Research Article

COMPARISON OF ANASTOMOTIC LEAKAGE RATE AMONG PATIENTS UNDERGOING ILEOSTOMY REVERSAL WITH SKIN STAPLER VERSUS HANDSEWN TECHNIQUE

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ABSTRACT

Introduction: All the temporarily made ileostomies require subsequent closure or reversal. The anastomotic technique may be hand sewn or stapled. We are using skin stapler for gut anastomosis, which is much cheaper than modern stapling devices but equally effective, and comparing the frequency of anastomotic leakage with handsewn technique of bowel anastomosis. The rationale to carry out this study is that if this study concludes in favor of stapled technique over conventional hand sewn technique patients would not only benefit in terms of safer reversal, but also would be benefited from shorter duration of operation. Moreover the local surgeons would gain confidence in adopting recent advancements in gut anastomosis.

Methodology: All procedures were done by skilled forth year surgical trainees under consultant's supervision. Ileostomy reversals was done via stapling or suturing technique according to patient's randomization. The patients were then evaluated for signs of anastomotic leakage by consultants at the day of discharge (5th post-operative day) and as an outpatient at 10th (the day of skin stitches / staplers removal) and 20th day after operation.

Results: Nine of 162 (5.6%) patients in the handsewen group and six of 162 (3.7%) in stapler group develop anastomotic leakage within 20 post-operative days after ileostomy reversal (p = 0.428). Hence the alternate hypothesis is rejected and though the number of hand sewn anastomosis leaked i.e. 9 were more than number of leaked stapled anastomosis i.e. 6, this difference is not found to be statistically significant.

Conclusion: Skin staples are easily available, cost effective, the technique employed has a low learning curve and gives comparable results in terms of anastomotic leakage with hand sewn anastomotic technique as well as other modern stapling devices.

INTRODUCTION

An ileostomy is a segment of distal ileum brought through the defect in the abdominal wall.[1] It could be a loop or end, temporary or permanent. All the temporarily made ileostomies require subsequent closure or reversal. An anastomosis is then created and the intestine returned to the peritoneal cavity. Anastomosis may be created between two segments of bowel in a multitude of ways.[1] The geometry of the anastomosis may be end-to-end, end-to-side, side-to-end or side-to-side.[1] The anastomotic technique may be handsewn (single or double layer) or stapled.[1]

Anastomosis in the bowel were not undertaken successfully until the 19th century.[2] Lembert described his seromuscular suture technique for bowel anastomosis in 1826.[2] Then Kocker's method, a 2 layer anastomosis, became the standard for many years.[2] The single layer extramucosal anastomosis, advocated by Matheson, is now known for the least tissue necrosis or luminal narrowing.[2] Mechanical stapling devices were first used successfully by Humer Hultl, in Hungary in 1908.[2] Evolved over time now a wide variety of modern staplers are in use. Anastomotic leakage is very serious and life threatening complication.[3] The frequency of anastomosis related complications are comparatively higher in emergency cases than elective cases.[3] The reason seems to be that emergency patients undergo surgery unprepared.[3] The theory behind a good bowel anastomosis remains consistent weather a sutured or stapled technique is applied: the bowel ends must have a good blood supply, be under no tension and be anastomosed with meticulous technique.[4] In recent years, however, evidence has shown particular anastomotic techniques to be advantageous in specific settings.[4,5] Hand sewn end-to-end anastomosis can be performed with continuous or interrupted pattern using one or two layers of sutures.[6] Single layered extramucosal interrupted intestinal anastomosis is simple, safe and associated with less risk of dehiscence.[6] Modern gut staplers are available in an assortment of sizes and features. These advanced staplers are procedure specific, effective but expensive. The use of a technique using a hand-stapling device (skin stapler) has been successfully

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used for small bowel anastomosis for more than 10 years, showing that it is safe, relatively quick and easy to learn, and cost effective.[7] The purpose to carry out this study is that majority of the international studies available on gut anastomosis done with skin stapler, though are in favour of this technique, date back to 1990's due to advent of modern, advanced and expensive stapling devices used in recent researches. Majority of the available studies enroll patients undergoing various types of gut anastomosis whereas my study population only includes ileostomy reversal cases. And if this study concludes in favor of stapled technique patients would not only benefit in terms of better and safer reversal, but also would be benefited from shorter time of operation.[8] Moreover the local surgeons would gain confidence in adopting recent advancements in gut anastomosis.

