

# Efficacy of staplers in comparison with conventional (Hand-Sewn) anastomosis in gastrointestinal surgery – A prospective and randomized study



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## ABSTRACT

**Background:** Gastrointestinal anastomosis is a regularly carried out surgical technique to set up communication between two distant portions of the intestine since the era of Sushruta. There exist different methods of intestinal anastomosis. The newer techniques are Stapling devices over to conventional hand-sewn method of anastomosis. It is proved that a key to a successful anastomosis is accurate anastomosis of two viable ends of the bowel maintaining good vascularity and less tension. Due to consistency, stapler's can be used at difficult locations. **Aims and Objectives:** The objective of present study was to compare the outcome of hand-sewn versus stapler anastomosis in elective gastrointestinal surgeries. **Materials and Methods:** We conducted a prospective and randomized study including 30 study participants each in stapler's method and hand-sewn method at surgery outpatient department of Kempegouda Institute of Medical Sciences Hospital and Research Center. **Results:** Stapling procedure took less days to get restored, less time to return of bowel sounds, shorter duration of hospital stays, and less time to resume for oral feeds compared to hand-sewn method and which were statistically significant ( $P < 0.05$ ). Complications such as anastomotic leaks accounted for 3.3% in stapler group and 13.3% in hand-sewn anastomosis, which was not significant statistically. **Conclusion:** We concluded that time for anastomosis during the procedure, restoration of the gastrointestinal function, oral feeding resumption, and post-operative hospital stay took significantly less time in stapling technique than hand-sewn anastomosis and the staplers looked technically easy compared to hand-sewn method. Complications related to procedure did not show significant differences which helped us to conclude that one can use staplers with similar safety and accuracy as hand suturing method.

**Key words:** Hand-sewn anastomosis, Stapled anastomosis, Abdominal surgeries, Post-operative recovery

## INTRODUCTION

The word anastomosis comes from the Greek “ana” – without, and “stoma” – a mouth, reflecting the join of a tubular viscous (bowel) or a vessel, after resection or a bypass procedure.<sup>1</sup> Bowel anastomosis is a common procedure done in both elective as well as emergency gastrointestinal surgeries. It establishes a communication

between the formerly two different portions of the intestine.<sup>2</sup> Bowel anastomosis can be done either by hand-sewn method, mechanical staplers, or fibrin glue.<sup>2</sup>

The time required for the surgery, restoration of function, effective hemostasis, less tissue trauma, and post-operative morbidity reduction like leak (sepsis) are the factors which will be considered for constructing of an anastomosis.

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The most important factor to be kept in mind is accurate approximation without tension and with a good blood supply either it is suturing or stapling.<sup>3,4</sup> Staplers have been researched to fulfill all these criteria and staplers could cut and staple without the need for clamping.<sup>3,5</sup> Anastomosis can be done by suturing or stapling. It is useful to study the two approaches to bowel anastomosis. Hence, the objective of present study was to compare the outcome of hand-sewn versus stapler anastomosis in elective gastrointestinal surgeries.

### Aims and objectives

Compare the outcome of hand-sewn versus stapler anastomosis in elective gastrointestinal surgeries.

## MATERIALS AND METHODS

The study was conducted on patients admitted in the Department of Surgery, Kempegowda Institute of Medical Sciences, Bengaluru, requiring gastrointestinal anastomosis surgery either elective or emergency basis. It was a prospective, randomized, comparative, and clinical study conducted from November 2018 to October 2020. The sample size was calculated using the formula

$$N = \frac{(Z_{\alpha/2} \sqrt{2p(1-p)} + Z_{1-\beta} \sqrt{p_1(1-p_1) + p_2(1-p_2)})^2}{(p_1 - p_2)^2}$$

$p_1$  and  $p_2$  are the proportion of event of interest (outcome) for Group I and Group II and  $P$  is  $(P_1 + P_2)/2$

$Z_{\alpha/2}$  is normal deviate at level of significance

$Z_{1-\beta}$  is the normal deviate at  $1-\beta$  % power with  $\beta$  % of type II error

For an outcome variable on anastomotic leak of minimum difference of 17% in two groups comparison derived from previous literature for 90% statistical power at 5% level of Type I error rate and 10% Type II error rate, the sample size of 60 (30 in each group) is adequate. Ethical approval was taken from the Institutional Ethical Committee of Kempegowda Institute of Medical Sciences, Bangalore (Ref no.: KIMS/IEC/D68/2018, dated November 10, 2018). Details were recorded in the pro forma prepared after taking written informed consent from all the study subjects.

### Inclusion criteria

Patients admitted in the Department of Surgery, Kempegowda Institute of Medical Sciences, Bengaluru, requiring gastrointestinal anastomosis surgery were included in the study.

