Original Article

Comparison of Stapled vs. Hand-Sewn Anastomosis: A Prospective Randomized Controlled Trial

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ABSTRACT

Background: Colorectal cancer is the third most commonly diagnosed cancer and the second leading cause of cancer-related mortality worldwide. For patients undergoing colorectal surgery, anastomotic methods are essential. Although the data for comparable findings between the two techniques is consistent for different outcomes, they will likely be very valuable in their application. Thus, the study aimed to compare the clinical disparities between hand-sewn and stapled anastomosis in colorectal surgery.

Methods: This single-blinded randomized trial was conducted from July 2023 to September 2024 at Allama Iqbal Teaching Hospital, Dera Ghazi Khan, Punjab, Pakistan. One hundred fourteen patients undergoing elective colorectal surgery were randomly assigned to Group-A, who hand-sewn anastomosis, and Group-B, who received stapled anastomosis using a computer-generated random number sequence. Outcomes included post-operative time, surgical site infection and length of hospital stay. Data was analyzed using intention-to-treat analysis, and outcomes were compared using the chi-square test.

Results: Mean operating time was significantly more excellent in the Group-A (96.0 ± 9.2 minutes) than in the Group-B (82.5±8.5 minutes, p<0.001). The duration of hospital stay was significantly low in group B, who received stapler anastomosis, compared to Group-A, who received hand-sewn anastomosis (12.12±1.21 vs 14.01±1.32, p<0.01), respectively. Early surgical complications, including hematoma and wound infection, were rare.

Conclusion: Stapled and hand-sewn anastomoses demonstrated comparable rates of anastomotic leaks and surgical site infections. However, stapled anastomosis was associated with a reduced operative time. Both methods are considered adequate in colorectal surgery, with the choice often influenced by the surgeon's preference and specific patient-related factors.

Keywords: Colorectal surgery, Hand-sewn anastomosis, Randomized controlled trial, Stapled anastomosis, Surgical outcomes.

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INTRODUCTION

In the past few decades, colorectal surgery has changed dramatically regarding techniques and outcomes[1]. Anastomosis is an integral part of these procedures, which guarantees continuity of the gastrointestinal tract after resection[2]. Anastomosis technically means joining two parts of the bowel together, and the method of performing anastomosis directly affects the surgical outcome, recovery, and quality of life for the patient[3-4]. Traditionally, anastomoses were hand-sewn on the operating table, which required careful suturing done by the surgeon[5]. On the other hand, mechanical devices for stapling introduce a new picture in surgery because of the time-effectiveness and uniformity they provide[6].

Nevertheless, the superiority of stapled versus hand-sewn anastomosis has not been fully settled, requiring more prospective randomized investigations. Colorectal cancer and other diseases that warrant surgical bowel resections are much burdening to the world in morbidity and mortality. At present, it is reported that colorectal cancer is the third most commonly diagnosed cancer and the second leading cause of cancer-related mortality worldwide[7]. Early detection and adjuvant therapies have contributed to improving survival; however, resection remains the gold standard in treatment for those with potentially resectable colorectal cancer. With the increased

numbers, optimizing surgical techniques, including anastomosis techniques, becomes a priority in improving patient output.

By using a mechanical tool to make consistent and firm connections between bowel segments, the stapled anastomosis may cut down on the operating time and unpredictability that come with hand suturing. On the other hand, hand-sewn anastomosis gives the surgeon more control over the procedure because it depends on their ability to stitch the gut ends together manually[8-9]. Each technique's proponents make a case for its benefits; stapled anastomosis is praised for its speed and uniformity, while hand-sewn anastomosis is recommended in situations that call for accuracy and customization, including small bowel sizes or delicate tissues[10]. There is a lot of research and debate surrounding the results of these two methods. Anastomotic leakage rates, post-operative complications, operational time, cost-effectiveness, and long-term functional results are critical comparison parameters[11-12]. A serious complication, such as anastomotic leakage, may result in peritonitis, sepsis, and death. Research has yielded varying results, with some indicating low leakage rates in stapled anastomoses and some showing no significant difference[13]. Post-operative complications, including stricture formation, infection, and bowel obstruction, also complicate the comparison of methods[14].

Operative time and cost are essential factors that impact the selection of an anastomosis technique[15]. Stapled anastomosis typically reduces operative time due to the efficiency of stapling devices, which is particularly advantageous in lengthy or complex surgeries. However, the expense of disposable staplers can be considerably higher than sutures, raising concerns about economic viability, especially in resource-constrained settings. In contrast, hand-sewn anastomosis, though more time-intensive, provides a cost-effective option and eliminates the need for specialized equipment[16].

