

Stapled Versus Hand-Sewn Anastomosis in Colorectal Cancer Surgery : A comparative study

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Abstract

Introduction: In spite of long journey of intestinal anastomotic techniques surgeons still are not free from doubt about the leakage after colorectal anastomosis. In distal rectal anastomosis after cancer surgery it poses more risk due to poor colonic vascularity and reduced remaining tissue to nourish the anastomotic site. Exploration of surgical staplers has provided some procedural advantages and sense of security to surgeons as well as to patients in respect to sphincter saving and thereby improving quality of life. However, outcome measures of these devices should be made to see its efficacy over conventional hand-sewn technique because their cost play role in treatment plan. The result of such comparative study may help surgeons to counsel the patients. **Objectives:** To find out whether stapled anastomosis is safer than hand-sewn anastomosis in colon and rectal cancer surgery. **methods:** The quasi-experimental study was undertaken in the department of general and colorectal surgery, Bangabandhu Sheikh Mujib Medical University hospital during Feb 2005 to June 2008. Total 100 patients were selected. 48 patients underwent 'Stapled' and 52 underwent 'Hand-sewn' anastomosis. The patients were treated and postoperatively managed by same colorectal surgeon. The outcome variables were 'time required for anastomoses, 'postoperative hospital stay' and early and late 'complications' in postoperative and follow-up period. **Result and observation:** The age, sex, socio-economic status or co-morbidities did not show any statistical difference between two groups as in the hospital stay ($p=.821$). The time required for anastomosis showed strongly significant difference (18.17 min and 26.85 min; $p=.000$) in favor of stapling group. The hemorrhage from anastomotic line ($p=1.00$), anastomotic leakage ($p=.413$), ileus/ obstruction ($p=.640$) and wound dehiscence ($p=.640$) were much less in stapled group though they lack statistical power. All others except anastomotic stenosis ($p=.514$) showed almost similar results. **Conclusion:** Considering user perspective, time requirement and postoperative complications stapling technique appear to be safer and superior to hand-sewn technique though it demands statistical strengthening on large scale study.

Key words : Stapled; Hand-sewn; Colorectal cancer.

INTRODUCTION

Although improved surgical techniques, anesthetic care, diagnostic accuracy, and antibiotic prophylaxis all have contributed to improved results in intestinal surgery, yet surgeons still are not free from doubt about the leakage after colorectal anastomosis. In the last decades, advances in intestinal stapler devices have led to an increased frequency of stapled bowel anastomosis for a variety of proposed beneficial reasons like 1) better blood supply, 2) reduced tissue manipulation, 3) minimum tissue trauma and edema, 4) uniformity of sutures, 5) adequate or perhaps wider lumen at the site of anastomosis than double-layered suturing and 6) the ease and rapidity of anastomosis. These factors are believed to save anastomotic time and facilitate sound healing of the anastomosis. Historically, many studies from its evolution showed variable results compared to hand sewn technique. In spite of continuing debate stapling is now the preferred method of anastomosis of colon and rectum by most colorectal surgeons. Recent adoption of the use of surgical staplers by some surgeons of our country has prompted to undertake this comparative study between stapled and hand-sewn technique of anastomosis. Many patients are unable to undergo stapling due to financial constraints.

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Nonetheless, a good number of patients agree when they are assured of avoidance of a permanent stoma and preservation of anal sphincter in rectal cancer patients. If result of the study conclusively proves its safety and superiority over hand-sewn anastomosis then it will help counseling the patient in favor of stapling technique.

Hypothesis: Stapling is safer than hand-sewn anastomosis in colorectal surgery because of its low postoperative complication rate.

Objectives:

General objectives: To find out whether stapled anastomosis is safer than hand-sewn one in colorectal surgery.

Specific objectives: 1)To compare ‘time required for anastomosis’ and ‘post-operative hospital stay’ between stapled and hand-sewn groups of patients, 2)To compare post-operative complications among two groups.