MATERIALS AND METHODS

This study was conducted in the Department of Surgery, Jinnah Hospital Lahore. The duration of study was from 20th July' 2014 to 30th November' 2016. Sample size of 324 cases (162 in each group) was calculated with 5% level of significance, 80 % power of test and taking expected proportion of anastomotic leakage in both groups i.e 6.7 % in those undergoing sutured anastomosis versus 1.3 % in those undergoing stapled anastomosis. GROUP A included patients undergoing sutured anastomosis and GROUP B included patients undergoing stapled anastomosis. In GROUP A the reversal was done with ETHICON Coated VICRYL™ (polyglactin 910) Suture Size 3-0. Single layer, interrupted, extramucosal end-to-end or end-to-side ileo-colic or ileo-ileal anastomosis were performed. In GROUP B the reversal was done using ETHICON PROXIMATE® Skin Staplers. End-to-end or end-to-side single layered stapled anastomosis was done.

The stapling technique used was as follows: Two cut ends of the bowel were brought in close apposition and held together with 2 vicryl stay sutures placed at mesenteric and anti-mesenteric borders. This helps to maintain traction during stapling. The anterior circumference of the anastomotic line (between the two stay sutures) was stapled together first and then the anastomotic site was flipped over to bring the posterior side in front, which was then stapled in the same manner as the anterior layer. At the end the corners where stay sutures were placed were secured with staples. Full thickness wall stapling with inverted mucosa was done by keeping the inter-staple distance of approximately 2-3 mm. (FIGURE 2) Sampling technique was non probability purposive sampling.

Inclusion Criteria

- Patients undergoing ileostomy reversal.
- Age between 18 – 50 years.
- With BMI ranging from 16 – 28
- With Pre-operative Blood Heamoglobin Level equal or above 10 g/dl
- With Pre-operative Serum Albumin Level equal or above 3.5 g/dl
- With Pre-operative Serum Na+ level 135-145 mEq/L
- With Pre-operative Serum K+ level 3.5-5.0 mEq/L

Exclusion Criteria

- Those undergoing recurrent anastomosis after leakage.
- Diabetic patients. (HbA1c $\geq$ 6.5 % or previously diagnosed cases)

Data Collection Method

All patients, fulfilling the inclusion and exclusion criteria, were selected from Out Patient Department of hospital after approval from ethical committee. The patients were not aware of the randomization arm and were selected via lottery method. After signed informed consent all patients were operated under general anesthesia with ETT. Predictable bias and confounding factors like Hb, S/Albumin, S/Na+, S/K+, BMI, Age were controlled by restriction (inclusion and exclusion criteria) and randomization. Rest were addressed during final analysis. BMI was calculated by: (weight (kg) / [height (m)]^2 All procedures were done by skilled forth year surgical trainees under consultant's supervision. Ileostomy reversals were done via stapling or suturing technique according to patient's randomization.

All patients were given intravenous analgesia and intravenous antibiotics post-operatively during hospital stay and were discharged in case of uneventful recovery on 5th post-operative day on oral analgesia for 5 days. Skin stitches were removed on 10th post-operative day. The patients were evaluated for frank feaculent discharge from wound, intra-abdominal leak on contrast study (FIGURE 3 & 4) and were clinically assessed for re-exploration by consultants at the day of discharge (usually 5th post-operative day) and as an outpatient at 10th (the day of skin stitches / staplers removal) and 20th day after operation.

Data Analysis Procedure

All data was entered and analyzed by using SPSS version 21. Quantitative variables like age was presented in the form of mean $\pm$ Standard Deviation. Qualitative variables like gender, anastomotic leakage was presented in the form of frequency and percentage. Chi square test was used to compare the anastomotic leakage rate in both groups. P value $\leq$ 0.05 was considered as significant.