### Exclusion criteria

Patients below the age of 18 years, with esophageal and anorectal anastomosis, with trauma and who were not willing to give the consent were excluded from the study.

The patients were randomized to Group 1 and Group 2, during abdominal surgeries, the anastomosis was done with the staplers for the Group 1 patients and simple hand-sewn anastomosis was done for Group 2 patients. Randomization was performed as follows: 60 envelopes were prepared, with 30 as Group A (Stapler's group) and 30 as Group B (Hand-sewn group).

Preoperatively, anemia, uncontrolled diabetes, and uncontrolled hypertension were treated. Standard bowel preparation was given to all elective cases and prophylactic antibiotics are given to all the cases half an hour before the surgery. When planned for resection and anastomosis, patients who fulfilled the inclusion and exclusion criteria were randomly assigned one envelope and segregated to respective groups.

- Group A – Stapled anastomosis
- Group B – Hand-sewn anastomosis.

The various observations such as time taken for the procedure, time taken for the bowel sounds to return, resumption of oral feeds, and post-operative complications such as anastomotic leak and mortality were recorded in the charts. The patients are assessed till discharge from the hospital. Data were analyzed and expressed in terms of rates, ratios, and percentages. The statistical evaluation was accomplished using the Chi-square test and unpaired t-test.  $P < 0.05$  was considered significant. The reports are compared between the stapler and hand-sewn anastomosis and compared with other studies.

## RESULTS

A total of 60 patients who are admitted for elective as well as emergency resection and anastomosis for various illnesses requiring anastomosis were allocated in Group 1 of GI staplers and control Group 2 of conventional hand-sewn technique. There were 26 (86.7%) males in stapled anastomosis with 4 females (13.3%) and 17 (56.7%) males in the hand-sewn anastomosis with 13 females (43.3%). There were 14 (46.7%) of the age group 51–70 years in stapled anastomosis with 10 (33.3%) patients of the same age group in the hand-sewn anastomosis. Most of the patients who underwent stapled anastomosis (66.7%) were diagnosed to have hernia, obstruction, perforation, and only 33.3% were diagnosed with carcinoma. Among those who had undergone hand-sewn anastomosis, 7 (23.3%) were diagnosed with perforation and obstruction (Table 1). Among all the abdominal surgeries, stapled anastomosis required a significant less time for completing the surgical procedure with mean

time was  $175 \pm 32.48$  min when compared to the mean time in the hand-sewn group was  $211.33 \pm 75.31$  min with  $P=0.01$  (Table 2 and Graph 1). Similarly, the reappearance of bowel sounds was significantly ( $P=0.002$ ) quicker in the stapled anastomosis with a mean of  $3.03 \pm 0.76$  days than the hand-sewn anastomosis with mean of  $3.80 \pm 0.76$  days (Graph 2). In abdominal surgeries anastomosis, mean post-operative hospital stay was  $14.26 \pm 6.81$  days in the hand-sewn group compared to  $10.03 \pm 3.18$  days in the stapler group. This difference was also found a significance on statistical analysis ( $P=0.003$ ) (Graph 3). Oral feeds were started earlier in stapled anastomosis with a mean of  $4.86 \pm 1.16$  compared to hand-sewn anastomosis with mean

of  $6.30 \pm 1.74$  days which was again statistically significant ( $P=0.003$ ) (Graph 4). Only 3.3% developed complications following stapled anastomosis whereas 13.3% developed anastomosis following hand-sewn anastomosis with 10% and 16.7% mortality in both the groups, respectively.

## DISCUSSION

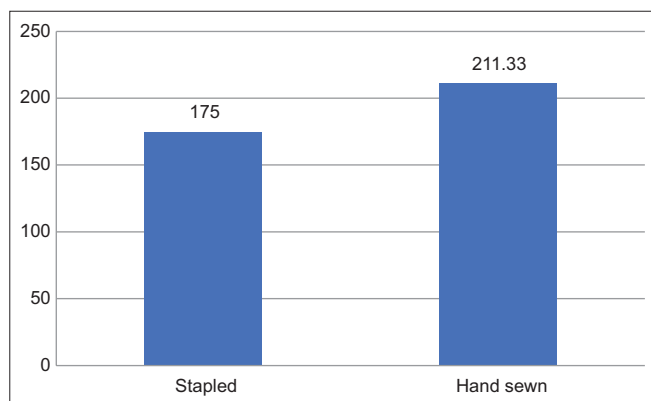
Surgical stapling devices were first introduced by Hultl, Hummer (Budapest) in 1908, but their use has increased recently since the introduction of new and reliable disposable instruments in the past 20 years. In our study, a total of 60 cases who were admitted in Kempegowda

