

Stapler versus Hand Sewn Anastomosis in Elective Small Bowel Surgeries –A Comparative Study

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Abstract

Background and Objectives: Even though abdominal and bowel surgeries have been practiced for many decades, the optimal technique for anastomosis of small bowel remains controversial. The preference to choose between stapler or hand sewn anastomosis depends on experience and preference of surgeon. This prospective study intends to study the outcome of stapler and hand sewn anastomosis for elective small bowel surgeries.

Methods: This prospective comparative study was conducted at department of General Surgery, ESIC Model hospital, Rajajinagar, Bengaluru on 50 patients from January 2018 to June 2019. 25 cases each were allotted to group A (stapler group) and group B (hand sewn group) randomly.

Results: The mean time needed to perform the small bowel anastomosis was 24 minutes in the hand sewn group and 11.2 minutes in the stapled group ($p < 0.001$). The mean operative time was 2.6 hours in the hand sewn group versus 2.4 hours in the stapled group ($p = 0.313$). There was no significant difference in postoperative complication namely anastomotic leak rate among the two groups.

Interpretation and Conclusion: Time duration needed for small bowel anastomosis and hence the overall procedure is significantly lesser with use of GI staplers when compared to hand sewn anastomosis. There is no significant difference in postoperative complication like anastomotic leak between stapler and hand sewn group. Hence, stapler anastomosis is superior to hand sewn anastomosis for elective small bowel surgeries.

Key words: Anastomosis; anastomotic leak; handsewn anastomosis; stapled anastomosis.

Introduction

Restoring intestinal continuity after partial enterectomy and/or colectomy is central to gastrointestinal surgery. Prior to nineteenth century, intestinal surgeries were limited to exteriorization by means of a stoma or closure of simple lacerations. Lembert then described his seromuscular suture technique in 1826, while Senn advocated a two layer technique for closure. Kocher's method utilized a two-layer anastomosis, first a continuous all-layer suture using catgut, then an inverting continuous seromuscular layer suture using silk.^[1]

Currently, the single-layer extramucosal anastomosis is popular, as advocated by Matheson of Aberdeen, as it

probably causes the least tissue necrosing, minimal damage to submucosal vascular plexus and lesser luminal narrowing.^[2,3]

Many surgical conditions require the resection of bowel segments and the creation of reliable anastomoses. As such, anastomotic techniques have been central to the development of modern surgical practice.

Anastomosis may be created between two segments of a bowel in a multitude of ways. It may be end-to-end, side-to-side, or side-to-end. The submucosal layer of the intestine provides the strength of the bowel wall and must be incorporated in the anastomosis to assume healing.^[4]

Traditionally, a wide variety of suture materials have been used to create hand-sewn anastomoses. However, in all cases catgut and silk are being replaced by synthetic polymers.

Even though surgical stapling devices have existed since the early 20th century, their use in routine gastrointestinal and bowel surgeries has not been widespread until approximately 30 years ago when their design became much more efficient and convenient. Presently, stapled anastomoses are an integral part of most major abdominal operations.

Undoubtedly, two of the most significant complications related to intestinal anastomosis remain dehiscence and leakage. Breakdown of an anastomosis is associated with considerable perioperative morbidity and mortality. Leakage from the bowel anastomoses in the gastrointestinal tract is major complication and accounts for about 1.3 to 7.7%, that is often associated with increased morbidity and mortality and prolonged stay.^[5,6]

Intestinal anastomoses can nevertheless leak despite optimal conditions, hence the need for dependable and consistent methods.

In this context, the present review focuses on operative techniques for stapled small bowel anastomoses. This is

one of the most frequently encountered areas of elective general abdominal surgery.

Methodology

The present study was conducted in the department of General Surgery, ESIC Model hospital attached to ESIC medical college & PGIMSR, Rajajinagar, Bengaluru from January 2018 to June 2019 between the groups of hand sewn and stapler anastomosis.

A total of 50 cases which met the inclusion and exclusion criteria were included in this hospital based prospective comparative study conducted for duration of 18 months. The study population included all patients who underwent small bowel surgeries.

Study Design: Prospective, randomized, controlled study to compare surgical and subject outcomes between stapled and hand-sutured groups.

Study Period: From January 2018 to June 2019.

Sample Size: A total of 50 cases.

