

Efficacy and Safety between Stapled Versus Hand Sewn Anastomosis in Anterior Resection for Carcinoma of Rectum

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DOI: [10.36347/sajs.2024.v10i06.016](https://doi.org/10.36347/sajs.2024.v10i06.016)

| Received: 18.04.2024 | Accepted: 27.05.2024 | Published: 21.06.2024

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Abstract

Original Research Article

Background: Colorectal anastomosis in anterior resection poses a challenge due to the risk of leakage. Surgical staplers offer procedural advantages and a sense of security, but their efficacy compared to conventional hand-sewn techniques remains uncertain, particularly regarding cost-effectiveness. **Objective:** This study aimed to compare the outcomes of stapled anastomosis versus conventional hand-sewn anastomosis in patients undergoing surgery for rectal cancer, focusing on operative time, anastomotic time, hospital stay duration, and early postoperative complications. **Method:** This quasi-experimental study was conducted over a period of one and half years from January 2022 to June 2023 in the Department of Surgery, Rajshahi medical college were divided into two groups: stapled anastomosis (Group A) and hand-sewn anastomosis (Group B). Follow-up was conducted after discharge, and data were analyzed using SPSS (version 26.0), with significance set at $p < 0.05$. **Results:** The stapled group (Group A) demonstrated a statistically significant higher mean monthly income compared to the hand-sewn group (Group B). Operative time exceeding 90 minutes was significantly lower in the stapled group (73.3% vs. 100%). Anastomotic time ≤ 30 minutes was achieved in 100% of the stapled group versus 46.7% in the hand-sewn group. Postoperative hospital stay duration (>7 days) was significantly shorter in the stapled group (96.7% vs. 100%). Additionally, the stapled group experienced fewer cases of fever (16.3% vs. 46.7%) and wound infection (13.3% vs. 33.3%), with no clinical anastomotic leakage compared to 10% in the hand-sewn group. **Conclusions:** Stapled anastomosis demonstrated superior outcomes in terms of operative efficiency, postoperative recovery, and early complication rates compared to conventional hand-sewn anastomosis. This suggests that stapled techniques may offer a safer and more efficient alternative in rectal cancer surgeries.

Keywords: Colorectal anastomosis, Stapled anastomosis, Hand-sewn anastomosis, Operative efficiency, Postoperative complications.

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INTRODUCTION

Surgery stands as the cornerstone in the treatment arsenal for rectal cancers, offering the only avenue towards definitive cure [1]. The overarching objective of treatment revolves around striking a delicate balance between radical tumor resection and the imperative to preserve sphincter function, thereby upholding the patient's quality of life. A pivotal aspect in surgical management is the pursuit of sphincter-saving resections coupled with the restoration of bowel continuity, a milestone initially realized for rectosigmoid

tumors, progressively extending to mid and low rectal tumors as well [2]. The two most commonly used anastomotic techniques are: (A) hand-sewn sutured anastomosis and (B) stapled anastomosis. Although both are well established, they are not without their faults. Neither provides an immediately "sealed" anastomosis and both are prone to uncommon but serious complications such as anastomotic bleeding, infection or leaks. However, controversy remains regarding which of the two methods of creating an anastomosis yields better clinical outcomes [3].

Citation: Md. Rokonzaman, Md. Alim Al Razy, Zafia Afrin, Towhidul Hasan Nahid, Md. Romijul Karim, Md. Habibulla Sarkar, Md. Ariful Alam, Md. Rezaul Islam. Efficacy and Safety between Stapled Versus Hand Sewn Anastomosis in Anterior Resection for Carcinoma of Rectum. SAS J Surg, 2024 Jun 10(6): 712-721.

Prospective, randomized trials have not demonstrated any differences between stapled and hand-sewn anastomosis in terms of leakage rates, length of hospital stay, or overall morbidity [4]. Comparing local recurrence, 3 - and 5-year survival rates after anal preserving surgery and abdominoperineal resection of Miles for rectal cancer, it showed no significant difference $p>0.05$ [5]. After colorectal resection, the incidence of anastomotic leak ranges from 2.9% to 15.3%. These complications may require further surgical intervention and can lead to significant mortality and morbidity [6]. In colorectal surgery, the advantages of the stapled technique are said to be a lower percentage of complications, such as leaks, better blood supply, reduced tissue manipulation, less edema, uniformity of sutures and shorter hospital stay and operation time.

