 days; while mean duration of stay for patients operated with hand sewn anastomosis was 23.8 days. Applying

unpaired t-test, there is significant association between mean duration of stay and type of anastomosis performed.

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