ORIGINAL RESEARCH

Single Layered Versus Double Layered Intestinal Anastomosis: A Randomized Controlled Trial

[1]Dr. Ashok Kumar Singh, [2]Dr. Chandranshu Kumar

[1,2]Assistant Professor, Department of General Surgery, Santosh Medical College & Hospital, Ghaziabad, NCR Delhi, India

Corresponding Author: Dr. Chandranshu Kumar
Assistant Professor, Department of General Surgery, Santosh Medical College & Hospital, Ghaziabad, NCR Delhi, India

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ABSTRACT

Background: Intestinal anastomosis is a critical surgical procedure performed to restore the continuity of the gastrointestinal tract after resection. This study aimed to compare the outcomes of single-layered versus double-layered intestinal anastomosis in terms of operative time, postoperative complications, hospital stay, readmission rates, and overall morbidity and mortality.**Material and Methods:** This randomized controlled trial was conducted at a tertiary care hospital after obtaining ethical approval. A total of 120 patients requiring intestinal anastomosis for various indications were randomly assigned into two groups: Group A (single-layered anastomosis, n=60) and Group B (double-layered anastomosis, n=60). Standardized anastomotic techniques were performed under general anesthesia. Postoperative monitoring included anastomotic leakage, wound infection, ileus, stricture formation, mortality, and hospital stay. Data were analyzed using SPSS, with statistical significance set at $p<0.05$.**Results:** The mean operative time was significantly lower in the single-layered anastomosis group (82.45 ± 12.56 minutes) compared to the double-layered group (96.78 ± 15.32 minutes, $p<0.001$). Postoperative complications, including anastomotic leakage (8.33% vs. 6.67%, p=0.72), wound infection (11.67% vs. 15.00%, p=0.59), ileus (10.00% vs. 13.33%, p=0.57), and mortality (1.67% vs. 3.33%, p=0.57), were comparable between the two groups. The mean hospital stay was slightly shorter in the single-layered group (7.45 ± 2.12 days) than in the double-layered group (8.02 ± 2.45 days, p=0.48), though not statistically significant. Readmission within 30 days was observed in 6.67% of the single-layered group and 8.33% of the double-layered group (p=0.73). Overall morbidity was similar between the two groups (23.33% vs. 26.67%, p=0.67).**Conclusion:** Single-layered anastomosis significantly reduces operative time without increasing the risk of anastomotic leakage, wound infection, or overall morbidity and mortality. Given its efficiency and comparable safety profile, the single-layered approach may be preferable in clinical settings where minimizing surgical duration and optimizing resource utilization are priorities.

Keywords: Intestinal anastomosis, Single-layer anastomosis, Double-layer anastomosis, Postoperative complications

INTRODUCTION

Intestinal anastomosis is a critical surgical procedure performed to restore the continuity of the gastrointestinal tract after resection. This technique is widely used in various gastrointestinal surgeries, including those related to malignancies, inflammatory bowel disease, trauma, and ischemic conditions. The success of an anastomosis is essential to ensure optimal postoperative outcomes, minimize complications, and enhance the recovery process. However, the choice of the anastomotic technique remains a subject of ongoing debate among surgeons, particularly regarding the use of single-layered versus double-layered suturing methods.[1,2]

The traditional double-layered anastomotic technique has long been considered the gold standard in bowel surgery. This method involves