Colorectal surgery continues to evolve, driven by technological innovations and growing evidence from clinical research. Although randomized controlled trials (RCTs) have offered valuable insights, inconsistencies in outcome measures have resulted in conflicting conclusions about whether stapled or hand-sewn anastomosis is superior. Consequently, many surgeons rely on personal experience and institutional guidelines rather than conclusive evidence when choosing a technique. This prospective randomized trial bridges this gap by directly comparing stapled and hand-sewn anastomosis methods in colorectal surgery.

METHODOLOGY

This single-blinded randomized experiment was carried out at Allama Iqbal Teaching Hospital, a tertiary care hospital at Dera Ghazi Khan, Punjab, Pakistan with a high volume of colorectal procedures, over fourteen months from July 2023 to September 2024. All patients provided written informed consent before being enrolled in the trial.

Sample Size and Study Population

A sample of 114 patients was calculated with a mean difference of 4.77, a confidence interval of 95% and a level of significance set at 5%. Inclusion criteria included patients aged 18 years or older, diagnosed with colorectal pathology requiring surgical resection, and deemed fit for surgery based on preoperative assessment.

Exclusion criteria included emergency surgeries, prior radiation to the pelvis, or abdominal surgeries.

Randomization and Allocation

Participants were randomly allocated to one of two groups: Group-A (n=57) received hand-sewn anastomosis, and Group-B (n=57) received stapled anastomosis.

Randomization was done using a computer-generated random number sequence and group allocation concealed in sequentially numbered, opaque envelopes. The operating surgeon only revealed the allocation following patient preparation in the operating room. Follow-up and postoperative assessments of patients were done non-consecutively and independent of the intervention, with blinding of physicians assessing those outcomes to the intervention.

Surgical Technique

The surgeons experienced in colorectal surgery performed all surgeries under standardized

protocols. General anaesthesia was used for the procedure, and the patient was in the supine position. The skin was prepared, and then sterile draping was used. An incision was made around the ileostomy, approximately 1 to 2 mm from its lateral edge, to detach it from the abdominal wall. The following step was to dissect the subcutaneous tissue to expose the fascial layer. The intestine was mobilized carefully from the surrounding tissues and fascia to access the intraperitoneal cavity.

- ***Group-A: Hand-sewn Anastomosis***
  In this approach, the bowel ends were manually sutured end-to-end using a two-layer technique. The outer seromuscular layer was closed with interrupted non-absorbable sutures, while the inner mucosal layer was joined using absorbable sutures. Alternatively, depending on the surgeon's preference, a single-layer anastomosis was performed using continuous or interrupted absorbable sutures. Anastomotic patency was verified, and additional reinforcement sutures were applied if necessary.

- ***Group-B: Stapled Anastomosis***
  The anastomosis was done with the diseased bowel segment removed and both ends aligned. The anastomosis technique required either a circular or linear stapler, depending on the location and type of anastomosis. The ends of the bowel were dual stapled while excising redundant tissue during the operation.

Post-Operative Care

Patients were transferred to the surgical ward after the procedure, where they were monitored with a nasogastric (NG) tube. Following the first gas passage, oral feeding began. Starting with liquids, feeding progressed to a soft diet and, if well tolerated, to a regular diet. The timing of gas passage, faeces, and food initiation were among the recorded post-operative and surgical details.

Outcome Measures

The study's primary outcome was the incidence of anastomotic leakage, defined as clinical or radiological evidence of leakage within 30 days post-surgery. Secondary outcomes included surgical site infection, operative time, and length of hospital stay. Surgical site infections were classified as superficial or deep based on CDC criteria. Operative time was recorded from the first incision to skin closure.

Data Collection

Demographic and clinical data were collected preoperatively, including age, gender, comorbidities, and indication for surgery. Intraoperative details such as the type of surgery, anastomosis technique, and any complications were documented.

Post-operative outcomes were assessed through clinical examination and imaging, as necessary. All data were recorded in a standardized case report form.

Statistical Analysis

Data was analyzed based on intention-to-treat principles, whereby all randomized participants were included in their assigned groups for analysis. Continuous variables (operative time and length of hospital stay) were expressed as mean and standard deviation and compared using independent t-tests. Categorical variables (incidence of anastomotic leakage and surgical site infections) were expressed as frequencies and percentages and analyzed using chi-square or Fisher's exact tests. A p-value <0.05 was considered statistically significant.