RESULTS

Three hundred and twenty four (324) patients undergoing ileostomy reversal were evaluated for anastomosis leakage after using two different techniques of closure. In group A, 162 patients, hand-sewn technique was used and in group B, 162 patients, skin stapler technique of closure was used. Average age of sample population is 28.73 ± S.D 9.25 and range of age is 16-52 years (TABLE 1). Gender wise distribution in both groups is shown in FIGURE 1.

Table 1 Age of population

Group	N	Mean	Std. Deviation	Minimum	Maximum
A	162	28.29	8.75	16	50
B	162	29.17	9.737	18	52
Total	324	28.73	9.253	16	52

Table 2 Post-op Hospital stay

Group	N	Mean	Std. Deviation	Minimum	Maximum
A	162	7.94	3.985	4	32
B	162	7.82	4.022	4	36
Total	324	7.88	3.998	4	36

Table 3a & 3b Hospital Stay in Group A & B **Table 3a**

			Group		Total
			A	B	
Hosptial Stay	< 15 days	Count	155	156	311
		% within GROUP	95.7%	96.3%	96.0%
	> 15 days	Count	7	6	13
		% within GROUP	4.3%	3.7%	4.0%
	Total	Count	162	162	324
		% within GROUP	100.0%	100.0%	100.0%

Table 3b

Chi-Square Tests			
	Value	Df	Asymp. Sig. (2-sided)
Pearson Chi-Square	.080ᵃ	1	0.777

Table 4a & 4b Anastomotic Leakage in Group A & B

Table 4a

			Group		Total
			A	B	
Leakage	Absent	Count	153	156	309
		% within GROUP	94.4%	96.3%	95.4%
	Present	Count	9	6	15
		% within GROUP	5.6%	3.7%	4.6%
Total		Count	162	162	324
		% within GROUP	100.0%	100.0%	100.0%

Table 4b

Chi-Square Tests			
	Value	Df	Asymp. Sig. (2-sided)
Pearson Chi-Square	.629ᵃ	1	.428

Table 5a & 5b Post-op day of Anastomotic Leakage

Table 5a

			Group		Total
			A	B	
Leakageonp ostopday	No	Count	153	156	309
		% within GROUP	94.4%	96.3%	95.4%
	0-5 Days	Count	1	2	3
		% within GROUP	.6%	1.2%	.9%
	6-10 Days	Count	6	3	9
		% within GROUP	3.7%	1.9%	2.8%
	11-20 Days	Count	2	1	3
		% within GROUP	1.2%	.6%	.9%
Total		Count	162	162	324
		% within GROUP	100.0%	100.0%	100.0%

Table 5b

Chi-Square Tests			
	Value	Df	Asymp. Sig. (2-sided)
Pearson Chi-Square	1.696ᵃ	3	.638

Table 6a & 6b Expired patients in group A & B

Table 6a

			Group		Total
			A	B	
Expired	No	Count	159	161	320
		% within GROUP	98.1%	99.4%	98.8%
	Yes	Count	3	1	4
		% within GROUP	1.9%	.6%	1.2%
Total		Count	162	162	324
		% within GROUP	100.0%	100.0%	100.0%

Table 6b

Chi-Square Tests			
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	1.013ᵃ	1	.314

Table 7a & 7b Comparison of leakage between age above and below 40 years

Table 7a

Age2				GROUP		Total
				A	B	
16 - 40 years	Leakage	Absent	Count	138	134	272
			% within GROUP	94.5%	96.4%	95.4%
		Present	Count	8	5	13
			% within GROUP	5.5%	3.6%	4.6%
	Total		Count	146	139	285
			% within GROUP	100.0%	100.0%	100.0%
41 years and above	leakage	Absent	Count	15	22	37
			% within GROUP	93.8%	95.7%	94.9%
		Present	Count	1	1	2
			% within GROUP	6.3%	4.3%	5.1%
	Total		Count	16	23	39
			% within GROUP	100.0%	100.0%	100.0%