Meta-analysis was performed to compare the safety and effectiveness of stapled versus hand-sewn colorectal anastomosis surgery. Outcome measures were mortality, anastomotic bleeding, leak, wound infection, anastomotic Duration (time taken to perform the anastomosis) and hospital stay. NO significant statistical difference were found except that time taken to perform the anastomosis was longer with handsewn techniques ($p<0.05$) [7]. The time taken to perform the anastomosis may, when analyzed in isolation, have some importance. It may influence the total length of the operative procedure or hospitalization of the patient. The other variables analyzed did not demonstrate any advantage of one technique over the other [8]. Aim of this study to compare the stapled versus Hand sewn anastomosis in anterior resection in RMCH which will help the surgeons for counseling the patient in favor of appropriate anastomosis technique efficacy and safety for the treatment of rectal cancer surgery which will also reduce morbidity and mortality of such patients.

OBJECTIVES

General Objective

- To compare the safety and efficacy between stapled versus Hand sewn anastomosis in anterior resection for carcinoma of rectum.

Specific Objectives

- To assess and compare the time required for anastomosis and post-operative hospital stay among the hand-sewn anastomosis group and stapled anastomosis group of anterior resections for carcinoma of rectum.
- To assess and compare the early postoperative complications among the hand-sewn anastomosis group and stapled anastomosis group of anterior resections for carcinoma of rectum.
- To compare anastomotic leak among two groups

MATERIAL AND METHODS

Study Design

This study employed a quasi-experimental study to compare the safety and efficacy of stapled versus hand-sewn anastomosis in anterior resection for rectal carcinoma. Conducted over a one-and-a-half-year period from January 2022 to June 2023, the study was carried out in the Department of Surgery at Rajshahi Medical College, Rajshahi. The study population comprised patients undergoing surgery for rectal cancer, with 30 patients allocated to each group based on the type of anastomosis deemed appropriate by the surgeon's clinical judgment.

Inclusion criteria

- Patients undergoing resection for anterior resection.
- Lower limit of lesions >10 cm from anal verge for carcinoma of rectum.
- Carcinoma rectum confined to rectal wall (Dukes stage –A&B)
- Consent after adequate counseling including cost of staplers and also participation in study.

Exclusion criteria

- Patients with widespread loco-regional and distant metastasis or those down-staged after neo adjuvant therapy, (Dukes stage-C&D)
- Patients with lesion <10 cm from anal verge, involving anal sphincter or requiring emergency operation,
- Patients with complicated co-morbidities
- pediatric age group (<16 years)
- patients with prior chemo-radiation

Data Collection

Data collection involved administering a semi-structured questionnaire, utilizing a measuring tape and weight machine, and recording anastomosis time with a digital device. Patients undergoing rectal cancer surgery at Rajshahi Medical College were included. Data on demographics, operative details, and postoperative outcomes were gathered. Investigations were conducted at a standard laboratory. Data completeness and internal consistency were ensured.

Data Analysis

After collecting data, the questionnaires were categorized into groups. Then I was checking the completeness and internal consistency of questions. and their completeness and internal consistency were verified. Statistical analysis was conducted using Statistical Package for the Social Sciences (SPSS, version 26.0, Chicago, IL) software. Frequency distribution described qualitative variables, while mean and standard deviation characterized quantitative variables. Mean \pm Standard Deviation (SD) was calculated for each parameter of interest in patients separately, and the difference between group means was

assessed using an unpaired t-test. Categorical data were analyzed using the chi-square test, with statistical significance set at $p < 0.05$ or $< .001$ for all tests.

Ethical Considerations

The study obtained prior approval from the Ethical Review Committee (ERC) of RMCH, Rajshahi, adhering to the Helsinki Declaration for Medical Research Involving Human Subjects (1964, revised in

2008 and 2013). Subjects were verbally informed about the study's design, purpose, risks, and benefits, ensuring their full understanding. Participants were assured of their right to withdraw from the study at any time for any reason. Only patients who provided informed consent were included in the study sample.