Ethical Considerations

The study adhered to the principles of the Declaration of Helsinki. Ethical approval was obtained from the hospital's review board, and patient confidentiality was maintained throughout the study. Adverse events were monitored and managed according to hospital protocols.

RESULTS

Table-1 shows the demographic and preoperative laboratory data of 114 patients divided into Group-A, hand-sewn anastomosis (n = 57) and Group-B, Stapled anastomosis (n = 57). The mean age of patients was 55.92±12.34 years, and there were no significant differences between the two groups. Most patients were male, 62.28%, and there were more males in the stapled anastomosis group (71.92%) than in the hand-sewn group (52.63%). The mean BMI of Group-B was slightly higher than that of Group-A, recording a BMI of 29.04±2.86

kg/m² and 26.81 ± 4.21 kg/m², respectively; however, this difference was not statistically significant (p = 0.06). Preoperative laboratory values for haemoglobin, albumin, and WBC count showed no significant difference between the groups. The haemoglobin levels of Group-B were slightly higher (12.81±1.31 g/L) than those of Group-A (11.21±0.99 g/L, p = 0.56). Thus, it can be assumed that both groups were comparable in terms of baseline characteristics in terms of surgery.

Table-1 Patients Demographic and Pre-Operative Data

Variable	Total (n = 114)	Group A (n = 57)	Group B (n = 57)	p-value
Age (years) *Mean± SD*	55.92±12.34	54.96±11.23	57.23±10.68	0.083
Gender, n (%)				
Male	71 (62.28%)	30 (52.63%)	41 (71.92%)	
Female	43 (37.71%)	27 (47.36%)	16 (28.07%)	
BMI (kg/m^2) *Mean± SD*	28.36±3.23	26.81±4.21	29.04 ± 2.86	0.06
Pre-operation Laboratory Data *Mean± SD*				
Hemoglobin (g/L)	12.31±1.55	11.21±0.99	12.81±1.31	0.56
Albumin (g/L)	3.46±0.32	3.12±0.12	4.11±0.86	0.23
WBC (× 10^9/L)	5.31±1.64	5.35 ±1.81	5.23 ±1.63	0.072

Group-A; Hand-sewn anastomosis, Group-B; Stapled anastomosis, WBC; White blood cell, SD; Standard deviation

Accidental partial injury occurred in 7.0% of cases, with a similar distribution between the groups. Mean operating time was significantly greater in the group A (96±9.2 minutes) than in the Group-B (82.5±8.5 minutes, p<0.001). The number of gauze used was also significantly higher in Group-A (p<0.001). The length of hospital stay was significantly lower in Group-B, who received stapler anastomosis, compared to Group-A, who received hand-sewn anastomosis (12.12±1.21 vs. 14.01±1.32, p<0.01), respectively. The stapled anastomosis group had a more significant number of medical complications, although they were not statistically significant. Early surgical complications included hematoma and wound infection and were rare (Table-2).

Table-2 Intraoperative and Post-operative Characteristics of Patients Categorized by Surgical Approach

Variable	Total (n = 114)	Group A (n = 57)	Group B (n = 57)	p-value
Accidental Partial Damage *n (%)*	8 (7%)	3 (5.3%)	5 (8.8%)	0.601
Operation Duration (Minutes) *Mean± SD*	87.50±10.5	96±9.2	82.5±8.5	<0.001*
Number of Gauzes *Mean± SD*	3.2±0.8	3.3±0.9	3.5±0.7	<0.001*
Medical Complication *n (%)*				
Hypokalemia	20 (17.5%)	8 (14%)	12 (21.1%)	0.090
Hyponatremia	5 (4.4%)	3 (5.3%)	2 (3.5%)	

Both	4 (3.5%)	2 (3.5%)	2 (3.5%)	
None	85 (74.6%)	44 (77.2%)	41 (71.9%)	
Length of Hospital Stay (Days) *n (%)*	12.91±3.2	14.01±1.32	12.12±1.21	<0.05
Early Surgical Complications *n (%)*				
Hematoma	2 (1.8%)	1 (1.8%)	1 (1.8%)	0.315
Wound infection	3 (2.6%)	2 (3.5%)	1 (1.8%)	0.097

Group-A; Hand-sewn anastomosis, Group-B; Stapled anastomosis, WBC; White blood cell, SD; Standard deviation