MATERIALS AND METHODS

Study design: The study was a ‘quasi-experimental study’. Here, conventional ‘hand-sewn anastomosis’ was taken as ‘control group’ and the intervention ‘stapled anastomosis’ as ‘experimental group’.

Place of study: Department of general and colorectal surgery of Bangabandhu Sheikh Mujib Medical University.

Period of study: From February, 2005 to June, 2008, the period of MS final part apprenticeship.

Study population: Patients with colorectal disease admitted and operated within the study period in BSMMU and private hospitals assigned by supervisor and clinical advisor.

Sample and sampling: In this small study at regional level the sample size was determined on ‘empiric’ or institutional approach (WHO training guide, 1992) rather than analytical approach. Sample size of 100 with 50th percentile of significance was empirically determined for the study. The sampled patients were operated, postoperatively managed and followed-up depending sequentially on date of admission. Categorization of patients into *stapled* (n=48) and *hand-sewn* (n=52) groups was also done on similar sequence. The need of stapling was prioritized by pathologic site, operation type, need of lifelong colostomy avoidance and consent of patient after cost description of stapler. Final sample selection was dependent on surgeon’s clinical judgment on use of stapler. So, it was a *non-probability convenience sampling* due to lack of randomization.

Inclusion criteria: 1)Patients undergoing curative resection followed by anastomosis due to colorectal cancer irrespective of age and sex, 2)Lower limit of lesion >3 cm from anal verge for carcinoma rectum, 3) Consented after adequate counseling including cost of staplers and also participation in study.

Exclusion criteria: 1) Patients with widespread loco-regional and distant metastasis or those not down-staged after neo-adjuvant therapy, 2) Patients with lesion <3 cm from anal verge, involving anal sphincter or requiring emergency operation, 3) Patients with complicated co-morbidities or unwilling to give informed consent

Data collection: Data collection was done during patient management in hospital and follow-up visit both in hospital and private chambers of supervisor and clinical advisor. After discharge, patients were communicated with phone and follow-up visit were after 3 months and 6 months. Data was recorded on preformed data collection sheet. The patients were provided

a ‘code number’ for identification in both groups. In addition to particulars of the patients the recorded nominal and ordinal data were *age, sex, socio-economic and nutritional status and co-morbidities* like anemia, diabetes and hypertension. Socio-economic status was categorized assessing monthly income of the patients or their guardian i.e. *poor* with <4000.00, *average* with 4000.00–10000.00 and *affluent* with >10000.00 taka. Nutritional status was categorized on serum albumin level i.e. *poor* with <3 gm/dl, *average* with 3 - 3.5 gm/dl and *good* with >3.5 gm/dl. Anemia was assessed and recorded as *present* or *absent* on the demarcation line of 10 gm/dl. Data of histopathological diagnosis was categorized as *carcinoma right colon, carcinoma left colon* and *rectal carcinoma*. Stratification of rectal cancer was done based on *distance of lower limit of lesion from anal verge*. Accordingly, type of operation were *right and left hemicolectomies* and anterior resection (AR). Anterior resection was stratified as *high AR, low AR* and *ultra-low AR* based on the said distance respectively i.e. >10 cm, >5 - 10 cm and >3 - 5 cm. The anastomotic sites were *ileocolic, colorectal* and *coloanal* and the stomal sites were *ileostomy* and *colostomy*. Data of the outcome variables were *time required for anastomosis, postoperative hospital stay* and *postoperative early and late complications*.

Data analysis: After collection of data, these were evaluated and analyzed thoroughly by SPSS 12.0 version program. Student’s t’ test and Chi-square test were done for analysis of significance. P value of less than .05 was considered significant.

RESULT AND OBSERVATION

The age, sex, socio-economic status or co-morbidities did not show any statistical difference between two groups. The time required for anastomosis showed strongly significant difference (18.17 min and 26.85 min; p=.000) in favor of stapling group but there was no significant difference regarding hospital stay (Table 1). The hemorrhage from anastomotic line (p=1.00), anastomotic leakage (p=.413), ileus/ obstruction (p=.640) and wound dehiscence (p=.640) were much less in stapled group though they lack statistical power (Table 2). All others except anastomotic stenosis (p=.514) showed almost similar results (Table 3).