RESULT

Table 1: Distribution of the study patients by demographic characteristics (N=60)

Characteristics	Stapled (n=30)	Hand-sewn (n=30)	p value
Age in years			
≤30	1 (3.3%)	3 (10.0%)	
31-40	7 (23.3%)	2 (6.7%)	
41-50	10 (33.4%)	13 (43.3%)	
51-60	9 (30.0%)	7 (23.3%)	
>60	3 (10.0%)	5 (16.7%)	
Mean ± SD	48.5 ± 10.47	49.63 ± 12.42	a0.704ns
Range (Min-Max)	29-70	25-76	
Sex			
Male	20 (66.7%)	13 (43.3%)	
Female	10 (33.3%)	17 (56.7%)	b0.069ns
Monthly income (TK)			
Mean ± SD	24467 ± 5581.6	20100 ± 4212.9	a0.001s
Range (Min-Max)	18000-40000	15000-30000	
Nutritional status			
Normal	30 (100.0%)	30 (100.0%)	

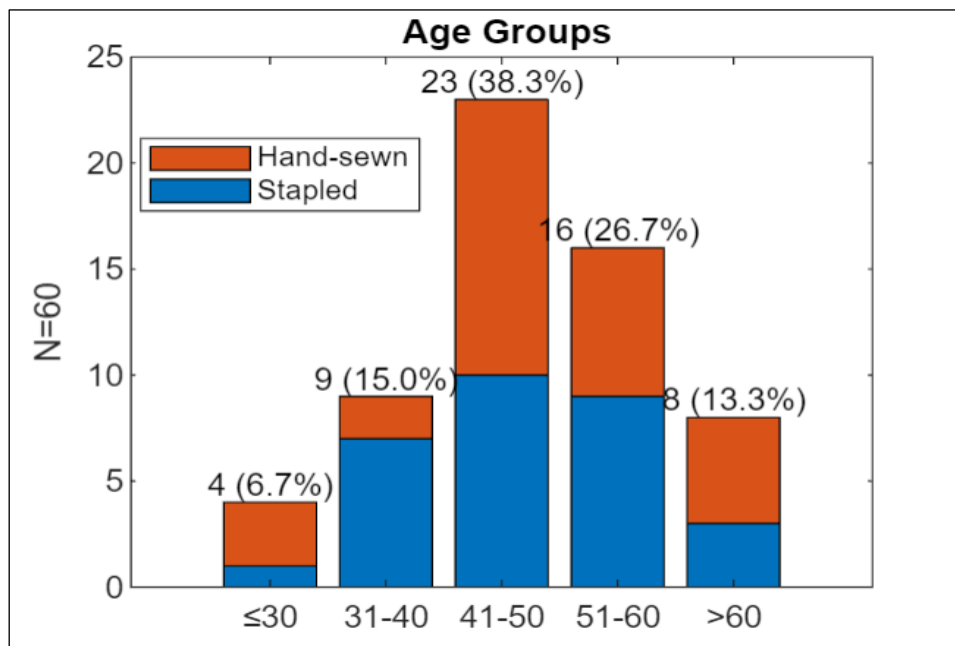


Figure 1: Demographic Characteristics According to Age

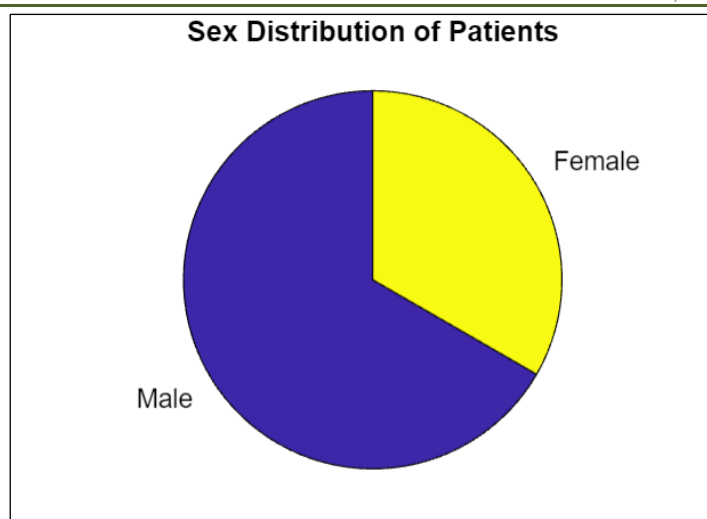


Figure 2: Demographic Characteristics According to sex

Distribution of the study patients by demographic characteristics. It was observed that almost half 13 (43.3%) of patients belonged to age was 41-50 years in the sewn group and 10(33.4%) in stapled group. The mean age was 49.63 ± 12.42 years in the Hand sewn group and 48.5 ± 10.47 years in stapled group. More than half 17 (56.7%) of the patients were female in Hand sewn