DISCUSSION

This study compares the outcomes of hand-sewn and stapled anastomosis techniques in elective colorectal surgery, providing valuable insights into their respective advantages and limitations. The findings indicate that both methods are safe and effective, with some notable differences in secondary outcomes. The incidence of anastomotic leakage, a critical complication, was slightly lower in the hand-sewn group (5.3%) compared to the stapled group (8.8%). However, this difference was not statistically significant (p = 0.601), aligning with similar studies that report comparable leakage rates between the two techniques, suggesting equivalent safety profiles for anastomotic integrity[17]. Surgical site infection rates were also similar (1.8 % for stapled vs. 3.5% for hand-sewn; p = 0.097), consistent with previous literature emphasizing the importance of standardized infection control practices over the choice of technique. One of the most significant findings was the reduced operative time associated with stapled anastomosis (82.5 ± 8.5 minutes) compared to hand-sewn anastomosis (96.0±9.2 minutes, p<0.001), a difference widely reported in the literature and potentially beneficial in high-volume surgical centres for reducing operating room costs and surgeon fatigue[18]. While both techniques demonstrated comparable safety and efficacy, the shorter operative time with stapled anastomosis may offer a strategic advantage in specific contexts. However, cost, surgeon expertise, and patient-specific anatomical variations remain essential. Some studies[19-20] have highlighted the higher cost of stapling devices as a potential limitation, particularly in resource-constrained settings. Overall, while the clinical outcomes were essentially equivalent, the efficiency of stapled anastomosis positions it as a preferred choice where operative time is a critical consideration, contributing to optimizing surgical practices and improving patient outcomes in colorectal surgery. Strengths of this study include its prospective randomized design, outcome measures, and comprehensive comparison of primary and secondary outcomes. Nonetheless, limitations such as the single-centre setting, relatively small sample size, and absence of long-term follow-up constrain the generalizability of the findings. Future research should consider multi-centre trials involving larger cohorts and longer follow-ups to validate these results and investigate other factors that affect surgical outcomes. Ultimately, the type of anastomosis performed, either stapled or hand-sewn, should depend on particular patient attributes, the experience of the surgeon, and the medical resources available for a specific institution, focusing only on what is best for the patient in terms of care and surgical efficiency.

CONCLUSION

Hand-sewn and stapled anastomosis techniques are equivalent in safety and efficacy in colorectal surgery, but some particular advantages favour the stapled method. The lesser operative time in the stapled group underlines the case for usage in high-volume settings, which could make surgery more efficient and reduce costs. Both techniques led to similar rates of anastomotic leakage and surgical site infections, confirming their safety. However, the cost of stapling devices and specialized skill requirements might keep them off the mainstream in resource-poor settings.

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None.

Author Contributions
Asif Nadeem was responsible for conceptualization, study design, and manuscript drafting. **Ghulam Hassan** handled data collection and analysis, while **Muhammad Ali Lund** contributed to methodology and statistical analysis. **Malik Nazar Farid** conducted the literature review and assisted in manuscript editing. **Sana Iqbal** played a key role in data interpretation and critical revision. **Nadeem Shahzad** provided supervision and gave final approval for the manuscript.

Ethical Approval
This study received approval from the Institutional Ethical Review Committee (Ref No: AITH/2023/024/Sc.) of Allama Iqbal Teaching Hospital, Dera Ghazi Khan, Punjab, Pakistan.

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None.

Conflict of Interests
None.

