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Research Article

Single Layer Extra-Mucosal Versus Double Layer Intestinal Anastomosis for Colostomy Closure: A Prospective Comparative Study

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ABSTRACT

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Introduction

The intestinal anastomosis is a fundamental procedure in gastrointestinal surgery. A significant challenge is the integrity of the anastomosis to avoid the risk of anastomotic leaking and subsequent high morbidity and mortality rates. 1,2 Although a variety

Background: The main objective was to compare the outcome of single layer interrupted extra-mucosal sutures with that of double layer suturing in the closure of colostomies. Subjects and Methods: Sixty-seven patients with closure colostomy were assigned in a

prospective randomized fashion into either single layer extra-mucosal anastomosis (Group A) or double layer anastomosis (Group B). Primary outcome measures included mean time taken for anastomosis, immediate postoperative complications, and mean duration of hospital stay. Secondary outcome measures assessed the postoperative return of bowel function, and the overall mean cost. Chi-square test and student t-test did the statistical analysis..

Results: Thirty-two patients were allocated to group A and 35 patients to group B. The mean time taken for anastomosis was significantly shorter in group A $(23.25 \pm 1.20 \text{ min})$ in group A vs. $36.71 \pm 1.93 \text{ min}$ in group B; P<0.001). A significant shorter duration of hospital stay was seen in group A $(7.00 \pm 1.778 \text{ days})$ in group A vs. $9.74 \pm 1.990 \text{ days}$ in group B; P<0.001). The detection of bowel sound was substantially quicker in group A as compared to group B $(4.56 \pm 0.50 \text{ days})$ in group A vs. $6.46 \pm 0.50 \text{ days}$ in group B; P<0.001). There was no significant discrepancy between the two groups regarding anastomotic leak rates (P= 0.543). The mean cost of double layer intestinal anastomosis method was significantly higher than that of single layer anastomosis (P<0.001).

Conclusions: The use of single layer extra-mucosal anastomosis of the intestine has the advantage of taking less time, less morbidity and cost-effective to perform with the same rate of anastomotic leak in the closure of colostomy.

of techniques, materials, and devices have been used successfully to achieve intestinal anastomosis in the past 150 years, there is no single technique which is internationally accepted.3,4 Historically two-layer anastomosis has been approved for most medical situations, but, it is slightly dull, time wasting to complete, and costly technique.5,6,7 Single layer extra-mucosal anastomosis using

synthetic absorbable suture material has gained popularity as it requires less time and cost without incurring any added risk of leakage, and associated with improved postoperative return to normal bowel function.8,9 In developed countries intestinal anastomosis is mainly performed by staplers; however, manual anastomoses (single interrupted, single continuous, double layer) are still in use worldwide.10 Practically, the hand-sewn anastomosis is the most frequently used technique worldwide because of the accessibility and affordability of suture materials and fluency with the procedure.

The present study aimed to compare the outcome of single layer extra-mucosal interrupted technique with that of double layer technique in intestinal anastomosis for safety and efficacy. To prevent any bias in the study a single procedure was chosen, colostomy closures, to compare the two methods of the anastomosis.

Subjects and Methods

This was a single-center prospective randomized comparative study done from January 2015 to September 2017. Any patient requiring intestinal anastomosis if fulfills the inclusion criteria were assigned to the single layer extra-mucosal (Group A) or double layer (Group B) technique randomly using opaque sealed envelopes to avoid bias in case selection.

Inclusion criteria included adults' patients aged 18-65 years of either sex requiring end-to-end intestinal anastomosis for colostomy closure were enrolled in this study. Only hemodynamically stable patients with no peritoneal contamination, and Hb level> 8 gm/dl were included.

The cause for colostomy in all included patients was penetrating abdominal trauma. All patients were loop colostomy in which the entire loop of bowel was exteriorized and both the proximal limb and the distal limb opened into a common stoma opening and were not transected.

Excluded criteria included patients with compromised immunity, malignancy, diabetes mellitus, steroid therapy, nephrotic syndrome and liver cirrhosis were excluded.

Primary outcome measures included mean time taken for anastomosis in minutes, the incidence of postoperative complications (anastomotic leak and surgical site infection), the mean duration of hospital stay.