an inner layer of full-thickness, continuous or interrupted sutures to ensure mucosal apposition, followed by an outer layer of seromuscular sutures that reinforce the closure and provide additional tensile strength. Proponents of this technique argue that the second layer serves as an additional protective barrier, reducing the risk of anastomotic dehiscence and leakage. Furthermore, the double-layered approach is believed to provide better hemostasis, reducing the likelihood of bleeding-related complications. Despite these advantages, concerns have been raised regarding its potential drawbacks, including prolonged operative time, increased tissue ischemia due to excessive suturing, and higher overall costs.[3]On the other hand, the single-layered anastomotic technique has gained significant attention due to its simplicity, shorter procedural duration, and potential for better perfusion at the anastomotic site. This method typically involves the use of either continuous or interrupted sutures that incorporate all layers of the bowel wall or selectively involve only the mucosa and submucosa. Advocates of single-layered anastomosis suggest that it minimizes ischemic injury by reducing the number of sutures, thereby promoting faster healing and reducing the risk of strictures. Additionally, with increasing emphasis on cost-effectiveness and efficiency in surgical practice, the single-layered technique has been increasingly adopted in various clinical settings. However, concerns remain regarding its mechanical strength, potential for anastomotic leakage, and long-term durability compared to the conventional double-layered method.[4,5]The choice between single-layered and double-layered anastomosis is influenced by various factors, including the surgeon's expertise, patient-related variables such as nutritional status and comorbidities, and the anatomical location of the anastomosis. Despite extensive research on this topic, there is no universal consensus on the superior technique, and both approaches continue to be employed based on individual surgeon preferences and institutional protocols. Some studies suggest comparable outcomes in terms of anastomotic integrity, while others highlight differences in complication rates, healing patterns, and postoperative morbidity. Given the impact of anastomotic failure on patient outcomes—including prolonged hospital stays, increased morbidity, and the need for reoperations—it is imperative to establish evidence-based guidelines on the most effective technique.[6]

AIM AND OBJECTIVES

This study aims to compare single-layered and double-layered intestinal anastomosis through a randomized controlled trial, assessing key parameters such as anastomotic integrity, complication rates, operative time, and overall patient outcomes.

MATERIALS AND METHODS

Study Design

This study was a **randomized controlled trial (RCT)** comparing single-layered versus double-layered intestinal anastomosis techniques. Patients were randomized into two groups using a computer-generated sequence to ensure an unbiased distribution.

Study Population

A total of **120 patients** requiring intestinal anastomosis due to various indications, including bowel resection for malignancy, trauma, ischemia, or inflammatory bowel disease, were enrolled.

Study Place

The study was conducted in theDepartment of General Surgery at Santosh Medical College & Hospital, Ghaziabad, NCR Delhi, India.

Study Period

The study was conducted over a period of one year, from April 2015 to March2016.

Ethical Considerations

Ethical approval was obtained from the Institutional Ethics Committee before initiation of the study. Written informed consent was obtained from all participants prior to enrollment, ensuring confidentiality and adherence to ethical guidelines as per the Declaration of Helsinki.

Inclusion Criteria

- Patients aged 18–70 years undergoing elective or emergency bowel resection with primary anastomosis.
- Patients fit for surgery and anesthesia as per ASA (American Society of Anesthesiologists) classification I–III.

Exclusion Criteria

- Patients with severe sepsis or hemodynamic instability.
- Patients with known malignancies with distant metastasis.
- Patients undergoing diverting stomas.
- Patients with severe malnutrition or immunosuppression.

Methodology/Procedure

All procedures were performed by experienced gastrointestinal surgeons under general anesthesia. The anastomosis technique was

standardized across both groups to ensure uniformity. Intraoperative parameters, such as anastomotic site, duration of anastomosis, and need for additional reinforcement, were recorded. Patients were monitored for postoperative complications, including anastomotic leakage, stricture formation, ileus, wound infection, and mortality. Patients were followed for 30 days postoperatively, with clinical assessments and imaging as needed.

After enrollment, patients were randomized into two groups (n=60 each):

Group A (Single-Layered Anastomosis):

- Underwent single-layer continuous or interrupted suturing using polydioxanone (PDS) or polyglycolic acid sutures.
- The anastomosis was performed in an end-to-end, end-to-side, or side-to-side fashion based on intraoperative assessment.

Group B (Double-Layered Anastomosis):

- Underwent a double-layered technique, comprising:
  - An inner continuous layer of absorbable sutures.
  - An outer interrupted seromuscular layer using non-absorbable or slowly absorbable sutures.
- The anastomotic integrity was assessed intraoperatively using air-leak or methylene blue testing.