REFERENCES

1. Toiyama Y, Kusunoki M. Changes in surgical therapies for rectal cancer over the past 100 years: A review. Annals of gastroenterological surgery. 2020 Jul;4(4):331-42. **DOI:** https://doi.org/10.1002/ags3.12342
2. Michel AS, Bonovas T, Raine A, Spinelli J, Warusavitarne A, Armuzzi O, et al., European C. Colitis Organisation [ECCO], ECCO Guidelines on Therapeutics in Crohn's Disease: Surgical Treatment, Journal of Crohn's and Colitis. 2020;14(2):155–68. **DOI:** https://doi.org/10.1093/ecco-jcc/jjz187
3. Vargas HD, Margolin DA. Anastomotic construction. The ASCRS Textbook of Colon and Rectal Surgery. 2022:157-87.
4. Man J, Hrabe J. Anastomotic Technique—How to Optimize Success and Minimize Leak Rates. Clinics in colon and rectal surgery. 2021 Nov;34(06):371-8. **DOI:** https://doi.org/10.1055/s-0041-1735267
5. Triantafyllou T, Sgromo B. The evolution of anastomotic techniques in robot-assisted Ivor Lewis esophagectomy. Mini-invasive Surgery. 2023 Sep 11;7:N-A. **DOI:** https://doi.org/10.20517/2574-1225.2023.48
6. Ghosh S, More N, Kapusetti G. Surgical staples: Current state-of-the-art and future prospective. Medicine in Novel Technology and Devices. 2022 Dec 1;16:100166. **DOI:** https://doi.org/10.1016/j.medntd.2022.100166
7. Baidoun F, Elshiwy K, Elkeraie Y, Merjaneh Z, Khoudari G, Sarmini MT, Gad M, Al-Husseini M, Saad A. Colorectal cancer epidemiology: recent trends and impact on outcomes. Current drug targets. 2021 Jul 1;22(9):998-1009. **DOI:** https://doi.org/10.2174/1389450121999201117115717
8. Gueye ML, Thiam O. Bowel Anastomoses: Manual or Mechanical. Abdominal Surgery: A Brief Overview. 2021 Sep 1:27.
9. Raff L, Reid T. Small Bowel Resection and Anastomosis. InIllustrative Handbook of General Surgery 2024 Sep 25; 273-283. Cham: Springer Nature Switzerland. **DOI:** https://doi.org/10.1007/978-3-031-63878-7_22
10. Varela C, Nassr M, Razak A, Kim NK. Double-layered hand-sewn anastomosis: a valuable resource for the colorectal surgeon. Annals of Coloproctology. 2022 Jun;38(3):271. **DOI:** https://doi.org/10.3393/ac.2021.00990.0141
11. Feng JS, Li JY, Yang Z, Chen XY, Mo JJ, Li SH. Stapled side-to-side anastomosis might be benefit in intestinal resection for Crohn's disease: a systematic review and network meta-analysis. Med (Baltim). 2018;97(15):e0315. **DOI:** https://doi.org/10.1097/MD.0000000000010315. PMID: 29642162; PMCID: PMC5908623.
12. He X, Chen Z, Huang J. Etal. Stapled side-to-side anastomosis might be better than handsewn end-to-end anastomosis in ileocolic resection for Crohn's disease: a meta-analysis. Dig Dis Sci. 2014;59:1544–51.
13. Goulder F. Bowel anastomoses: the theory, the practice and the evidence base. World journal of gastrointestinal surgery. 2012 Sep 9;4(9):208. **DOI:** https://doi.org/10.4240/wjgs.v4.i9.208
14. Kshirsagar VV, Himashree MP. A Comparative Study of Hand-Sewn and Stapled Anastomosis in Gastrointestinal Surgeries. Cureus. 2024 Oct 11;16(10). **DOI:** https://doi.org/10.7759/cureus.71264
15. Steger J, Jell A, Ficht S, Ostler D, Eblenkamp M, Mela P, Wilhelm D. Systematic review and meta-analysis on colorectal anastomotic techniques. Therapeutics and Clinical Risk Management. 2022 May 4:523-39. **DOI:** https://doi.org/10.2147/TCRM.S335102
16. Ghafoor MT, Sabir S, Tumrani R, Kauser N, Haider SS. Outcome Comparison of Stapled Versus Hand-Sewn Anastomosis in Elective Gastrointestinal Surgeries: Stapled Versus Hand-Sewn Anastomosis in Elective Gastrointestinal Surgeries. Pakistan Journal of Health Sciences. 2022 Sep 30:165-70. **DOI:** https://doi.org/10.54393/pjhs.v3i04.154
17. Mullen KM, Regier PJ, Fox-Alvarez WA, Case JB, Ellison GW, Colee J. Evaluation of intraoperative leak testing of small intestinal anastomoses performed by hand-sewn and stapled techniques in dogs: 131 cases (2008–2019). Journal of the American Veterinary Medical Association. 2021 May 1;258(9):991-8. **DOI:** https://doi.org/10.2460/javma.258.9.991
18. Schineis C, Fenzl T, Aschenbrenner K, Lobbes L, Stroux A, Weixler B, Beyer K, Kamphues C, Kreis ME, Lauscher JC. Stapled intestinal anastomoses are more cost effective than hand-sewn anastomoses in a diagnosis related group system. The Surgeon. 2021 Dec 1;19(6):321-8. **DOI:** https://doi.org/10.1016/j.surge.2020.09.002
19. Peltrini R, Greco PA, Manfreda A, Luglio G, Bucci L. Kono-S anastomosis after intestinal resection for Crohn's disease. Updates Surg. 2020;72(2):335–40. **DOI:** https://doi.org/10.1007/s13304-019-00700-w
20. Williams H, Alabbadi S, Khaitov S, Egorova N, Greenstein A. Association of hospital volume with postoperative outcomes in Crohn's disease. Colorectal Dis. 2023;25(4):688–94. **DOI:** https://doi.org/10.1111/codi.16421