Table 7b

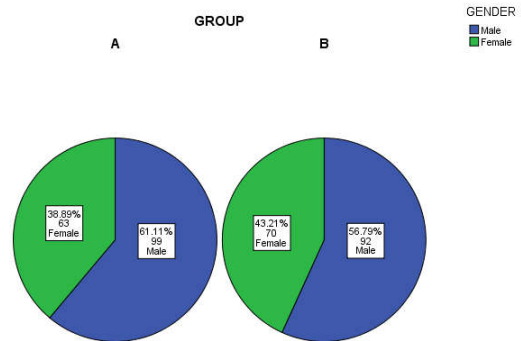| Age2		Value	Df	Asymp. Sig. (2-sided)
16 - 40 years	Pearson Chi-Square	.050ᵃ	1	.822
41 years and above	Pearson Chi-Square	070ᶜ	1	.791

Figure 1 Pie Chart showing gender distribution among groups

Figure 2 Stapled anastomosis with skin staples

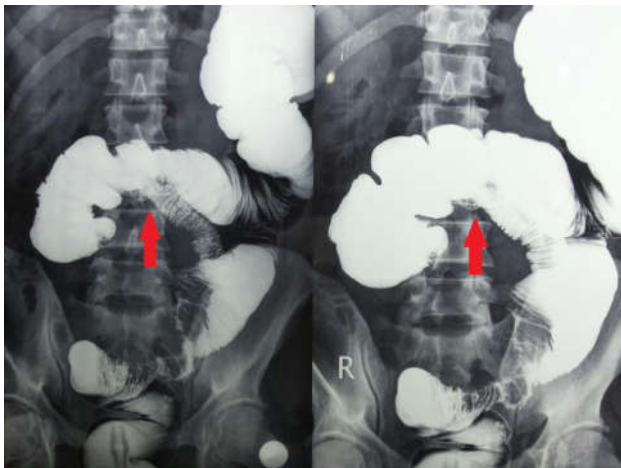**Figure 3** Arrow marking the metallic ring of staples on plain film

Figure 4 Arrow shows contrast passing through the metallic stapled ring (bowel anastomosis) without spillage externally.

In group A, 99 (61.11%) were male and 63 (38.89%) females. Similarly in group B, 92 (56.79%) were males and 70 (43.21%) were females. Average duration of post-operative hospital stay after ileostomy reversal is 7.88 ± S.D 4 days. Group A has mean duration of hospital stay of 7.94 ± S.D 3.98 days and group B has 7.82 ± S.D 4.02 days which were less than group A (TABLE 2).

In our study population about 155 (95.7%) patients of Group A stayed less than 15 days and 7 (4.3%) has stayed more than 15 days in hospital post-operatively. In group B, 156 (96.3%) had stayed less than 15 days and 6 (3.7%) patients stays more than 15 days (p=0.78) (TABLE 3a & 3b). Nine of 162 (5.6%) patients in the handsewen group and six of 162 (3.7%) in stapler group develop anastomotic leakage within 20 post-operative days after ileostomy reversal (p = 0.428) (TABLE 4a & 4b). Hence the alternate hypothesis is rejected and though the number of hand sewn anastomosis leaked i.e. 9 were more than number of leaked stapled anastomosis i.e. 6, this difference is not found to be statistically significant. Within (0-5) post-operative days there was only 1 anastomotic leakage in group A and 2 anastomotic leakages in group B. There were 6 and 3 leakages in group A and B respectively in 6-10 post-operative days. In the next 11-20 days, there was 2 leakages in group A and 1 leakage in group B (p<0.5) (TABLE 5a & 5b). There was 3 (1.9%) expires in group A and only 1 (0.6%) expiry in group B (p=0.31) (TABLE 6a & 6b). In population, below 40 years, there was 8 leakages in group A and 5 leakages in group B (p = 0.822). Above 40 years patients, have only 1 leakage in both groups (p = 0.791) (TABLE 7a & 7b).