Secondary outcome measures included the mean duration for the return of bowel sounds postoperatively (in days), the period of the abdominal drain in situ (in days), and the mean overall cost.

Before colostomy closure, each of the cases underwent a barium enema to establish the patency of the distal bowel. All patients received a preoperative bowel preparation, mechanical bowel cleansing with polyethylene glycol (PEG) solutions for proximal loop and the distal loop was prepared with a normal saline wash. They also received antibiotics prophylaxis on a preoperative day.

Operative technique:

All anastomoses in both groups were performed by the same suture materials and by the same surgical team. All the anastomoses arranged were an end-to-end type. The edges of the loop of the stoma were trimmed and freshened before constructing the

Single layer extra-mucosal intestinal anastomosis was performed using interrupted 2-0 polyglactin sutures on a round body needle. The suturing began at the mesenteric border and incorporated all the layers except the mucosa. The stitching was used to anastomose the bowel at 5 mm from the cut edge and 5 mm from each other. The double layered intestinal anastomosis was performed using 2-0 polyglactin Connell sutures for the transmural inner layer and Lembert sutures for the seromuscular inverting outer layer in an interrupted manner. The stitch was introduced 5 mm on either side of the first anastomotic layer and 5 mm from each other. This suturing was done in a circumferential way around the inner layer to bury it inside. The surgeon utilized merely pressure to the suture and not tightly pulled up while holding the ends of the bowel approximated to avoid ischemia of the anastomosis and guarantee that the anastomosis is instantly watertight.

Intraoperative findings, hemodynamics, and complications if any, quantity and cost of suture material used were noted. The time of construction of the anastomosis was calculated from the placement of the first stitch and ended with cutting the excess material from the last stitch. The completed anastomosis was tested to be airtight by milking air from the adjacent bowel into the area of the anastomosis. The mesenteric defect was closed. To enhance early detection of complications such as anastomotic leakage and to prevents the collection of fluid or pus, a closed system flexible tube abdominal drain was put near the site of the anastomosis in all cases. After completion of the bowel closure, the loop is dropped back into the peritoneal cavity, the abdominal wall closed by layers. The dressing of the wound was done.

Postoperatively all the patients were followed for 14 days, in which they received similar antibiotic (injection ceftriaxone and metronidazole) and same standard postoperative care.

The time taken for postoperative return of bowel function was assessed. Any immediate or delayed complications were recorded. Anastomotic leak was defined as radiographic demonstration of a fistula or non-absorbable material draining from the wound after oral administration.

Surgical site infection was seen as persistent wet dressing, unexplained fever, unexplained pain at the site of operation, tachycardia, and elevated leucocytes.

The abdominal drain was removed when the daily output was less than 25 ml, and skin sutures removed on the tenth day postoperatively.

As there were various patient and hospital linked factors lead to a delay in the operation, the total length of hospital stays (in days) was calculated from the day of surgery rather than from the date of admission.

The overall cost of each case was calculated according to the following forming:

Cost = number of days patient stay in the hospital * cost of single day + number of minutes patient stay in the operation room. The cost of each day was = 40,000 IQD. The cost of each minute patient stays in the operative room under general anesthesia was = 3000 IQD.

Ethical consideration:

This study was conducted under the Declaration of Helsinki and was approved by the Al-Kindy hospital's ethics and scientific research committee (registration code: 12/2015). Informed consent was gained from all the patients involved in the study, and their personal health information was safeguarded.

Statistical analysis:

Descriptive statistics were first used to record data and presented as a mean and standard deviation. All statistical analyses were done in SPSS software (IBM SPSS Statistics for Windows, version 22.0 Armonk, NY, USA) Chi-square test was applied to find out associations between related categorical variables, while student's t-test was used to detect differences between means of numerical variables. P-value < 0.05 was considered as significant points for discrimination of significance.

Results

A total of 67 patients were incorporated in a randomized manner. Thirty-two (47.76%) patients were allocated to a single layer intestinal anastomosis (Group A) and 35 (52.24%) patients to double layered anastomosis (Group B). Table 1 shows a comparative distribution of both study groups concerning age and sex.