The sample size for the present study was calculated by considering the proportion of anastomotic leak in hand sewn technique as 29% and in stapler technique as 10% (assumed) from the previously published literature. The minimum sample size was calculated to be 25 cases in each group with 19% as effect size at 5% level of significance assuming one tailed hypothesis. Therefore, the minimum total sample size of the study was 50 cases. Following formula was used to calculate the sample size:

$$n = \frac{\left[Z_{\alpha} \sqrt{2 * \bar{P}(1-\bar{P})} + Z_{\beta} \sqrt{P_0(1-P_0) + P_1(1-P_1)} \right]^2}{(P_0 - P_1)^2}$$

Where, $Z_{\alpha} = 1.64$, $Z_{\beta} = 0.0$, $P_0 = .29$, $P_1 = 0.10$ and

$$\bar{P} = \frac{P_0 + P_1}{2}$$

Method of Collection of Data

Data was collected from patients who got admitted in surgical wards of ESIC Model Hospital, requiring small bowel surgeries.

Clinical study was conducted through questionnaires and clinical examination.

All patients underwent routine and specific investigations. All patients were classified accordingly into 2 groups with 25 in each of them. The first group, Study group, is the stapler anastomosis group (Group A) which included cases with at least one small bowel anastomosis done with linear stapler. The second group, control group, is the hand-sewn anastomosis group (Group B) which included cases with small bowel anastomosis done by single layer or double layer using vicryl 2-0/3-0 without the use of staplers.

Following parameters were compared:

1. Duration of anastomosis in minutes.
2. Duration of overall procedure.
3. Postoperative anastomotic leak.

Patients were randomly allotted to control or study group by computer based software method. The following statistical test was used to compare the results of control group and study group.

Independent samples t-test to compare mean values between methods.

Chi-Square test was used to compare proportion of the two values.

Inclusion Criteria

- Subjects who give informed and written consent after reviewing the informed consent document, are eligible for enrollment into the study.
- All patients admitted to the surgery wards requiring bowel surgeries and who are undergoing small bowel anastomosis.
- Male or female subjects (between the ages of 18 and 80 years) undergoing elective surgery requiring small bowel anastomosis.

Exclusion Criteria

- Gastro-intestinal anastomosis done in emergency setting, Biliary-enteric anastomosis.

- Patients with prior chemo-radiation.
- Patients refusing to join the study or left the hospital before final evaluation.

Statistical Analysis

All characteristics were summarized descriptively. For continuous variables, the summary statistics of mean ± standard deviation (SD) were used. For categorical data, the number and percentage were used in the data summaries and diagrammatic presentation. Chi-square (χ^2) test was used for association between two categorical variables.

The formula for the chi-square statistic used in the chi square test is:

$$\chi^2_c = \sum \frac{(O_i - E_i)^2}{E_i}$$

The subscript “c” are the degrees of freedom. “O” is observed value and E is expected value.

The difference of the means of analysis variables between two independent groups was tested by unpaired t test.

The t statistic to test whether the means are different can be calculated as follows:

$$t = \frac{(\bar{x}_1 - \bar{x}_2) - (\mu_1 - \mu_2)}{\sqrt{\frac{s_1^2}{n_1} + \frac{s_2^2}{n_2}}}$$

where \bar{x}_1 = mean of sample 1

\bar{x}_2 = mean of sample 2

n_1 = number of subjects in sample 1

n_2 = number of subjects in sample 2

s_1^2 = variance of sample 1 = $\frac{\sum(x_1 - \bar{x}_1)^2}{n_1}$

s_2^2 = variance of sample 2 = $\frac{\sum(x_2 - \bar{x}_2)^2}{n_2}$

If the p-value was < 0.05, then the results were considered to be statistically significant otherwise it was considered

as not statistically significant. Data were analyzed using SPSS software v.23.0. and Microsoft office 2007.

Observations and Results

Age(years)	Group A(Stapler)		Group B(Hand sewn)		p value
	N	%	N	%	
<20	1	4.0%	0	0.0%	0.403
21-30	0	0.0%	3	12.0%	
31-40	3	12.0%	4	16.0%	
41-50	7	28.0%	8	32.0%	
51-60	7	28.0%	4	16.0%	
>60	7	28.0%	6	24.0%	
Total	25	100.0%	25	100.0%	

Table 1: Distribution Of Age Between Study Groups

Parameters	Group A(Stapler)		Group B(Hand sewn)		p value
	Mean	SD	Mean	SD	
Age(years)	51.5	11.7	49.9	14.3	0.666

Table 2: Mean Age between Study Groups

The present study had two groups, Group A being the Stapler anastomosis group and Group B being the hand sewn anastomosis group. In Group A ,patients with age group from 41-50,51-60 and patients aged more than 60 had maximum and equal number of patients i.e., 7(28%) each. In Group B, maximum number of patients belonged to age group of 41 to 50 years i.e., 8(32%).The mean age of Group A was 51.5 years with a standard deviation of 11.7 and mean age of Group B was 49.9 years with the standard deviation of 14.3 years. p value was found to be 0.666 and hence statistically insignificant.