group and 10(33.3%) in stapled group. The mean monthly income was 24467 ± 5581.6 TK in stapled group and 20100 ± 4212.9 TK in hand-sewn group. All 30 (100.0%) patients had normal nutritional status in stapled group and 30(100.0%) in hand-sewn group. The differences of monthly income was statistically significant ($p < 0.05$) between two groups.

Table 2: Distribution of the study patients by Duration of operation (N=60)

Duration of Operation (Minutes)	Stapled (n=30)	Hand-sewn (n=30)	p value
≤ 90 min	8 (26.7%)	0 (0.0%)	
> 90 min	22 (73.3%)	30 (100.0%)	
Mean \pm SD	111.33 ± 16.97	149.33 ± 8.68	0.001s
Range (Min-Max)	90-140	130-170	

The study patients by Duration of operation Regarding operative time ,8(26.7%) patients needed < 90 min and 22(73.3%) patients needed > 90 min in stapled group, All 30(100%) patients needed > 90 min in Hand

sewn group. The mean was 111.33 ± 16.97 min in stapled group and 149.33 ± 8.68 min in hand-sewn group. The difference was statistically significant ($p < 0.05$) between two groups.

Table 3: Distribution of the study patients by anastomosis time (N=60)

Anastomosis Time (Minutes)	Stapled (n=30)	Hand-sewn (n=30)	p value
≤ 30 min	30 (100.0%)	14 (46.7%)	
> 30 min	0 (0.0%)	16 (53.3%)	
Mean \pm SD	20.07 ± 2.27	31.53 ± 2.94	0.001s
Range (Min-Max)	17-25	26-35	

Distribution of the study patients by anastomosis time. Regarding anastomotic time, All 30(100.0%) of patients needed ≤ 30 min in stapled group and 14(46.7%) patients needed in hand-sewn group and

16(53.3%) patients needed > 30 min in Hand sewn group. The mean was 20.07 ± 2.27 min in stapled group and 31.53 ± 2.94 min in hand-sewn group. The difference was statistically significant ($p < 0.05$) between two groups.

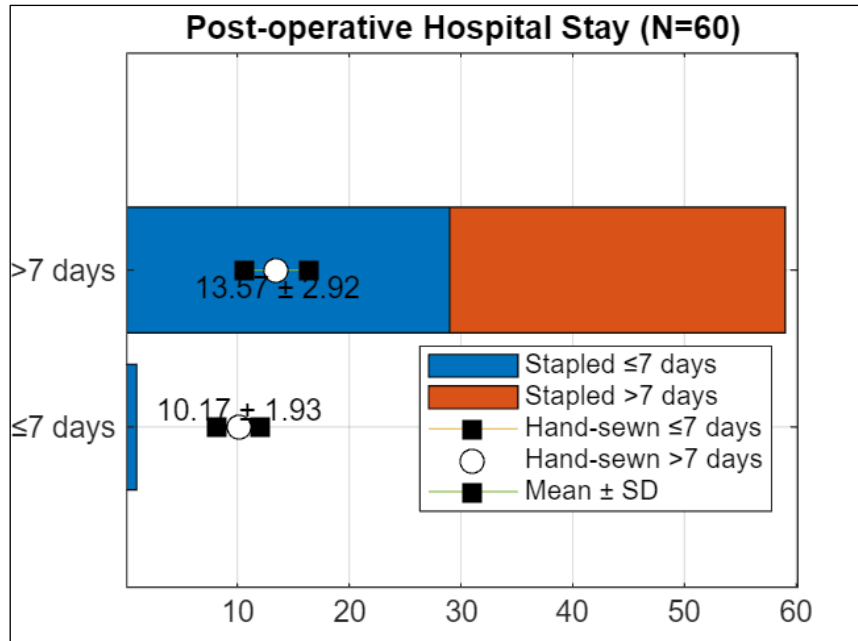


Figure 3: Distribution of the study patients by postoperative hospital stay (N=60)

It was observed that the majority 29(96.7%) of patients who belonged to postoperative hospital stay was >7 days in the stapled group and 30(100.0%) in hand-sewn group. The mean was 10.17±1.93 days in stapled

group and 13.57±2.92 days in hand-sewn group. The difference was statistically significant (p<0.05) between two groups.