Outcome Measures

The primary and secondary outcome measures were:

Primary Outcome:

- Incidence of anastomotic leak within 30 days postoperatively.

Secondary Outcomes:

- Surgical site infection (SSI).
- Hospital length of stay.
- Time to return of bowel function (first flatus, bowel movement).
- Need for reoperation due to anastomotic failure.
- 30-day mortality rate.

STATISTICAL ANALYSIS

- Data were analyzed using SPSS (Version XX) or similar statistical software.
- Categorical variables were expressed as percentages and compared using the Chi-square test or Fisher's exact test.
- Continuous variables were expressed as mean ± standard deviation (SD) and analyzed using the independent t-test or Mann-Whitney U test, depending on normality.
- A p-value < 0.05 was considered statistically significant.

RESULTS

The study included 120 patients, evenly divided into two groups: single-layered anastomosis (n=60) and double-layered anastomosis (n=60). The results were analyzed across demographic characteristics, intraoperative parameters, postoperative complications, hospital stay, readmission rates, and overall morbidity and mortality.

Table 1: Demographic Characteristics

Variable	Single-Layered Anastomosis (n=60)	Double-Layered Anastomosis (n=60)	p-value
Age in years (Mean ± SD)	52.45 ± 10.32	51.98 ± 9.87	0.72
Male	35 (58.33%)	33 (55.00%)	0.69
Female	25 (41.67%)	27 (45.00%)	0.69
BMI kg/m^2 (Mean ± SD)	24.12 ± 3.45	24.05 ± 3.78	0.84

Table 1, shows that the demographic characteristics of the study population. The mean age in the single-layered anastomosis group was 52.45 ± 10.32 years, whereas in the double-layered group, it was 51.98 ± 9.87 years (p=0.72), indicating no significant difference between the groups. Similarly, the gender distribution was comparable, with males constituting 58.33% in the single-layered group and 55.00% in the double-layered group (p=0.69). The proportion of females was also similar, with 41.67% in the single-layered group and 45.00% in the double-layered group (p=0.69). The mean BMI was almost identical in both groups, at 24.12 ± 3.45 in the single-layered group and 24.05 ± 3.78 in the double-layered group (p=0.84). Since all p-values were greater than 0.05, there were no statistically significant differences in demographic variables between the two groups, ensuring a balanced comparison.

Table 2: Intraoperative Parameters

Variable	Single-Layered Anastomosis (n=60)	Double-Layered Anastomosis (n=60)	p-value
Mean Operative Time (min)	82.45 ± 12.56	96.78 ± 15.32	<0.001
Anastomotic Site (Small Bowel)	38 (63.33%)	35 (58.33%)	0.61
Anastomotic Site (Large Bowel)	22 (36.67%)	25 (41.67%)	0.61

Table 2shows the intraoperative findings. The mean operative time was significantly lower in the single-layered anastomosis group (82.45 ± 12.56 minutes) compared to the double-layered anastomosis group (96.78 ± 15.32 minutes), with a highly significant p-value of <0.001. This indicates that the single-layered technique was associated with a shorter operative time, potentially reducing anesthesia exposure and surgical stress. The distribution of anastomotic sites was comparable, with the small bowel being the site of anastomosis in 63.33% of patients in the single-layered group and 58.33% in the double-layered group (p=0.61). Large bowel anastomoses were performed in 36.67% of patients in the single-layered group and 41.67% in the double-layered group (p=0.61). These findings confirm that the selection of anastomotic sites was similar across both groups.