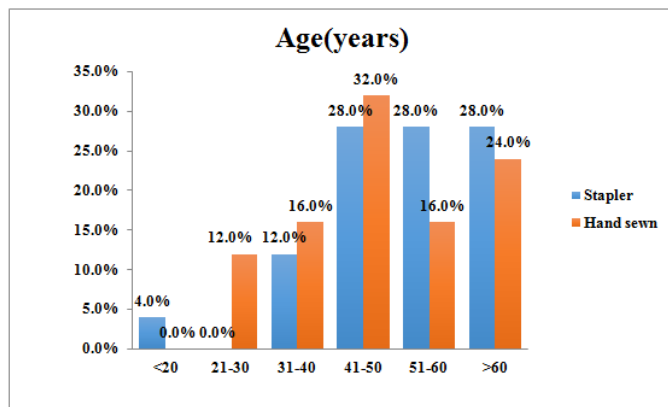


Fig.1: Graph representing distribution of age between study groups

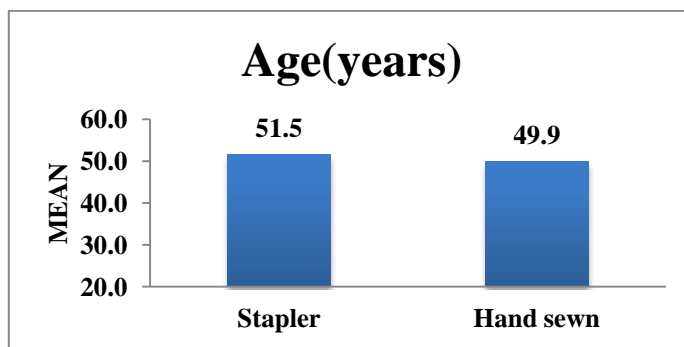


Fig.2: Graph representing mean age between study groups

Sex	Group A(Stapler)		Group B(Hand sewn)		p value
	N	%	N	%	
Male	18	72.0%	17	68.0%	0.758
Female	7	28.0%	8	32.0%	
Total	25	100.0%	25	100.0%	

Table 3: Distribution of Sex between Study Groups

In present study, there were 25 patients each in group A and B. Group A had 18 males (72%) and 7 females(28%).In case of Group B there were 17(68%) males and 8(32%) females. p value was found to be 0.758 and hence was statistically insignificant.