Table 1: Comparison of ‘time required for anastomosis’ (minutes) and ‘post operative hospital stay’ (days) between stapled and hand-sewn groups:

	Anastomotic technique	N	Mean	Std. Deviation	Std. Error Mean	t value	Df	p value
Time required for anastomosis (minutes)	Stapled	48	18.17	3.84	.5591	10.68	98	.000
	Hand-sewn	52	26.85	4.25	.58924			
Post operative hospital stay(days)	Stapled	48	13.44	3.92	.56564	.227	98	.821
	Hand-sewn	52	13.62	3.93	.54451			

Table 2: Comparison of postoperative 'early complications' between stapled and hand-sewn group:

		Stapled		Hand-sewn		Chi-square value	df	P value
		Frequency	Percent	Frequency	Percent			
Anastomotic hemorrhage	Absent	46	95.8	49	94.2	.135	1	1.000*
	Present	2	4.2	3	5.8			
Fever	Absent	39	81.3	42	80.8	.004	1	.951
	Present	9	18.8	10	19.2			
Ileus/intestinal obstruction	Absent	43	89.6	45	86.5	.219	1	.640
	Present	5	10.4	7	13.5			
Wound infection	Absent	35	72.9	40	76.9	.214	1	.644
	Present	13	27.1	12	23.1			
Wound dehiscence	Absent	43	89.6	45	86.5	.219	1	.640
	Present	5	10.4	7	13.5			
Clinical anastomotic leakage	Absent	44	91.7	45	86.5	.670	1	.413
	Present	4	8.3	7	13.5			
Pelvic sepsis	Absent	47	97.9	50	96.2	.267	1	1.000*
	Present	1	2.1	2	3.8			

*Fisher's Exact Test was done

Table 3: Comparison of postoperative 'late complications' between stapled and hand-sewn groups:

		Stapled		Hand-sewn		Chi-square value	df	P value
		Frequency	Percent	Frequency	Percent			
Urinary retention/incontinence	Absent	43	89.6	46	88.5	.032	1	.858
	Present	5	10.4	6	11.5			
Anal fecal incontinence	Absent	42	87.5	45	86.5	.020	1	.886
	Present	6	12.5	7	13.5			
Anal flatus incontinence	Absent	42	87.5	42	80.8	.841	1	.359
	Present	6	12.5	10	19.2			
Sexual dysfunction	Absent	41	85.4	44	84.6	.013	1	.911
	Present	7	14.6	8	15.4			
Pelvic pain	Absent	42	87.5	47	90.4	.212	1	.645
	Present	6	12.5	5	9.6			
Anastomotic stenosis	Absent	42	87.5	48	92.3	.641	1	.514*
	Present	6	12.5	4	7.7			
Local recurrence	Absent	43	89.6	47	90.4	.018	1	1.00*
	Present	5	10.4	5	9.6			
Death	Absent	46	95.8	49	94.2	.135	1	1.00*
	Present	2	4.2	3	5.8			

* Fisher's Exact Test was done

DISCUSSION

This study of 100 patients (stapled-48, hand-sewn-52) showed multivariate analysis of both categorical and metric data to identify the safer anastomotic technique. Empiric sample size of 100 was justified and approved by ethical committee based on WHO training guide¹, 1992. The mean age (39.67 yrs vs. 44.83 yrs) of patients showed no difference ($p=.106$) in both stapled and hand-sewn groups. Sex distribution showed more female (54.2% vs 45.8%) in stapled group and more male (71.2% vs 28.8%) in hand-sewn group of anastomosis. Though there is statistically significant ($p=.010$) difference it is reasonable in clinical study where convenience sampling was acceptable like that of Cuk¹ with 2:1 male-female ratio. Socio-economic status has direct implication on the use of staplers for anastomosis as to the nutritional status upon anastomosis and wound healing. The patients were categorized as 'poor', 'average' and 'affluent' on the basis of profession and resources culminating to monthly income. Nutritional status of patients was assessed clinically and biochemically by serum albumin level. The categorization 'poor', 'average' and 'good' showed no significant difference ($p=.218$). The recorded incidence of the co-morbidities i.e. diabetes or hypertension and others showed no significant differences in between two groups ($p=.933$, .107, .228). Use of neo-adjuvant (10.4% vs 5.8%) and adjuvant (72.9% vs. 61.5%) therapy peri-operatively might confound the outcome. So, they were studied but showed no significant affection ($p=.475$ & .227).