Table 3: Postoperative Complications

Complication	Single-Layered Anastomosis (n=60)	Double-Layered Anastomosis (n=60)	p-value
Anastomotic Leakage	5 (8.33%)	4 (6.67%)	0.72
Wound Infection	7 (11.67%)	9 (15.00%)	0.59
Ileus	6 (10.00%)	8 (13.33%)	0.57
Stricture Formation	2 (3.33%)	3 (5.00%)	0.65
Mortality	1 (1.67%)	2 (3.33%)	0.57

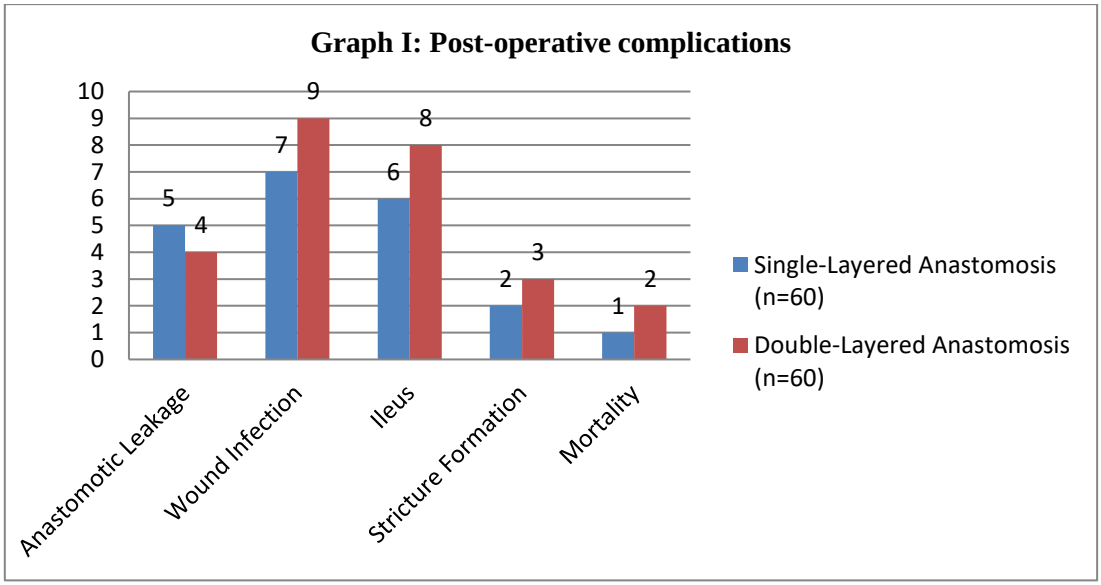

Table 3and graph I, shows that the postoperative complications observed in the study. Anastomotic leakage was recorded in 8.33% of patients in the single-layered group and 6.67% in the double-layered group (p=0.72), indicating a comparable risk between the two techniques. Wound infection occurred in 11.67% of patients in the single-layered group and 15.00% in the double-layered group (p=0.59), showing no statistically significant difference. The incidence of ileus was slightly higher in the double-layered group (13.33%) compared to the single-layered group (10.00%) (p=0.57). Stricture formation was observed in 3.33% of the single-layered group and 5.00% of the double-layered group (p=0.65). Mortality was low in both groups, with 1.67% in the single-layered group and 3.33% in the double-layered group (p=0.57). None of these

complications showed statistically significant differences, suggesting that both techniques had comparable postoperative safety profiles.

Table 4: Length of Hospital Stay and Readmission Rates

Variable	Single-Layered Anastomosis (n=60)	Double-Layered Anastomosis (n=60)	p-value
Mean Hospital Stay (days)	7.45 ± 2.12	8.02 ± 2.45	0.48
Readmission within 30 days	4 (6.67%)	5 (8.33%)	0.73

Table 4 describes hospital stay and readmission outcomes. The mean length of hospital stay was 7.45 ± 2.12 days in the single-layered anastomosis group and 8.02 ± 2.45 days in the double-layered group (p=0.48), indicating a slightly shorter but statistically insignificant difference in hospital stay for the single-layered group. Readmission within 30 days was reported in 6.67% of patients in the single-layered group and 8.33% in the double-layered group (p=0.73). These findings suggest that both techniques had similar impacts on postoperative recovery and readmission rates.

