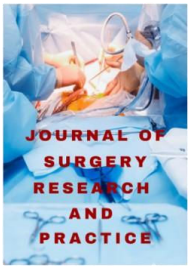

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Research Article

Single-Layer Versus Double-Layer Hand-Sewn Intestinal Anastomosis: A Prospective Randomized Study in a Resource-Limited Setting

Abin Biju Varghese[1], Sailesh I S Kumar[2*], Raja Vel Shantharam[3], Sivsankar Sivanandam[4], Ashok Nimmakanty Ramadas[2], Ashfaq Sulaiman Arif Abdul Rahuman[2]

[1]Department of General Surgery, Government Kilpauk Medical College, Chennai, India

[2]Institute of General Surgery, Madras Medical College, Rajiv Gandhi Government General Hospital, Chennai, India

[3]Assistant Professor, Community Medicine, Sri Lalithambigai Medical College and Hospital, Dr. MGR Educational and Research Institute, Chennai, India

[4]Government Erode Medical College, Erode, India

***Correspondence author:** Sailesh I S Kumar, MBBS, Institute of General Surgery, Madras Medical College, Rajiv Gandhi Government General Hospital, Chennai, India-600003; Email: Sailesh.isk@gmail.com

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Abstract

Background: The choice of suturing technique for intestinal anastomosis remains a critical consideration in bowel surgery. Evidence comparing single-layer and double-layer techniques in terms of operative efficiency, post-operative recovery and resource utilization is limited, particularly in emergency surgical settings. This study aimed to compare clinical outcomes and cost-effectiveness of single-layer versus double-layer anastomosis in adult patients undergoing bowel resection.

Methods: A prospective, single-center randomized controlled trial was conducted from June to November 2024. Adults aged 20-59 years undergoing small or large bowel resection with primary hand-sewn anastomosis were randomized to receive either single-layer or double-layer closure (31 patients per group). The primary outcome was time to return of bowel sounds. Secondary outcomes included anastomosis time, time to first bowel movement, length of hospital stay, post-operative complications and cost-effectiveness. Data were analyzed on an intention-to-treat basis using standard statistical tests.

Results: Baseline characteristics were comparable between groups. Single-layer anastomosis required significantly less operative time (16.4 ± 3.3 vs 24.1 ± 3.3 minutes; P = 0.01). Post-operative recovery was faster in the single-layer group, with earlier return of bowel sounds (2.3 ± 0.9 vs 3.4 ± 1.1 days; P = 0.01), earlier first bowel movement (4.2 ± 1.1 vs 5.5 ± 1.2 days; P = 0.01) and shorter hospital stay (5.9 ± 1.5 vs 7.3 ± 1.4 days; P = 0.01). Post-operative complications occurred in 9.7% of single-layer patients and 22.6% of double-layer patients, without a statistically significant difference. One anastomotic leak occurred in the double-layer group, with none in the single-layer group. Although procedural costs were slightly higher per patient in the single-layer group, the technique demonstrated favourable cost-effectiveness due to reduced complications and shorter hospitalization.

Conclusion: Single-layer intestinal anastomosis is a safe and efficient alternative to double-layer closure, offering significant advantages in operative time and post-operative recovery without increasing complication rates. These findings support its use in high-volume and resource-constrained surgical settings.

Keywords: Intestinal Anastomosis; Single-Layer Closure; Double-Layer Closure; Postoperative Recovery; Randomized Controlled Trial

Introduction

Intestinal anastomosis is a fundamental procedure in gastrointestinal surgery and is routinely performed following bowel resection for a wide range of conditions, including malignancies, inflammatory diseases, trauma, congenital anomalies and

infective pathologies [1]. Depending on the site of resection, anastomosis may be entero-enteric, entero-colic or colo-colic, with the primary aim of restoring bowel continuity while ensuring optimal healing and minimal complications [2]. Globally, intestinal diseases requiring anastomosis constitute a major surgical burden. An estimated 1.93 million new cases of colorectal cancer were diagnosed globally in 2020, with approximately 0.94 million deaths attributed to the disease worldwide [3]. Emergency conditions such as intestinal obstruction, perforation and traumatic bowel injuries reported in nearly 10-15% of abdominal trauma cases frequently necessitate bowel repair or resection [4,5].