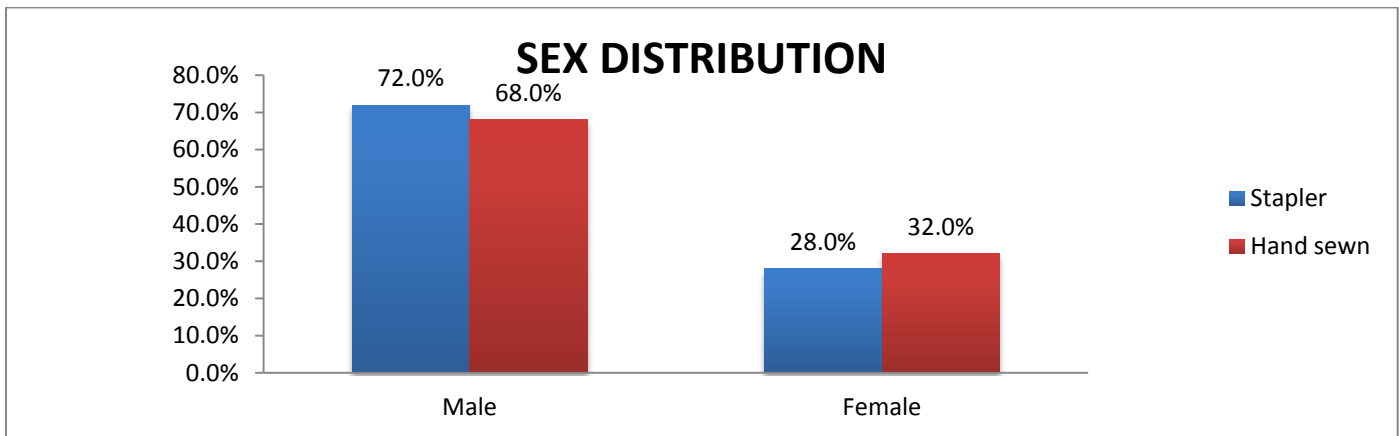


Fig.3: Graph showing distribution of sex between study groups

Diagnosis	Stapler (Group A)		Hand sewn (Group B)		P value
	N	%	N	%	
CA Head of pancreas	2	8.0%	1	4.0%	0.855
CA stomach	4	16.0%	8	32.0%	
Crohns disease	2	8.0%	2	8.0%	
D1D2 Stricture with EHBRD and IHBRD	0	0.0%	1	4.0%	
Duodenal GIST	0	0.0%	1	4.0%	
Duodenal stricture	1	4.0%	1	4.0%	
Enterocutaneous fistula	0	0.0%	1	4.0%	
Gastric Outlet Obstruction	1	4.0%	3	12.0%	
GIST stomach	1	4.0%	1	4.0%	
Hyperplastic Gastric polyp with Duodenal stricture	1	4.0%	0	0.0%	
Ileal GIST	2	8.0%	1	4.0%	
Incisional Hernia with Meckels Diverticulum	1	4.0%	0	0.0%	
Intussusception	1	4.0%	1	4.0%	
Jejunal GIST	1	4.0%	1	4.0%	
Jejunal GIST with COPD	1	4.0%	0	0.0%	
Jejunal Stricture	1	4.0%	0	0.0%	
Meckels Diverticulum	3	12.0%	1	4.0%	
Multiple Jejunal Polyps	1	4.0%	0	0.0%	
Pyloric Stenosis	2	8.0%	1	4.0%	
Subacute Intestinal Obstruction	0	0.0%	1	4.0%	
Total	25	100.0%	25	100.0%	

Table 4: Distribution of Diagnosis Between Study Groups

Among the study groups, both the groups had carcinoma of stomach as diagnosis in maximum number of patients i.e., 4 cases (16%) in case of Group A and 8(32%) in case

of Group B. p value was found out to be 0.855 and hence was not significant statistically.