Operation type and anastomotic sites varied due to variable location of malignancy. In stapled and hand-sewn group, patients of carcinoma rectum were 44 and 33 (91.7% & 63.5%), carcinoma right colon 3 and 13 (6.3% & 25.0%) and carcinoma left colon 1 and 6 (2.1% & 11.5%) respectively. There was a remarkable difference in sites of carcinomas between two groups which was statistically significant ($p=.004$). For sampling technique more carcinoma-rectum patients (44/48 vs. 33/52) underwent anterior resection with stapled anastomosis and more carcinoma-right colon patients (13/52 vs. 3/48) underwent hemicolectomy with hand-sewn anastomosis. The increased number of anterior resection enabled the stratification of the procedure into 'high' (>10 cm), 'low' (>5 - 10 cm), and 'ultralow' (within 3 - 5 cm) types on the basis of distance of the lower limit of lesion from anal verge^{3,4,5}. In stapled group 44 (91.7%) patients underwent anterior resection of which 12 (25.0%) for high, 22 (45.8%) for low and 10 (20.8%) for ultra-low type. In hand-sewn group 33 (63.5%) patients underwent anterior resection of which 10 (19.2%) for high, 10 (19.2%) for low and 13 (25.0%) for ultra-low type. Statistical test did not show any significant difference ($p=.167$). Regarding anastomosis, 3 patients (6.3%) underwent ileo-colic, 36 (75.0%) colo-rectal and 9 (18.8%) underwent colo-anal anastomosis in stapled group. On the contrary, in hand-sewn group, 13 (25.0%) underwent ileo-colic, 25 (48.1%) colo-rectal and 14 (26.9%) patients underwent colo-anal anastomosis. This variation in anastomotic sites may be questioned for clarification because of its bearing on outcome measures of such a comparative study. However, many authors^{6,7} have shown their results of study ignoring the variation in pathologic and anastomotic sites. So, it is usual, though not at all, to justify in context to our set up. Within this two and a half year study period use of stapler was far more (44/48) in distal rectal operations than hand-sewn (33/52) group. Similarly, the number of hemicolectomies was more in hand-sewn group (19 vs 4) than stapled group.

There was a statistically significant ($p=.000$) reduced 'time required' for stapled (mean-18.17 min) compared to hand-sewn (mean-26.85 min) anastomosis. The overall difference between two groups (8.68 minutes) is far less than that of Professor WD George¹² which was 14 minutes (14.3 vs 28.1 min) but is supported by Fingerhut⁸ and Sarker⁹ as both of them showed it 8 minutes. Didolkar⁷ showed difference of 10 minutes (9-19min) supporting our initial experience. With time, steeper learning curve might extend this period improving our expertise. Hospital stay showed no statistically significant outcome data in study. In stapled group, it was 13.44 days and in hand-sewn group it was 13.62 days. Other studies showed mean hospital stay of 13 vs 14 days⁸, 13 days both⁷ and 10.6 days overall¹⁰. So, our study strongly corresponded to above studies.