In India, this burden is amplified by the coexistence of non-communicable and infectious diseases. In India, colorectal cancer is among the most frequently diagnosed malignancies, with approximately 40,430 new cases in men and 24,433 cases in women in 2022. The age-adjusted incidence is higher in males (5.7 per 100,000) than in females (3.4 per 100,000). Overall, colorectal cancer contributes to more than 4% of the country's total cancer cases and related deaths [6]. While abdominal tuberculosis, accounting for 6-14% of extrapulmonary tuberculosis, remains a major cause of intestinal strictures, obstruction and perforation. Intestinal perforation due to infective causes continues to be a common surgical emergency, making intestinal resection and anastomosis one of the most frequently performed procedures in Indian surgical practice [7]. Despite advances in technique, anastomotic failure remains a serious complication, with reported rates ranging from 1.4% to 2.1%, influenced by patient-related factors, disease severity and surgical technique. Anastomotic failure is associated with increased morbidity, prolonged hospital stays, higher costs and increased mortality [8].

The optimal technique for intestinal anastomosis remains debated. Double-layer anastomosis traditionally involves an inner transmural layer and an outer seromuscular layer but may be associated with mucosal inversion and compromised submucosal vascularity [9]. Single-layer anastomosis has gained popularity due to reduced operative time, lower cost and potentially less tissue trauma without increasing leakage risk [10]. In light of this information, there is a paucity of evidence comparing single- versus double-layer anastomotic techniques, particularly in resource-limited settings where emergency surgeries for infective perforations and malignancies constitute a significant burden. This provides the impetus for a prospective interventional study designed to evaluate the efficacy (anastomotic leak rates, healing time), safety (postoperative complications, mortality) and cost-effectiveness (operative time, suture material costs) of single- versus double-layer intestinal anastomosis in adult patients undergoing resection for perforation, stricture or obstruction due to colorectal cancer or abdominal tuberculosis at a tertiary care center in India.

Materials and Methods

Study Design

We conducted a single-center randomized controlled trial comparing single-layer and double-layer hand-sewn intestinal anastomosis in adults undergoing small or large bowel resection. Patients were allocated 1:1 with no mid-study changes to the protocol. The study was registered prospectively at CTRI [11].

Study Setting and Participants

The trial ran from June to November 2024 in the General Surgery Department at Government Kilpauk Medical College Hospital, Chennai. We included adults aged 20-59 years scheduled for intestinal resection with primary hand-sewn anastomosis (ileoileal, ileocolic or colocolic) after obtaining written informed consent. We excluded cases involving stapled anastomosis, gross contamination or fecal peritonitis, hemodynamic instability, coagulopathy or immunosuppression, prior abdominal radiotherapy or anastomoses proximal to jejunum or distal to sigmoid.

Sample Size Justification

Using data from Kar, et al., where time to bowel sounds was 3.1 ± 1.34 days (double-layer) vs 2.42 ± 1.11 days (single-layer), we calculated 31 patients per group (total 62) for 80% power and α=0.05, allowing for 10% dropout.

Randomization and Blinding

An independent statistician generated the randomization sequence using stratified blocks (age <40 vs ≥40 years; sex) with block size 4. Allocation was concealed in sequentially numbered sealed envelopes opened in the operating room. Patients were kept blinded postoperatively through standardized care. Independent assessors (surgeons not involved in the operation) were blinded to group; operating surgeons were not, due to technique differences.