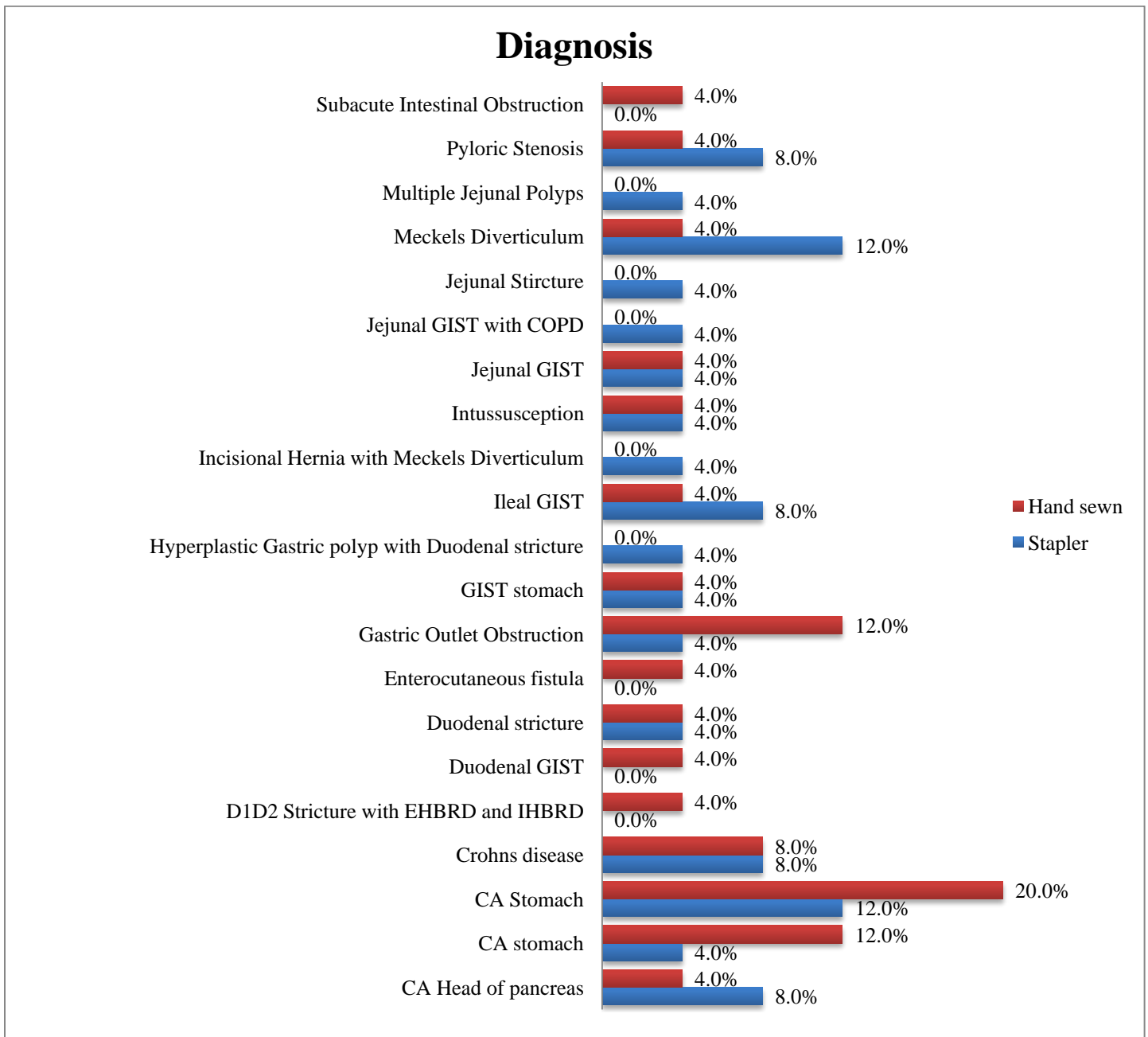


Fig.4: Graph representing distribution of diagnosis between study groups

Procedure Done	Stapler (Group A)		Hand sewn (Group B)		p value
	N	%	N	%	
Anterior GJ with Jejunojejunostomy	0	0.0%	1	4.0%	0.503
Billroth II with GJ and JJ	4	16.0%	5	20.0%	
Distal Gastrectomy with GJ with JJ	6	24.0%	5	20.0%	
Duodenectomy with anastomosis	0	0.0%	1	4.0%	
Posterior GJ with Jejunojejunostomy	0	0.0%	2	8.0%	
Resection and Anastomosis	13	52.0%	9	36.0%	
Whipples Procedure	2	8.0%	2	8.0%	
Total	25	100.0%	25	100.0%	

Table 5: Distribution of Procedure Done Between Study Groups

In our study, resection and anastomosis was performed in maximum number of cases i.e., in 13 patients (52%) in Group A and in 9 patients (36%) in Group B. p value calculated was found to be 0.503 and hence was insignificant.