**Table 1: Comparison of demographic and post-operative variables among both groups**

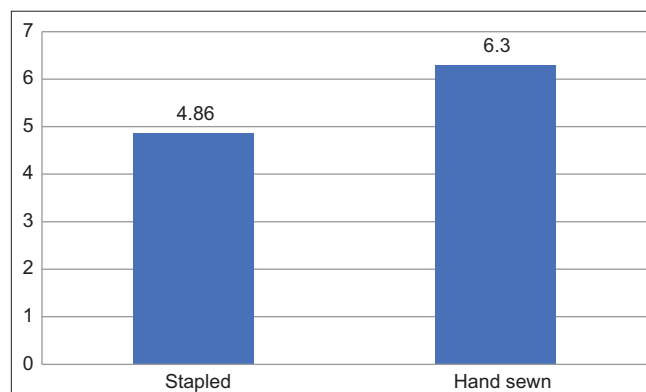
Variable	Group A (%)	Group B (%)	Chi-square test (P-value)
Sex			
Female	4 (13.3)	13 (43.3)	6.64 (0.009)
Male	26 (86.7)	17 (56.7)	
Age			
<30	3 (10)	5 (16.7)	1.76 (0.3)
30–50	10 (33.3)	13 (43.3)	
51–70	14 (46.7)	10 (33.3)	
>70	3 (10)	2 (6.7)	
Operation time			
<150	5 (16.7)	3 (10)	8.09 (0.01)
150–200	17 (56.7)	14 (46.7)	
201–250	8 (26.7)	5 (16.7)	
>250	0 (0)	8 (26.7)	
1Appearance of bowel sounds in days			
1–3	23 (76.7)	10 (33.3)	11.38 (0.002)
4–6	7 (23.3)	20(66.7)	
Duration of hospital stay in days			
<10	17 (56.7)	5 (16.7)	10.43 (0.005)
10–20	11 (36.7)	19 (63.3)	
>20	0 (0)	3 (10)	
Starting of oral feeds (in days)			
1–5	23 (76.7)	12 (40)	7.7 (0.003)
6–10	7 (23.3)	17 (56.7)	
11–15	0 (0)	1 (3.3)	
Complications			
No	29 (96.7)	26 (86.7)	1.96 (0.16)
Yes	1 (3.3)	4 (13.3)	
Mortality			
No	27 (90)	25 (83.3)	0.57 (0.447)
Yes	3 (10)	5 (16.7)	
Diagnosis			
Hernia	1 (3.3)	6 (20.0)	10.16 (0.037)
Obstruction	5 (16.7)	7 (23.3)	
Carcinoma	10 (33.3)	3 (10.0)	
Perforation	3 (10.0)	7 (23.3)	
Others	11 (36.7)	7 (23.3)	

**Table 2: Comparison of post-operative parameters among both groups**

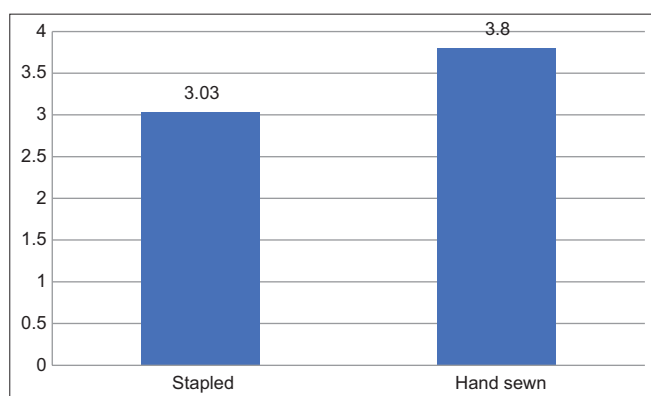
Post-operative parameters	Group A	Group B	t-test (P-value)
	Mean±SD	Mean±SD	
Operation time	$175.00 \pm 32.48$	$211.33 \pm 75.31$	-2.42 (0.018)
Appearance of bowel sounds in days	$3.03 \pm 0.76$	$3.80 \pm 0.76$	-3.92 (0.000)
Duration of hospital stay in days	$10.03 \pm 3.18$	$14.26 \pm 6.81$	-3.77 (0.000)
Starting of oral feeds (in days)	$4.86 \pm 1.16$	$6.30 \pm 1.74$	-3.08 (0.003)