Study Procedures

Senior surgeons (each with >50 prior cases) performed all operations under uniform conditions. Patients received preoperative optimization, including antibiotics (ceftriaxone 1g IV + metronidazole 500 mg IV). We resected diseased bowel at healthy margins (>5 cm) using staplers, ensured haemostasis, then performed anastomosis:

- For single-layer: continuous 3-0 Vicryl full-thickness (sparing mucosa), starting at the mesenteric border with 5 mm bites
- For double-layer: inner continuous transmural 3-0 Vicryl, plus outer interrupted 3-0 silk Lembert (4-6 mm seromuscular bites, wider mesenterically)
- We tested integrity with air leak under saline, avoiding excess tension. A blinded observer timed the anastomosis and noted suture use/costs. Postoperatively, we monitored daily for bowel sounds (primary outcome, by auscultation), flatus/stool, distension, wounds and leak signs. Suspected leaks prompted CT or ultrasound. Follow-up lasted until discharge (typically 7-14 days)

Outcomes

- Primary: days to return of bowel sounds
- Secondary: anastomosis time (min), first bowel movement (days), hospital stay (days), complications (Clavien-Dindo), cost-effectiveness (suture costs; cost per complication avoided)

Leak diagnosis required CT/ultrasound confirmation, feculent drain or reoperation.

Baseline variables: age, sex, Body Maas Index (BMI), haemoglobin, diabetes, indication (e.g., perforation, malignancy), anastomosis type/site.

Statistical Analysis

We used Stata 16.0 for intention-to-treat analysis. Continuous data (mean ± SD or median/IQR) were compared by t-test or Mann-Whitney U (after Shapiro-Wilk normality check). Categorical data (n, %) by χ^2 or Fisher's exact. Cost-effectiveness: total suture cost divided by complication-free patients. $p<0.05$ was significant (two-sided); no interim analyses.

Ethical Statement

Ethical clearance for the study was obtained from the Institutional Ethics Committee. The conduct of the research adhered to the principles outlined in the Declaration of Helsinki [12]. Prior to enrolment, all participants provided written informed consent after receiving clear information regarding the study objectives, potential risks and benefits and their rights as research participants. Confidentiality was ensured by anonymizing all study data in accordance with Indian Council of Medical Research (ICMR) guidelines. Any serious adverse events identified during the study period were promptly reported to the Data Safety Monitoring Board within 24 hours.

Results

A total of 62 patients were included in the analysis, with 31 patients in each group. The mean age of patients undergoing double-layer anastomosis was 40.0 ± 6.1 years, compared to 39.4 ± 5.7 years in the single-layer group, with no statistically significant difference (P = 0.68).

Sex distribution was comparable between the two groups, with males constituting 64.5% of the double-layer group and 67.7% of the single-layer group (P = 0.79). Mean body mass index and haemoglobin levels were similar in both groups (P = 0.44 and P = 0.23, respectively). The prevalence of diabetes mellitus did not differ significantly between the groups (25.8% vs 22.6%; P = 0.77), indicating baseline clinical comparability (Table 1). Stoma closure was the most common indication for surgery in both groups, followed by trauma and inflammatory conditions. Malignancy-related resections and strangulated hernia accounted for a smaller proportion of cases. There was no significant difference in the distribution of surgical indications between the two groups (P = 0.84). Entero-enteric anastomosis was the most frequently performed anastomotic site in both groups, followed by entero-colic and colo-colic anastomoses, with a comparable distribution between groups (P = 0.90). The majority of anastomoses were performed using an end-to-end configuration in both groups, with no significant difference observed (P = 0.50) (Table 2). The mean time required to perform the anastomosis was significantly shorter in the single-layer group (16.4 ± 3.3 minutes) compared with the double-layer group (24.1 ± 3.3 minutes). This difference was statistically significant (P = 0.01), demonstrating a clear reduction in operative time with the single-layer technique (Table 3).

Post-operative recovery parameters favoured the single-layer anastomosis group. The return of bowel sounds occurred earlier in the single-layer group (2.3 ± 0.9 days) compared with the double-layer group (3.4 ± 1.1 days; P = 0.01).

Similarly, the mean post-operative day of first bowel movement was significantly earlier in the single-layer group (4.2 ± 1.1 days) than in the double-layer group (5.5 ± 1.2 days; P = 0.01). The duration of hospital stay was also significantly shorter in patients undergoing single-layer anastomosis (5.9 ± 1.5 days) compared with those undergoing double-layer anastomosis (7.3 ± 1.4 days; P = 0.01) (Table 4). Post-operative complications were observed in 22.6% of patients in the double-layer group and 9.7% of patients in the single-layer group. Although the complication rate was numerically higher in the double-layer group, the difference did not reach statistical significance (P = 0.15). One anastomotic leak occurred in the double-layer group, while no leaks were observed in the single-layer group (Table 5).