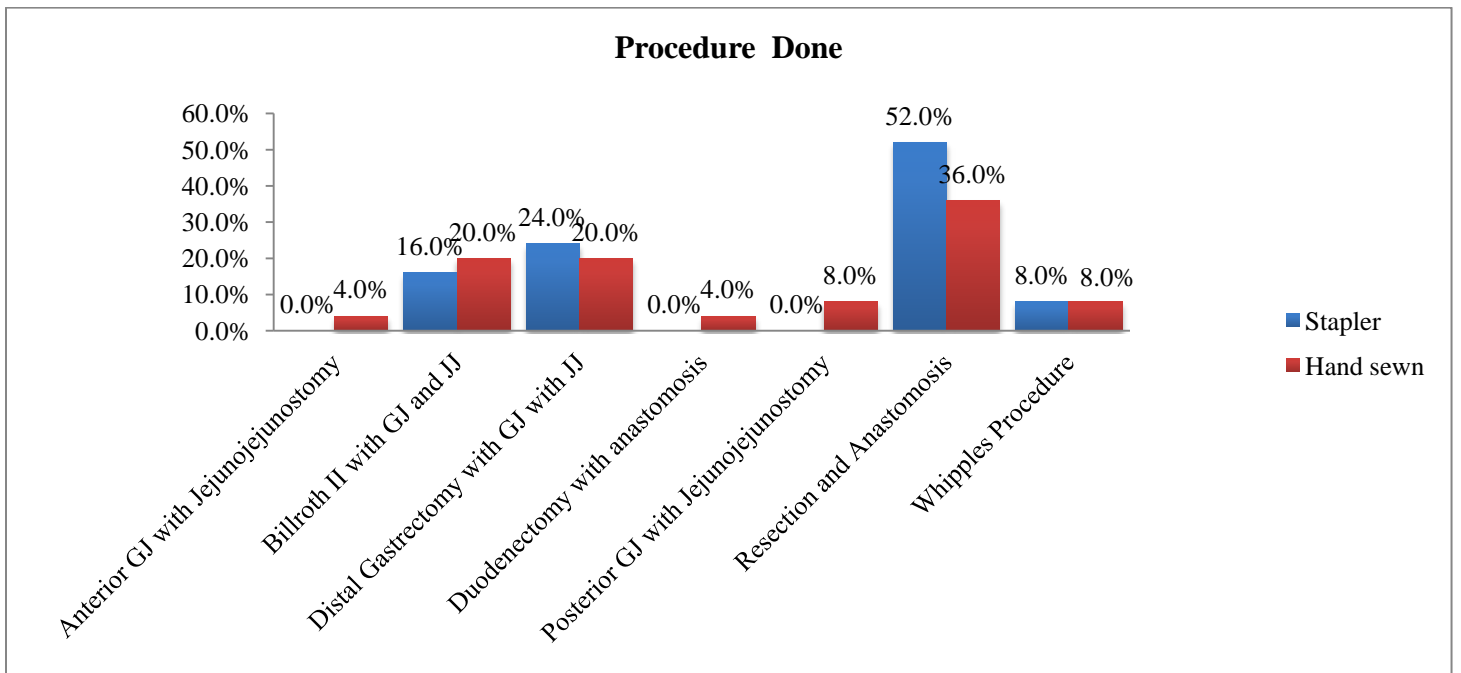


Fig.5: Graph representing distribution of procedure done between study groups

Anastomotic leak	Stapler (Group A)		Hand sewn (Group B)		p value
	N	%	N	%	
YES	1	4.0%	4	16.0%	0.157
NO	24	96.0%	21	84.0%	
Total	25	100.0%	25	100.0%	

Table 6: Complication-Anastomotic Leak Rate Between Study Groups

In this study, among Group A, out of 25 cases performed, 1 patient (4%) had anastomotic leak, whereas in Group B, 4 out of 25 (16%) had anastomotic leak. p value was calculated and was found out to be 0.157 and hence statistically insignificant.

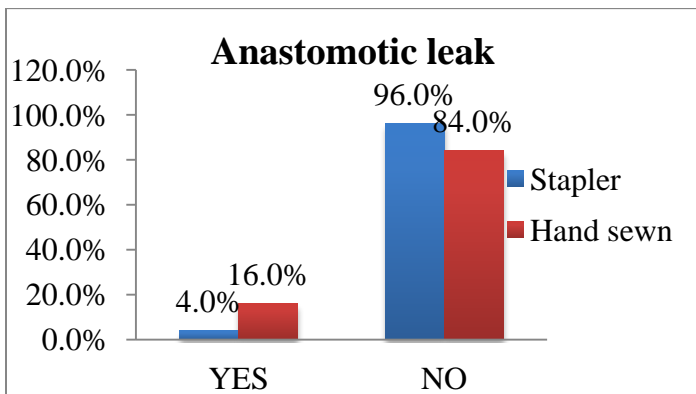


Fig. 6: Graph showing anastomotic leak rate between study groups

Parameters	Stapler (Group A)		Hand sewn (Group B)		p value
	Mean	SD	Mean	SD	
Time taken(overall) (hrs)	2.4	0.8	2.6	0.7	0.313

Table 7: Mean Time Taken (Overall) Between Study Groups

In the present study, the mean time taken for the overall procedure was 2.4 hours in Group A with a standard deviation of 0.8 hours. Among Group B, the mean time for overall procedure was 2.6 hours with a standard deviation of 0.7 hours. p value was calculated and was found out to be 0.313 and hence statistically not significant.

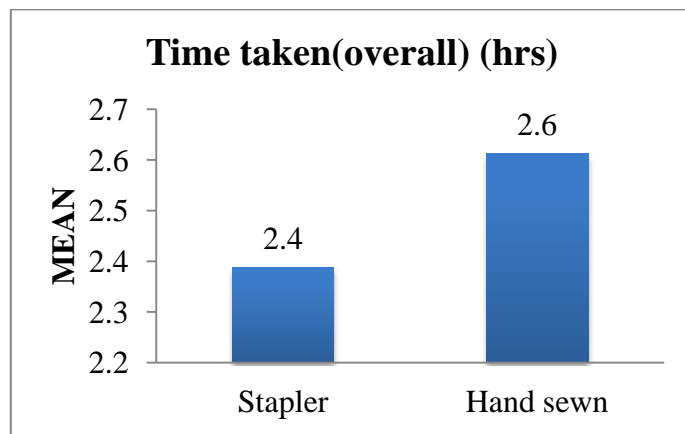


Fig.7: Graph Showing mean time taken (overall) between study groups

Parameters	Stapler (Group A)		Hand sewn (Group B)		p value
	Mean	SD	Mean	SD	
Time taken for small bowel (min)	11.2	2.6	24	2.5	<0.001*

Table 8: Mean Time Taken (For Small Bowel) Between Study Groups

In our study, the mean time taken for small bowel anastomosis in Group A i.e., using staplers was 11.2 minutes with a standard deviation of 2.6 min. The mean time taken for small bowel anastomosis in case of Group B was 24 mins with a standard deviation of 2.5 mins. p value calculated was found to be <0.001 and hence significant statistically.