Table 2 list the comparison between the two groups concerning the primary and secondary outcome measures. The mean time taken for anastomosis, the mean period needed to remove the abdominal drain, and the mean time of hospital stay was significantly shorter in group A than group B; P<0.001. The return of bowel function and detection of bowel sound was substantially quicker in group A as compared to group B; P<0.001. On the other hand, no significant discrepancy was noted between the two groups concerning anastomotic leak rates (P= 0.543) and surgical site infection (P= 0.417). The anastomotic leak happened in two cases (6.3%) of group A, and three cases (8.6%) of group B. Surgical site infection occurred in 3 (9.4%) cases of group A and 5 (14.3%) cases of group

Table 1: Comparison of study groups with respect to age and sex.

Parameter	Group A (n=32)	Croup B (n=35)	p value
Age (in years, Mean SD)	44.36± 4.22	43.96 ±4.18	0.736
Sex: Male	20	17	0.645
Female	12	18	

In all the patients who developed an anastomotic leak, return of bowel sounds was noted after the 5th postoperative day which was sluggish initially. The patients recovered with conservative management and did not require reexploration of the anastomotic leak. After the 10th postoperative day, the abdominal drain was removed, the patients starting oral feeds, and discharged later.

The number of suture material required for single layered anastomosis was lesser than for double layered anastomosis. The mean cost of double layer intestinal anastomosis method was

(499,855 \pm 13,607 IQD) which is significantly higher than the mean cost of single layer intestinal anastomosis (349,759 \pm 12,803 IQD); P<0.001.

Table 2: Characteristics of patients undergoing singe layered extra mucosal anastomosis versus double layered anastomosis for colostomy closure.

Observed parameter	Single layered extra-mucosal (n=32)	Double layered (n=35)	p value
Mean time taken			
for anastomosis	23.25±1.20	36.71±1.93	<0.001*
(in minutes)			
Duration of			
abdominal drain	6.16±1.98	8.11±2.39	<0.001*
in situ (in days)			
Return of bowel		6.46±0.50	<0.001*
sounds	4.56+0.50		
postoperatively	4.30±0.30		
(mean in days)			
Anastomotic leak			
(total no. of	2	3	0.543†
cases)			
Surgical site		5	0.417†
infection	3		
(total no. of	3		
cases)			
Mean duration of			
hospital stay (in	7.00 ± 1.778	9.74 ± 1.990	<0.001*
days)			
Overall Cost in	349,759±12,803	499,855±13,607	<0.001*
IQD	3 4 7,737±12,603		

Continuous variables expressed as Mean SD; *Student's t-test; †Chisquare test.

Discussion

The present study compared the classical double layered method of intestinal anastomosis with the single layered extra-mucosal interrupted method of anastomosis for colostomy closure regarding efficacy and safety.

Gender bias could be accounted in the studied population as the nutritional status of males concerning hemoglobin level was better as compared to females. Also, age bias could affect the process of healing. However, in this study, the ages and sex of the patients in both groups were not significantly different, and hence it did not affect the outcome of the study.

Controversy exists on whether mechanical bowel preparations influence the rates of anastomotic leaks in elective colorectal surgery. However, we decided to give all our patients a bowel preparation as a standard protocol. The lack of a prepared bowel causing contamination and hence leak in emergency cases could create bias in the study. Therefore, we chose colostomy closures, an elective procedure, as a model for comparing and evaluating single-and double-layer anastomosis.

On analysis of our data, it was found that the mean time required for anastomosis construction was 13 minutes less in single layer group which was statistically significant (p<0.001). This finding was in agreement with previous studies reported the considerably shorter duration of anastomosis for single anastomosis.5,11,12 However, the design of our study did not include the time required to prepare the bowel for anastomosis which is considerably more in the double layer. More meticulous circumferential clearing of the mesentery, appendices epiploica, and omentum was required before beginning the double layer anastomosis as we need a freer area to construct the second layer (inverting layer). While with the single layer method, less or no circumferential clearance was necessary. A greater length of bowel wall (1 cm) was needed to apply the two layers of sutures compared to the single layer. Sometime-related factors might influence the success of single layer method over double layer methods such as using only one layer of stitches which consumed less time and lesser lumen construction.