The mean cost per patient was lower in the double-layer group; however, when adjusted for outcomes, the cost per complication averted was marginally higher in the single-layer group. Despite this, single-layer anastomosis was associated with fewer complications and shorter hospital stay, suggesting favourable cost-effectiveness in terms of clinical recovery (Table 5).

Variable	Double-layer anastomosis (n = 31)	Single-layer anastomosis (n = 31)	P-value
Age (years), mean ± SD	40.0 ± 6.1	39.4 ± 5.7	0.68
Sex, n (%)			
Male	20 (64.5)	21 (67.7)	0.79
Female	11 (35.5)	10 (32.3)	
Body mass index (kg/m²), mean ± SD	25.8 ± 4.8	26.1 ± 4.1	0.44
Haemoglobin (g/dL), mean ± SD	11.5 ± 1.6	11.1 ± 1.3	0.23
Diabetes mellitus, n (%)	8 (25.8)	7 (22.6)	0.77

Table 1: Baseline demographic and clinical characteristics of patients undergoing double-layer versus single-layer intestinal anastomosis (n = 62).

Variable	Double-layer (n = 31)	Single-layer (n = 31)	P-value
Indication for surgery, n (%)			0.84†
Cancer (small/large intestine)	4 (12.9)	5 (16.1)	
Inflammatory conditions	6 (19.4)	5 (16.1)	
Stoma closure	12 (38.7)	11 (35.6)	
Strangulated hernia	2 (6.5)	1 (3.2)	
Trauma	7 (22.5)	9 (29.0)	
Site of anastomosis, n (%)			0.90†
Entero-enteric	22 (71.0)	23 (74.2)	
Entero-colic	6 (19.3)	6 (19.3)	
Colo-colic	3 (9.7)	2 (6.5)	
Type of anastomosis, n (%)			0.50†
End-to-end	30 (96.7)	29 (93.5)	
End-to-side	1 (3.3)	2 (6.5)	

Table 2: Comparison of indication for surgery and anastomotic characteristics between the two groups (n = 62).

Variable	Double-layer (n = 31)	Single-layer (n = 31)	P-value
Time taken for anastomosis (minutes), mean ± SD	24.1 ± 3.3	16.4 ± 3.3	0.01

Table 3: Comparison of operative time between double-layer and single-layer anastomosis.

Variable	Double-layer (n = 31)	Single-layer (n = 31)	P-value
Return of bowel sounds (days), mean ± SD	3.4 ± 1.1	2.3 ± 0.9	0.01
First bowel movement (days), mean ± SD	5.5 ± 1.2	4.2 ± 1.1	0.01
Length of hospital stay (days), mean ± SD	7.3 ± 1.4	5.9 ± 1.5	0.01

Table 4: Comparison of post-operative recovery outcomes between the two groups.

Variable	Double-layer (n = 31)	Single-layer (n = 31)	P-value
Any post-operative complication, n (%)	7 (22.6)	3 (9.7)	0.15†
Anastomotic leak, n (%)	1 (3.2)	0 (0)	—
Mean cost per patient (INR)	870	1040	—
Cost per complication averted (INR)	1011.6	1083.3	—

Table 5: Post-operative complications and cost-effectiveness comparison between the two groups.

Discussion

Intestinal anastomosis is a critical step in bowel surgery and even small technical differences can influence operative efficiency and post-operative recovery. In this prospective comparative study, single-layer anastomosis was associated with a clear reduction in operative time and a faster return of bowel function, while maintaining safety outcomes comparable to those of the double-layer technique.

Both study groups were similar in terms of age, sex distribution, haemoglobin levels and comorbidities such as diabetes mellitus. This comparability strengthens the inference that the observed differences in operative and post-operative outcomes were related primarily to the anastomotic technique rather than patient-related factors. Similar demographic balance has been noted in several prospective surgical studies evaluating bowel anastomosis, supporting the validity of comparative analyses in this context.