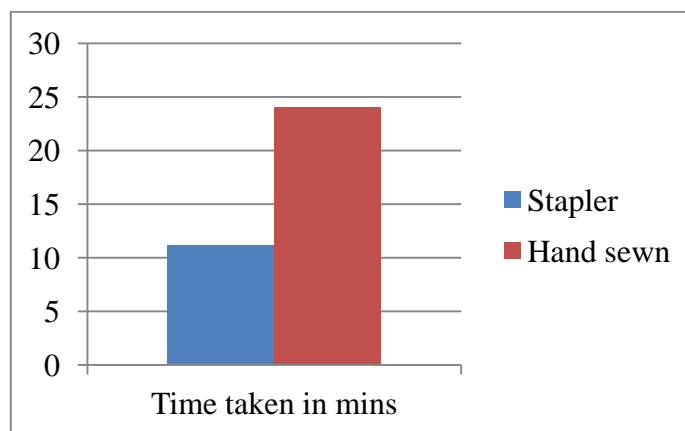


Fig.8: Graph showing time taken for small bowel anastomosis between study groups

Discussion

Even though surgical stapling was first introduced in 1908 by Hüttl and Humer, pioneer study on them was conducted by the Americans in the latter half of 20th century. As a result of which disposable surgical staplers were designed in 1960s. The use of surgical staplers has been rising and has revolutionized the field of bowel surgeries.

This study compares the safety and efficacy of the usage of surgical staplers with hand sewn anastomosis for elective small bowel surgeries. The study includes a total number of 50 cases in two groups with 25 cases in each group. Cases were randomly allotted to each group using computer based software method, for elective cases that involved small bowel anastomosis. The efficacy of both groups were assessed by measuring the time taken for small bowel anastomosis, safety in each group was assessed by calculating the postoperative complication, i.e., postoperative anastomotic leak.

Age

In the present study, the mean age of Group A (stapler) was 51.5 years with a standard deviation of 11.7 and mean age of Group B (hand sewn) was 49.9 years with the standard deviation of 14.3 years. p value was found to be 0.666.

Study conducted by Belbase NP et al.^[7], with 25 cases each in both groups, the mean age among stapled group was 50.40 years with a SD of 15.65 years and mean age among hand sewn group was 49.60 years with a SD of 14.69 years. p value was 0.853. Hence was statistically insignificant. This is comparable to present study

Other studies also showed similar age distribution and mean age:

Name of study	Stapled anastomosis	Hand sewn anastomosis
Reiling et al. ^[35]	56.8	55.1
Scher et al. ^[36]	58.6	54.4
Banurekha R et al. ^[37]	49	51
Present study	51.5	49.9

Table 9: Mean Age Between Two Groups In Various Studies

Postoperative Anastomotic Leak

In our study, among the stapled group, 1 out of 25 cases performed (4%) had anastomotic leak, whereas in Group B, 4 out of 25 (16%) had anastomotic leak. p value was calculated and was found out to be 0.157.

In study conducted by Belbase NP et al, 1 out of 25 (4%) cases in stapled anastomosis group were diagnosed to have postoperative anastomotic leak and 2 out of 25(8%) cases had postoperative anastomotic leak among the hand sewn group. p value calculated using Fischer’s exact test was 1.00. This was statistically insignificant similar to our study.

Various other studies also showed similar outcome:

Study name	Stapled group	Hand sewn group	p value
Banurekha R et al	3/22(6%)	8/28(16)	0.074
Scher et al	2.9%	2.1%	>0.05
Choy PY et al ^[8]	1.4%	6.02%	0.02
Present study	1/25(4%)	4/25(16%)	0.157

Table 10: Comparison of Postoperative Anastomotic Leak Rate Between Two Groups In Different Studies

Studies conducted by Reiling et al. and Adloff et al. also showed similar results and found to be insignificant statistically.

Similarly studies conducted by Hassanen et al.^[9] with 39 cases showed 16.6% leak in stapler group and 38% leak in hand sewn group.

Even though not significant statistically, all the above mentioned studies show lesser postoperative leak with usage of staplers for small bowel surgeries when compared with hand sewn anastomosis, consistent with the findings in our study.

Time Taken For Small Bowel Anastomosis

In our study the mean time taken for the small bowel anastomosis in stapler anastomosis group is 11.2 mins with a SD of 2.6 mins. In hand sewn anastomosis group mean time taken for small bowel anastomosis is 24 mins with SD of 2.5 mins. p value calculated was found to be <0.001, hence significant statistically.

In study conducted by Belbase NP et al., the mean time taken for stapled anastomosis group was 11 mins with a SD of 1.91 mins, whereas the mean time taken in hand sewn anastomosis group was 32.04 mins with a SD of 4.51 mins. p value was <0.001, being statistically significant.

In the study conducted by Shubhakar Bhandary et al.^[10] with a total number of 70 cases, 35 each in stapler and hand sewn group showed a mean anastomotic time of 12.92 mins among stapled group and 33.9 mins among the hand sewn group, being statistically significant.