DISCUSSION

Since the first report of the procedure by Turnbull and weakley[9] in 1966, loop ileostomies have increased in popularity because of their technical simplicity, lack of odour, liquid discharge and decreased rates of parastomal hernia and prolapse.[10-16] Moreover surgeons have also preferred protective loop ileostomies over protective colostomies because of the expected decrease in morbidity and mortality associated with the stoma closure.[10-15]

Loop ileostomies are frequently used after ileo-anal or colo-anal anastomosis in colorectal surgery to prevent probable complications associated with the anastomosis itself. They are most frequently performed for colorectal cancer and inflammatory bowel disorders. The temporary loop ileostomy is generally thought to be simple to construct and easy to close with limited perioperative morbidity and mortality.

A loop ileostomy is an opening constructed in intestine surgically for temporary fecal diversion and is usually closed after a period of time.[19,20] Although ileostomy is a life saving procedure but it causes significant physical and emotional trauma to patient as well as additional economic burden.[21] But reversal done after adequate nutritional buildup of the patient, at a suitable time with proper technique is associated with minimal morbidity.[21] A systematic review of 48 studies, including 6107 patients, showed a mean morbidity of 17.3% following ileostomy reversal surgery.[34] These results led to several concerns regarding the clinical utility of fecal diversion, emphasizing the need for better selection criteria in identifying patients who might gain an advantage from a diverting ileostomy.

In west common diseases leading to stoma formation are ulcerative colitis and crohn disease.[22] In our study no such case was observed as these diseases are uncommon in Pakisatn.[23] Typhoid, traumatic and tubercular perforation were found to be the most common indications of loop ileostomy (emergency surgeries) in our study population. The prevailing local literature also support these findings.[24-26]

The two principal anastomotic techniques are end-to-end hand sewn anastomosis and stapled anastomosis. Numerous studies have compared the integrity of hand sewn versus stapled bowel anastomosis and it is generally thought that their complication rates are similar.[17,18] But the cost of stapling devices apparently offsets their ease of usage and other advantages, we therefore decided to introduce an innovation and made use of skin staples for closure of loop ileostomies so that a major issue of cost can be dealt with. On comparison our results have been quite promising when compared with the hand sewn technique. Hull *et al.*[28] compared handsewn and stapled loop ileostomy closures and found that there are no significant differences in the time to the first bowel movement (defecation), solid food intake or duration of hospital stay. Moreover in another study conducted by Pittman *et al* [30] no significant difference in the anastomotic leak rate, length of surgery, or length of hospitalization in the both of groups (sutured versus stapled anastomoses) was found. Anastomotic leak is a dreadful complication and it is literally synonymous with failure of the operation.[21] Another study enrolling 225 patients reported that there were no statistically significant differences (p > 0.05) between the two groups in the rates of wound infection and anastomotic leakage.[31]

The risk of postoperative complications after ileostomy closure are associated with several factors including time interval between primary surgery and closure, antibiotic prophylaxis, the use of bowel preparation, and the technique implied i.e. staples vs sutures.[27,29] Literature shows that overall complication rates after ileostomy reversal range between 10% to 33%, with an all-cause reoperation rate of up to 12.5%.[32] Complications have been shown to be higher in subjects with increasing age, multiple comorbidities, and whose stomas were created as part of an emergency operation.[33]

In our study, the primary aim was to compare the two principal anastomotic techniques with respect to their complication rate in term of anastomotic leakage. Our results are consistent with majority of previous published literature as there was no significant difference was found in our research between the two techniques.

CONCLUSION & RECOMMENDATIONS

Proponents of each method of loop ileostomy closure claim several advantages, including a diminished risk of anastomotic complications and favorable surgical outcomes. Routine stoma closure can be performed either with a hand sewn, end-to-end anastomosis or through various techniques using staples.

Our study is unique and very rare due to the fact that we have actually made use of skin staples for stoma reversal. These staples are easily available, cost effective, the technique employs has a low learning curve and gives comparable results with hand sewn anastomotic technique as well as other modern stapling devices as is evident from our study.

Authors' Statements

Competing Interests
The authors declare no conflict of interest.

Ethical Approval

Ethical approval was obtained from the Clinical Research Ethics Committee of the Jinnah Hospital Lahore / Allama Iqbal Medical College in April' 2014.

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