In our study, we observed that the bowel sounds returned earlier in single layer anastomosis as compared to double layer anastomosis (4.56 days vs. 6.46 days, respectively). The difference was considered significant (P<0.001) which accords with observations from previous studies.5,13,14 In contrast, some researchers reported no difference in the time of return of bowel sounds between the two methods.15 The patients who underwent single layer anastomosis were started on oral feeds earlier than those who had undergone double layer anastomosis. The early resumption of the oral feeds caused improvement in the nutritional status and hence faster recovery.

The ultimate test for safety and efficacy of a technique for intestinal anastomosis is its rate of anastomotic leakage. An anastomotic leak increases the morbidity and mortality associated with the operation: it can double the length of the hospital stay and increase the death by threefold.16 They are diagnosed either clinically or radiographically by contrast enema or computed tomography scan.17

In this study, anastomotic leakage occurred in two patients of group A (6.3%), and in three patients of group B (8.6%) P=0.543. This finding was in agreement with the results of previous studies performed by Ayub M et al.18 which shows 4.7% leaks occurred in group (A) interrupted single layer and 8.3% in the group (B) double layer, and Khan RA et al.12 where leakage rate was 6% in group (A) while 12% in group (B). A 2006 meta-analysis analyzing 670 patients concluded that there was no difference in the rate of postoperative leakage between the two techniques.6 Burch JM et al.7 and Ceraldi CM et al.19 too observed no statistically significant difference in the rates of anastomotic leaks between the two techniques.

After the absence of leak was confirmed, the abdominal drain was removed on 6.16 days (mean) which was earlier in the single layer anastomosis group as compared to 8.11 days (mean) in the double layer anastomosis group.

In the current study, the mean time taken for anastomosis was 23.2 min in group A and 36.71 min in group B. This was comparable to the results of Khan RA et al. study12 where the average time for

construction of the single layer anastomosis was 20 min and in the double layer was 35 min, and Burch JM et al. study7 in which the mean time was 20.8 min in single layer anastomosis and 30.7 min in double layer anastomosis.

Significant shorter duration of hospital stay was seen in the single layer group as compared to the two-layer group (P<0.001); it might be due to the earlier resumption of bowel function in the former. Maurya SD et al. also observed a shorter duration of stay in the onelayer arm as compared to the two-layer arm (11.4 days vs. 18.6 days, respectively).13 Another study reported an equal length of hospital stay in both groups.11 Burch JM et al. observed a 2-day shorter length of stay in the one-layer group although it was not statistically significant.7 In this study, the mean duration of postoperative hospital stay was seven days in group A and 9.74 days in group B. The findings were comparable to the results of Khan RA et al. study12 which was 7 days in single layer anastomosis and 9 days in double layer anastomosis, and also was comparable with Burch JM et al. study7 in which the duration was 7.9 days in single layer anastomosis and 9.9 days in double layer anastomosis. These were less comparable to the results of Ayub M et al. study18 where the length of hospital stay was 8.2 days in single layer anastomosis while it was 10.5 days in double layer anastomosis.

Suture materials were more in the double layer technique using (3 to 4) absorbable suture materials while in the interrupted single layer using two absorbable suture materials, so longer stay added to that lead to more hospital expenses on double layer technique.

Our study, like the other studies 12,18 favors single layer interrupted extra-mucosal intestinal anastomosis, as it is faster to perform, cost-effective, less likely to leak and as strong as double layer anastomosis.

The present study has certain limitations. Since our conclusion was derived from a smaller number of patients, further clinical trials with large sample sizes are required to establish the significant advantage of single layered anastomosis over double layer regarding postoperative morbidity, complications and hospital stay. Moreover, long-term follow up is needed to evaluate the late complications of intestinal anastomosis which include bowel stenosis, stricture or obstruction.

Conclusion

The use of single layer extra-mucosal colostomy closure has the advantage of taking less operative time, less hospital stay duration, less morbidity and cost-effective to perform with no increased rate of the anastomotic leak as compared to patients undergoing double layered colostomy closure. Hence, we advocate the use of single layer extra-mucosal anastomosis for all cases of colostomy closure in the adult age group.

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Conflict of Interest

No conflict of interest

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