Table 4: Distribution of the study patients by early postoperative complications (N=60)

Early Postoperative Complications	Stapled (n=30)	Hand-sewn (n=30)	p value
Per Rectal Bleeding due to Anastomotic Hemorrhage			
Present	0 (0.0%)	2 (6.6%)	0.492ns
Absent	30 (100.0%)	28 (93.33%)	
Fever			
Present	5 (16.3%)	14 (46.7%)	0.012ns
Absent	25 (83.3%)	16 (53.3%)	
Wound Infection			
Present	4 (13.3%)	10 (33.3%)	0.047ns
Absent	26 (86.7%)	20 (66.7%)	
Wound Dehiscence			
Present	2 (6.7%)	5 (16.7%)	0.160ns
Absent	28 (93.3%)	25 (83.3%)	
Anastomotic Leakage Clinically			
Present	0 (0.0%)	3 (10.0%)	0.237ns
Absent	30 (100.0%)	27 (90.0%)	

Distribution of the study patients by early postoperative complications. It was observed that all 30(100.0%) patients had no per rectal bleeding due to anastomotic hemorrhage in stapled group and had develop in 2(6.6%) in Hand-sewn group. Two (6.7%) patients had wound dehiscence in stapled group and 5(16.7%) in hand-sewn group. five (16.3%) patients had

fever in stapled group and 14(46.7%) in hand-sewn group. Four (13.3%) patients had wound infection in stapled group and 10(33.3%) in hand-sewn group. 3 (10%) patient has clinical anastomotic leakage in hand-sewn group. The differences of wound infection was statistically significant (p<0.05) between two groups.

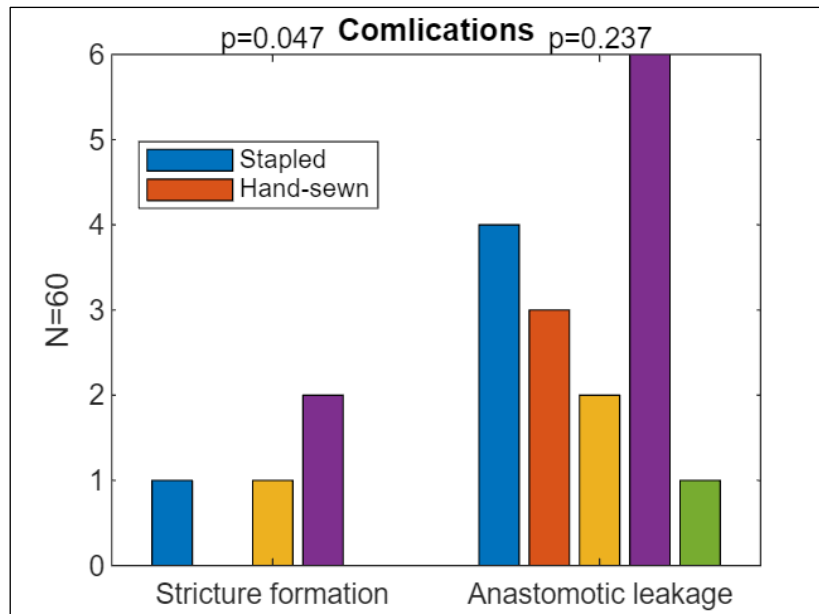


Figure 4: Distribution of Study Patients by Long-term Postoperative Complications (N=60)

long-term postoperative complications in patients treated with stapled and hand-sewn techniques. Stapled procedures showed lower rates of stricture formation (3.3% vs. 13.3%), fistula formation (3.3% vs. 6.7%), and adhesive intestinal obstruction (0.0% vs.

3.3%) compared to hand-sewn. Although not statistically significant, stapled cases had fewer instances of anastomotic leakage (0.0% vs. 10.0%) and bowel obstruction (6.7% vs. 20.0%). The p-values suggest no significant difference (ns) between the techniques.