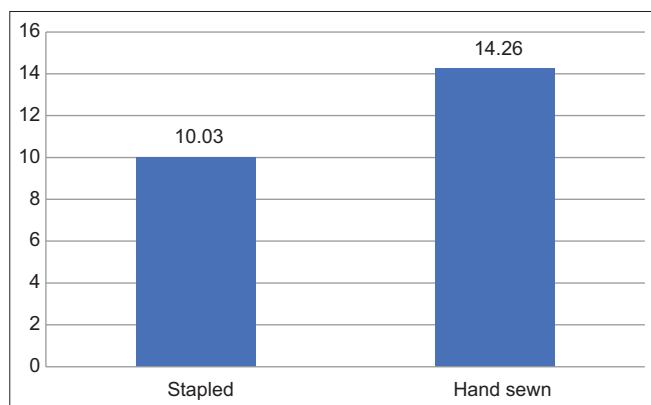
Graph 1: Operation time



Graph 4: Starting of oral feeds (in days)



Graph 2: Appearance of bowel sounds in days



Graph 3: Duration of hospital stay in days

Institute of Medical Sciences, Bengaluru, for either elective or emergency condition requiring resection and anastomosis from the period of November 2018 to October 2020 were included in the study. The cases were chosen randomly for the stapler group (30 cases) (Group 1) and the hand-sewn group (30 cases) (Group 2).

In the present study, stapler and hand-sewn groups were found comparable with the age, gender, presence, or absence of comorbid condition. Other studies done by Seo et al.,<sup>6</sup> Hassanen et al.,<sup>7</sup> and Nichkaode and Parakh<sup>8</sup>

compared hand-sewn and stapled gastrojejunostomy showed a similar result with the age and gender distribution between two groups.

The present study found a statistically significant difference ( $P=0.01$ ) in the duration of the procedure, in stapled anastomosis with a Mean $\pm$ SD of  $175\pm 32.48$  min compared hand-sewn anastomosis with a Mean $\pm$ SD of  $211.33\pm 75.31$ . This finding shows good congruence with other study done by Himabindu et al.,<sup>3</sup> Mitra et al.,<sup>9</sup> in their study reported that the mean total operative time was 65.71 min in the stapler group and 69.89 min in the hand-sewn group and time taken to achieve anastomosis was 23.92 min in the stapler group and 33.14 min in the hand-sewn group, this was statistically significant with  $P<0.05$ . The restoration of gastrointestinal function such as appearance of bowel sound ( $P=0.002$ ) and start of oral feeds ( $P=0.003$ ) was faster in stapled anastomosis than hand-sewn anastomosis in our study. Few studies<sup>3,9</sup> found that there was no statistically difference in the restoration of gastrointestinal functions. Our results are in context with Seo et al.,<sup>6</sup> and Nichkaode and Parakh<sup>8</sup> and Mitra et al.,<sup>9</sup> studies.

The study done by Beuran et al.,<sup>10</sup> reported that there was no statistical difference in the post-operative hospital stay among hand-sewn or stapled anastomosis. These findings are in congruence with the reports of the study done by Seo et al.,<sup>6</sup> comparing hand-sewn and stapled gastrojejunostomy. On the contrary, the present study reveals a significant decrease in post-operative hospital stay with stapled gastrojejunostomy. Mitra et al.,<sup>9</sup> reported that there was a significant difference in the start of oral feeds on an average 5.39 post-operative day in the stapler group patients and 7 post-operative days in the hand-sewn group.

In terms of complications such as anastomotic leak or mortality were more in hand-sewn, it was not significant when compared to both types of anastomosis. This result is in contrast with the report by Nichkaode and Parakh.<sup>8</sup> Shahin et al.,<sup>11</sup> reported similar results as our study.

### Limitations of the study

Our study sample was limited to 30 each in group, better to involve more sample size to see the results.

Because of time constraint We have done only on abdominal surgeries, the same can be done with other surgeries wherever staplers and handsewn method can be compared.

### CONCLUSION

The present study based on the clinical practice of surgeons showed stapled anastomosis to be patronizing to the conventional hand-sewn method in terms of time duration for operation, post-operative restoration of gastrointestinal function, and the incidence of complications as anastomotic leak. The findings were somewhat inconsistent with few reports, which concluded that stapled and hand-sewn sutures had similar outcome in terms of complications. However, most studies were in accordance with the present study results.

### ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee dated November 10, 2018.

### DATA AVAILABILITY STATEMENT

All data generated or analyzed during this study are included in this published article (and its supplementary information files).

### ACKNOWLEDGMENT

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**AD**- Definition of intellectual content, literature survey, prepared first draft of manuscript, implementation of study protocol, data collection, and manuscript preparation; **MGS**- Concept, design, clinical protocol, and prepared first draft of manuscript, editing; **SHN**- Review manuscript and review manuscript; and **NPN**- Literature survey and preparation of figures, data analysis, coordination, and manuscript revision.

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