One of the most consistent findings in the present study was the shorter time required to construct a single-layer anastomosis. On average, single-layer suturing required substantially less time than double-layer closure. This observation aligns with clinical experience and has been echoed in earlier work. In a prospective study by Kar, et al., single-layer anastomosis required approximately 15-17 minutes, whereas double-layer closure took nearly 27 minutes [13]. Modi, et al., highlighted that prolonged operative time exceeding 90 minutes was observed predominantly in the double-layer group, affecting 20 patients, compared to only 4 patients in the single-layer group. This marked difference highlights the technical simplicity and time efficiency of the single-layer technique [14].

Faster post-operative recovery was another important advantage observed with single-layer anastomosis. Patients in this group experienced earlier return of bowel sounds and earlier passage of stools, which translated into a shorter hospital stay. Comparable patterns have been reported in the literature. Dhamnaskar, et al., observed that the first bowel movement occurred more than a day earlier in patients undergoing single-layer anastomosis. They underscored that Single-Layer Intestinal Anastomosis (SLIA) leads to significantly faster bowel function recovery compared to Double-Layer (DLIA), with first bowel movements occurring roughly 1 day earlier [15]. Burch, et al., observed a shorter duration of hospitalization among patients undergoing single-layer anastomosis, with a mean length of stay of 7.9 days, compared with 9.9 days in those who received double-layer closure [16]. These findings suggest that minimizing tissue handling and foreign material at the anastomotic site may facilitate more rapid restoration of gut motility.

With regard to safety, the present study did not demonstrate any increase in anastomotic leak or major post-operative complications with the single-layer technique. Leak rates were low in both groups and the difference was not statistically significant. This finding is consistent with several independent studies. Rajesh, et al., documented similar rates of anastomotic leakage with both techniques. Leakage occurred in 7.25% of patients following single-layer anastomosis and 9.23% of those undergoing double-layer repair, giving an overall incidence of 8.20%. The marginal difference between groups indicates that the single-layer approach does not carry an increased risk of leakage when compared with the traditional double-layer method. These observations reinforce the concept that a well-constructed single-layer anastomosis is not inherently weaker than a double-layer repair.

From an economic perspective, although the immediate cost of sutures may not differ substantially between techniques, the overall cost of care appears to favour single-layer anastomosis. Shorter operative time and reduced length of hospital stay contribute to lower overall expenditure. Garude, et al., demonstrated a clear cost advantage with the single-layer technique, reporting a significantly lower procedural expenditure of ₹298 for single-layer anastomosis compared with ₹390 for double-layer anastomosis [18].

Taken together, the findings of the present study and those reported in the literature suggest that single-layer intestinal anastomosis offers a pragmatic balance between efficiency and safety. Its advantages are particularly evident in emergency surgery and in settings where reducing operative time and hospital stay can have a meaningful impact on patient outcomes and healthcare resource utilization. This study does have limitations. The sample size limits the ability to detect differences in uncommon outcomes such as anastomotic leak and long-term complications such as stricture formation were not assessed. Larger, multicentre studies with extended follow-up would help clarify these aspects further.

Conclusion

Single-layer intestinal anastomosis is associated with shorter operative time and faster post-operative recovery, without compromising anastomotic safety. These findings support its use as a reliable and efficient alternative to double-layer anastomosis in adult intestinal surgery.

Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

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Data Availability Statement

Not applicable.

Ethical Statement

Ethical clearance for the study was obtained from the Institutional Ethics Committee. The conduct of the research adhered to the principles outlined in the Declaration of Helsinki [12]. Prior to enrolment, all participants provided written informed consent after receiving clear information regarding the study objectives, potential risks and benefits and their rights as research participants. Confidentiality was ensured by anonymizing all study data in accordance with Indian Council of Medical Research (ICMR) guidelines. Any serious adverse events identified during the study period were promptly reported to the Data Safety Monitoring Board within 24 hours.

Informed Consent Statement

Informed consent was obtained from the participant involved in this study.

Authors' Contributions

All authors contributed equally to this paper.

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