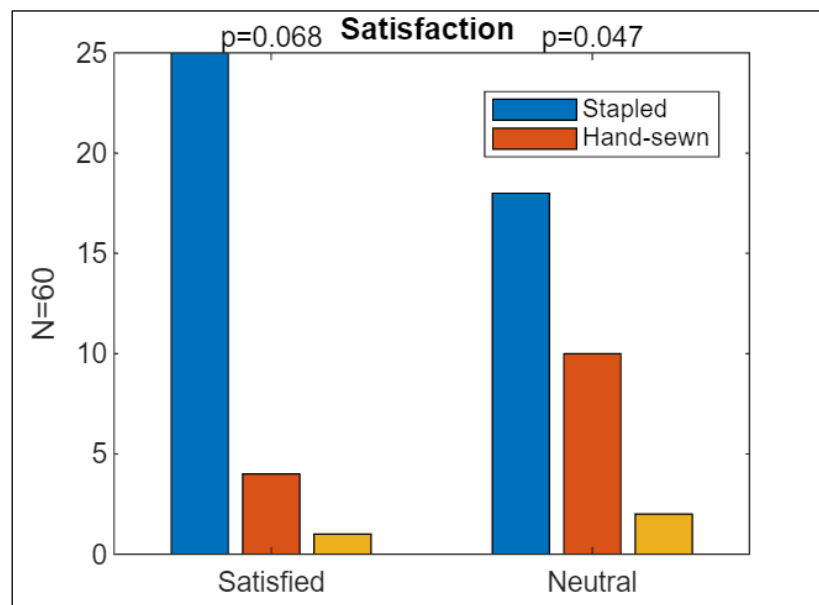


Figure 5: Distribution of Study Patients by Overall Patient Satisfaction (N=60)

The overall patient satisfaction levels between stapled and hand-sewn techniques following surgery. Stapled procedures exhibited higher satisfaction rates (83.3%) compared to hand-sewn (60.0%). Conversely, hand-sewn procedures had a higher percentage of neutral responses (33.3% vs. 13.3%). Dissatisfaction rates were

relatively low for both techniques, with stapled slightly lower (3.3% vs. 6.7%). While the satisfaction difference was not statistically significant ($p > 0.05$), a trend towards higher satisfaction was observed with stapled procedures.



Figure 6: Distribution of Study Patients by Quality of Life Scores (N=60)

The quality of life scores comparison between stapled and hand-sewn surgical techniques. Stapled procedures exhibited higher percentages of excellent scores (60.0%) compared to hand-sewn (40.0%). Conversely, hand-sewn techniques had higher percentages of good scores (46.7% vs. 30.0%). There was no significant difference in fair scores between the two groups. Although not statistically significant ($p > 0.05$), a trend towards better quality of life scores was observed with stapled procedures, particularly in the excellent category.

DISCUSSION

This observational study was carried out with an aim to compare the safety and efficacy between stapled versus Hand sewn anastomosis in anterior resection for carcinoma of rectum to compare 'time required for anastomosis and 'postoperative hospital stay' between stapled and hand-sewn groups of anterior resections for carcinoma of rectum and also to compare both early postoperative complications between two groups [9]. A total of 60 patients with rectal cancer underwent anterior resection in the department of Surgery in Rajshahi Medical College, Rajshahi were included in this study. The patients were divided in two groups, 30 in each group to receive either of the following two anastomosis procedure [10]. The subjects were allocated into two groups according to the type of anastomosis, stapler group and hand sewn group. The allocation of the groups was decided by affordability of stapler by the patient and need for use of stapler. Final group selection was dependent on the surgeon's clinical judgment on use of stapler.

Patients underwent anterior resection followed by anastomosis, lower limit of lesion $>10\text{cm}$ from anal verge for carcinoma rectum, Carcinoma rectum confined to rectal wall (Dukes stage –A&B) and consented after adequate counseling including cost of staplers and also

participation in study. Patients with widespread loco-regional and distant metastasis or those down-staged after neo adjuvant therapy, (Dukes stage-C&D), patients with lesion $<10\text{cm}$ from anal verge, involving anal sphincter or requiring emergency operation, patients with complicated co-morbidities, pediatric age group (<16 years), Although stapled anastomoses are becoming more popular among the surgeons, hand-sewn techniques, including resection or direct repair, have shown comparable results compared to the stapled technique [11]. In this study it was observed that 13(43.3%) of patients belonged to age was 41-50 years in stapled group and 10 (33.4%) in hand-sewn group. The mean age was 49.63 ± 12.42 years in stapled group and 48.5 ± 10.47 years in hand-sewn group. The mean age was almost alike between two groups, no statistical significant ($p > 0.05$) difference was between two groups. Study observed that majority (44.0%) of the study participants were belonged to 41-50 years of age group followed by 26.0% patients were belonged to 21-30 years of age group, which are comparable with the current study. Similar observations also observed by [12].