Table 5: Overall Morbidity and Mortality

Variable	Single-Layered Anastomosis (n=60)	Double-Layered Anastomosis (n=60)	p-value
Overall Morbidity	14 (23.33%)	16 (26.67%)	0.67
Overall Mortality	1 (1.67%)	2 (3.33%)	0.57

Table 5 presents data on overall morbidity and mortality. Morbidity was reported in 23.33% of patients in the single-layered group and 26.67% in the double-layered group (p=0.67), showing no statistically significant difference. The overall mortality rate was slightly higher in the double-layered group (3.33%) compared to the single-layered group (1.67%) (p=0.57), but this difference was not statistically significant. These results indicate that both techniques had similar overall safety profiles.

DISCUSSION

This randomized controlled trial evaluated the outcomes of single-layered versus double-layered intestinal anastomosis in 120 patients, focusing on operative time, postoperative complications, hospital stay, and overall morbidity and mortality. Our study demonstrated a significantly shorter mean operative time for the single-layered anastomosis group (82.45 ± 12.56 minutes) compared to the double-layered group (96.78 ± 15.32 minutes, p<0.001). This reduction aligns with the findings of Burch et al. (2000), who reported that single-layer continuous anastomosis was completed more rapidly than double-layer interrupted anastomosis, with mean times of 20.5 minutes and 28.7 minutes, respectively.[8]

Similarly, a study by Ceraldi et al. (1993) found that single-layer anastomosis required less time (mean of 25 minutes) compared to double-layer anastomosis (mean of 40 minutes). These consistent findings suggest that the single-layer technique is more time-efficient, potentially reducing anesthesia exposure and operative costs.[9]

In our study, the incidence of anastomotic leakage was comparable between the single-layered (8.33%) and double-layered (6.67%) groups (p=0.72). This observation is consistent with the results of a meta-analysis by Shikata et al. (2006), which found no significant difference in postoperative leak rates between single-layer and double-layer anastomoses.[10]Additionally, a study by Burch et al. (2000) reported an anastomotic leak rate of 2.5% in both groups, further supporting the equivalence in safety profiles. Regarding wound infections, our study observed rates of 11.67% in the single-layered group and 15.00% in the double-layered group (p=0.59), indicating no significant difference. These findings collectively suggest that both techniques have comparable postoperative complication rates.[8]

The mean length of hospital stay in our study was slightly shorter for the single-layered group (7.45 ± 2.12 days) compared to the double-layered group (8.02 ± 2.45 days), though this difference was not statistically significant (p=0.48). This aligns with the findings of Leslie and Steele (2003), who reported no significant difference in hospital stay duration between the

two techniques.[11]Similarly, a study by Ceraldi et al. (1993) observed comparable hospital stays between single-layer and double-layer groups. Readmission rates within 30 days were also similar between groups in our study, suggesting that the choice of anastomotic technique does not significantly impact short-term recovery or the likelihood of readmission.[9]

Our study found no significant difference in overall morbidity (23.33% for single-layered vs. 26.67% for double-layered, p=0.67) and mortality rates (1.67% vs. 3.33%, p=0.57) between the two groups. These results are in concordance with the meta-analysis by Shikata et al. (2006), which reported similar morbidity and mortality rates for both techniques. The comparable safety profiles suggest that the single-layered technique does not increase the risk of adverse outcomes and may be considered a viable alternative to the double-layered method.[10]

LIMITATIONS OF THE STUDY

- The follow-up period was limited to **30 days**, which may not capture long-term complications or outcomes of anastomotic techniques.
- **Surgeon expertise** and variations in surgical technique may have influenced the results, despite standardization efforts.
- The study did not account for **patient-specific factors** such as nutritional status, comorbidities, or previous abdominal surgeries, which could impact anastomotic healing.
- **Small sample size** may limit statistical power in detecting subtle differences between the two techniques.

CONCLUSION

This randomized controlled trial demonstrated that single-layered intestinal anastomosis significantly reduces operative time compared to the double-layered technique without increasing the risk of anastomotic leakage, wound infection, or overall morbidity and mortality. Both techniques exhibited comparable safety profiles, with no significant differences in postoperative complications, hospital stay duration, or readmission rates. Given its efficiency and similar clinical outcomes, the single-layered approach may be preferable, particularly in settings where reducing operative time and resource utilization is a priority.

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