Name of the study	Stapled group	Hand sewn group
Hassanen et al.	15 mins	30 mins
George et al ^[11]	14.3 mins	28.1 mins
Present study	11.2 mins	24 mins

Table 11: Comparison of Mean Duration of Anastomosis In Various Studies

Time Taken For Overall Procedure Between Study Groups

In our study, mean time taken for overall procedure was 2.4 hours in stapler group with a SD of 0.8 hours. Among the hand sewn anastomosis group the mean time taken for overall procedure was 2.6 hours with a SD of 0.7 hours. p value calculated was 0.313 and hence was not significant.

Study conducted by Belbase et al. showed a mean operating time of 132.52 mins in stapled anastomosis group and a mean operating time of 147.12 mins among hand sewn anastomosis group.

Study conducted by Banurekha et al. with a total number of 50 cases (22 cases in stapler and 28 in hand sewn anastomosis) showed a mean operating time of 2.25 hours among stapler group and a mean operating time of 3 hours among hand sewn group, with a p value of 0.04. Hence was not statistically significant.

Study name	Stapled anastomosis	Hand sewn anastomosis
Damesha N et al. ^[12]	125 mins	145 mins
George et al.	103.8 mins	115.5 mins
Present study	144 mins	156 mins

Table 12: Mean Time Taken For Overall Procedure In Various Studies

Similarly studies conducted by Catena et al.^[13] and Leung et al^[14] also showed that anastomosis done by staplers took significantly less time (p<0.05) in comparison with hand sewn technique.

All the above studies show significantly reduced procedure time with the usage of staplers with comparison to hand sewn anastomosis, consistent with our findings.

Conclusion

The present study was a prospective comparative study which included fifty cases of various clinical conditions that required resection and anastomosis of small bowel.

The study was conducted in two groups namely stapler anastomosis group and hand sewn anastomosis group with a sample size of 25 cases in each group. Both the groups were evaluated with respect to time taken for anastomosis and complications namely postoperative leak and hence efficacy and safety was of stapler versus hand sewn anastomosis was studied.

Even though to draw a dogmatic conclusion a large number of patients need to be studied, with our study following conclusions can be drawn:

1. Time duration needed for small bowel anastomosis and hence the overall procedure is significantly lesser with staplers when compared to hand sewn anastomosis.
2. Even though insignificant statistically, postoperative complication like anastomotic leak is less with use of surgical staplers compared to hand sewn anastomosis.

With the above observations, it can be concluded that stapler is superior to hand sewn anastomosis for elective small bowel surgeries.

Summary

The present study was a comparative study with a total number of fifty cases distributed randomly among two groups and a total of twenty five cases in each group. The study was conducted at ESIC model hospital attached to ESIC Medical College and PGIMSR, Rajajinagar, Bengaluru from January 2018 to June 2019.

Cases undergoing elective small bowel surgeries were included in the study. All subjects were subjected to thorough clinical and radiological examinations and the diagnosis was confirmed. Medical and anaesthetic fitnesses were obtained and the patients were subjected to surgeries after fulfilling inclusion and exclusion criteria

Patients' demographic details, intra-operative findings, time taken for anastomosis and overall procedure was noted and patients were followed up to assess for

postoperative complication namely postoperative anastomotic leak. Above data were collected in preformed proforma and entered in the masterchart of both groups. Every case was analyzed with respect to time taken for anastomosis and overall procedure, postoperative complication namely anastomotic leak in stapler and hand sewn small bowel anastomosis. Results were calculated using chi square test and were compared with other comparative studies. From our study following results were drawn:

1. With respect to duration of small bowel anastomosis, in stapler anastomosis group (Group A) the range was between 9 minutes to 18 minutes 30 seconds with a mean duration of 11.2 minutes, in hand sewn anastomosis group (Group B) the range was between 17 minutes to 27 minutes 40 seconds with a mean of 24 minutes. The mean difference in duration of anastomosis between the two study groups is 12.8 minutes. p value is <0.001 and hence statistically highly significant. The mean time taken for overall procedure in stapler group was 2.4 hours and mean time in hand sewn group was 2.6 hours. Calculated p value was 0.313, being statistically not significant. With these findings, use of GI Stapler for elective small bowel surgeries appears to be the optimal choice with shorter duration of anastomotic time.

2. In our comparative study, the complication in the form of anastomotic leak was present in 5 cases (10%). Among 25 cases who underwent stapler anastomosis 1 case (4%) had anastomotic leak, whereas in hand sewn group four patients (16%) had post-operative anastomotic leak. p value was 0.157 which was statistically not significant. With the above findings it can be concluded that complication rate is comparable between stapler and hand sewn anastomosis.

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