On the other hand, has been a higher mean age in patients having carcinoma of rectum, which was 56.42 ± 10.47 and 52.10 ± 10.24 years in groups A and B, respectively. Higher mean age also observed by [13-15]. The higher mean age and age range obtained by the above authors maybe due to geographical variations, racial, ethnic differences, and genetic causes may have significant influence on carcinoma rectum in their study subjects. In this study it was observed that 20(66.7%) of patients were male in stapled group and 13(43.3%) in hand-sewn group. The sex did not show any statistical difference between two groups, which is consistent with where they showed that sex did not any statistical difference between two groups [16,17]. Mentioned in their study that socio-economic status has direct implication on the use of staplers for anastomosis as to

the nutritional status upon anastomosis and wound healing. In this study it was observed that the mean monthly income was 24467±5581.6 TK in stapled and 20100±4212.9 TK in hand-sewn. The mean monthly income was significantly ($p<0.05$) higher in Stapled group. All 30 (100.0%) patients had normal nutritional status in stapled group and 30(100.0%) in hand-sewn group. Study observed that the socio-economic status and nutritional status did not showed any statistical ($p>0.05$) difference between two groups [18].

Mentioned in their study that the increased number of anterior resection enabled the stratification of the procedure into 'high' (>10 cm), 'low' (>6 - 10 cm), and 'ultralow' (within 3 – 6 cm) types on the basis of distance of the lower limit of lesion from anal verge. In this study it was observed that in this study it was observed that all (100%) patients had High (>10 cm) anterior resection in stapled group and hand-sewn group [19]. Study observed in stapled group 91.7% patients underwent anterior resection of which 25.0% for high, 45.8% for low and 20.8% for ultralow type. In hand-sewn group 63.5% patients underwent anterior resection of which 19.2% for high, 19.2% for low and 25.0% for ultra-low type. Statistical test did not show any significant difference ($p>0.05$). Deep dissection for low and ultra-low anterior resection with or without intersphincteric intervention and prolonged intraoperative anal retraction are potential factors for nerve and sphincteric muscle injury [20]. In this study it was observed that Duration of operative time was >90min in almost three fourth 22(73.3%) case of stapled group where as it was >90 min in 30(100%) cases of Hand sewn group. The mean was 111.33±16.97 min in stapled group and 149.33±8.68 min in hand-sewn group. The mean Duration of operation was significantly ($p<0.05$) prolonged in hand-swenn group. Study also found that the mean Duration of the operation was significantly longer in Hand- sewn group compared to Stapled group. Similar observations were also observed by [21,22].

In this study it was observed that anastomotic time was ≤30 min in 100% (30) case in stapled group where as it was <30 min in 14(46.7%) case of hand-sewn group and 16(53.3%) patients needed >30 min in Hand sewn group. The mean was 20.07±2.27 min in stapled group and 31.53±2.94 min in hand-sewn group. The mean anastomosis time was significantly ($p<0.05$) higher in Hand-sewn group. Found in their study that in stapler anastomosis group mean time taken to perform anastomosis was 11.80±2.44 minutes whereas in hand-sewn anastomosis group mean time taken to perform anastomosis was 17.80±2.53 minutes. Stapler anastomosis takes less time than Hand sewn anastomosis [23]. And this is similar to study that shown a significant reduction in the anastomotic times in the stapled group and also similar to Hori *et al.*, (2004) study conducted in Japan which demonstrated that the anastomosis time is less in stapler group (14 mins) than in Hand sewn group

(25 mins). Study found that the mean anastomotic time was 9.0±1.9 minutes and 19.7±12.2 minutes ($p<0.001$) in favor of the stapling group. Similar observations also observed by.

In this present it was observed that all (100.0%) patients had ileostomy stomal site in both groups, which is comparable with Ramage *et al.*, (2018), In this study it was observed that 29 (96.7%) of patients belonged to postoperative hospital stay was >7 days in stapled group and 30 (100.0%) in hand-sewn group. The mean was 10.17±1.93 days in stapled group and 13.57±2.92 days in hand-sewn group. The mean Duration of postoperative hospital stay was significantly ($p<0.05$) elevated in Hand-sewn group. Similarly, study also observed that mean Duration of postoperative hospital stay was significantly ($p<0.05$) higher in Hand- sewn group. This can be partially explained by the fact that most infections in the Hand--sewn group were treated by means of wound packing and frequent gauze dressing. Similar observations regarding the Duration of hospital stay were also observed [24]. About the early postoperative complications in this current it was observed that per rectal bleeding from an anastomotic line had developed in 2(6.6) % patients in Hand sewn groups [25]. Two 6.7% patients had wound dehiscence in stapled group and 5(16.7%) in hand-sewn group. Five (16.3%) patients had fever in stapled group and 14(46.7%) in hand-sewn group. Four (13.3%) patients had wound infection in stapled group and 10(33.3%) in hand-sewn group. 3 (10) % patient has clinical anastomotic leakage in hand-sewn group. Overall early postoperative complications were comparatively elevated in Hand-swenn group.

But the wound infection was significantly ($p<0.05$) higher in Hand-sewn group. Study reported that there is no significant difference in leakage after surgery between two groups. The two patient groups did not differ significantly with regard to wound infections observed by study observed that all superficial minor infection were treated successfully by conservative measures in the form of drainage, frequent dressings and proper antibiotics [26]. In study, two patients in each group had anastomotic line bleeding detected intra-operatively and controlled safely by under-running sutures. No major wound infections were detected post-operatively, ileus was observed in 8.0% patients and all were managed conservatively by the use of nasogastric decompression and correction of electrolyte imbalances [27, 28]. Study observed that the hemorrhage from anastomotic line, anastomotic leakage, ileus/obstruction and wound dehiscence were much less in stapled group though not statistically significant ($p>0.05$).

In their study, 4.2% patients of stapled group and 5.8% patients of Hand- sewn group had hemorrhage from anastomotic line. All were from anastomosis reachable per-anum. One of stapled group needed 'over and over' suturing and others were controlled by packing and antibiotics ($p>0.05$). Most of this complication

disappeared with time but 2 of each group were associated with leakage and wound complication and were accordingly treated by reoperation. Almost equal number 27.1% and 23.1% of patients had wound infection which was much more than that of study. Need of re-operation here in both patient groups was not taken into account in the study. The use of stapler in distal rectal resection and anastomosis encourages sphincter preservation and holds the drive of colorectal surgeons in favor of using this device [29-31]. Multi-center studies showed leak rate from 5% to 30%. Though there was increased radiological evidence of leak in conventional hand-sewn anastomosis in many studies its avoidance here was due to deficit of set-up. Study revealed comparable clinical leak rate of 8.3% in stapled and 13.5% in hand-sewn groups ($p>0.05$). Reviewed two prospective database of colorectal surgeons and showed overall leak rate of 2.7%. Meta-analysis by showed clinical leak of 7.1% and 6.33% in stapled and Hand sewn group respectively, which was not significant.

CONCLUSION

Duration of operative time, anastomosis time and postoperative hospital stay were significantly higher in the Hand-sewn group. Early postoperative complications were comparatively higher in hand-sewn group. So, considering of doing this study in user perspective, time requirement and postoperative complications, stapling technique could be appeared to be safer and superior to Hand sewn anastomosis among the anterior resection patients in RMCH.

Recommendations

- Further studies can be undertaken by including larger number of patients.
- Stapler technique could reduce the morbidity and mortalities among such anterior resection patients.

Acknowledgment

I extend heartfelt gratitude to the Almighty for His sustaining strength and guidance. I deeply appreciate the invaluable support and guidance provided by Prof. Dr. Md. Habibullah Sarkar, and the kind cooperation of Asso. Prof. Dr. Md. Ariful Alam. I am thankful for the insightful advice and constructive criticism from Prof. Dr. Md. Nowshad Ali. I am also grateful to all the students and medical officers at the Department of Surgery, RMCH, for their unwavering cooperation and support throughout this journey.

Funding: No funding sources

Conflict of interest: None declared

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