Postoperative complications were the prime outcome variables of this study of bowel union. In most of the previous studies the important outcome variable was anastomotic leakage both clinical and radiological. Mc Ginn's¹¹ multi-center studies showed leak rate from 5% to 30%. Though there was increased radiological evidence of leak in conventional hand-sewn anastomosis in many studies its avoidance here was due to deficit of set-up. In Large Bowel Cancer Project, no radiologic studies were performed. Upon 1,645 patients the investigation revealed 8.1% leaks. Here, this study revealed comparable clinical leak rate of 8.3% in stapled and 13.5% in hand-sewn groups. Despite the observed difference between two it failed to show statistical significance. WD George, Docherty^{6,12} and Fazio¹⁰ showed lower clinical leak rate in stapled group that averaged 3.8%. Recently, Hyman¹³ reviewed prospective database of 2 colorectal surgeons and showed overall leak rate of 2.7%. George¹² and Docherty⁶ also showed a wide difference in radiologic leak rate (4.1% vs. 12.2% and 5.2% vs. 14.4%) indicating more leak in hand-sewn anastomosis. Everett¹⁴ also showed more radiological leak i.e. 15.9% and 12.0% respectively in both groups. So, in this study, if radiological leak test was done, it might reflect significant data in favor of stapled anastomosis. However, Cuk² showed a rate of clinical leak as 10.7% vs 11.4% which strongly corresponded to our result. Finally, study of Karanjia¹⁵ upon leakage rate after total mesorectal excision and stapled low rectal anastomosis revealed major clinical leak of 11.0%, which also similarly supported our study. Meta-analysis by Lustosa¹⁶ and review of Cochrane¹⁷ showed clinical leak of 7.1% and 6.33% in stapled and hand-sewn group respectively, which was not significant.

In study, 2 (4.2%) patients of stapled and 3 (5.8%) patients of hand-sewn group had hemorrhage from anastomotic line. All were from anastomosis reachable per-anum. One of stapled group needed 'over and over' suturing and others were controlled by packing and antibiotics. However, statistical test did not show any difference ($p=1.00$). Postoperative ileus or intestinal obstruction developed in 5 (10.4%) and 7 (13.5%) patients respectively in stapled and hand-sewn patients. Most of this complication disappeared with time but 2 of each group were associated with leakage and wound complication and were accordingly treated by reoperation. The incidence did not show any statistical significance ($p=.640$). Almost equal number (27.1% and 23.1%) of patients had wound infection which was much more than that of Lustosa¹⁶ (4.3% vs. 5.9%). 10.4% and 13.5% patients had wound dehiscence respectively in the groups. Need of re-operation here in both patient groups was not taken into account in the study. Fever appeared in 18.8%

(9/48) of stapled and 19.2% (10/52) of hand-sewn anastomotic patients. However, 1 of stapled and 2 of hand-sewn group developed high fever and sweating and neutrophilic leucocytosis suggested development of pelvic sepsis.

Anastomotic stenosis found in this study was 12.5% (6/48) and 7.7% (4/52) in stapled and hand-sewn technique respectively. Recently Cochrane Database¹⁷ explored reverse dichotomous outcome picture of 8% in stapled and 2% in hand-sewn anastomosis, which declares statistical significance against stapling. Our result though nearer to Cochrane review result, lack statistical significance ($P=.514$). Two patients of each stapled and hand-sewn group developed local recurrence at stenosis site and were subsequently treated by abdominoperineal resection. Other patients had benign stricture and were managed by regular anal dilatation. Local recurrence was found 10.4% (5/48) and 9.6% (5/48) respectively within this short follow-up period. Brigand¹⁸ showed average 12% local recurrence. Wolmark¹⁹ explored 41 months follow-up study of colorectal cancer of NSABP. They showed local recurrence of 12% in stapled and 19% in hand-sewn group. However, Moore²⁰ studied local recurrence and showed only 3.5% and 5.9% which was much less than that of above but closer to our study. Though intersphincteric resection doesn't implicate on local recurrence or overall survival in long-term⁴, few ultra-low intersphincteric dissections in our experiencing period might have any impact on proportionately increased rate of local recurrence.

After removal of catheter and stoma reversion surgery a remarkable percentage of patients developed urinary retention (10.4% vs 11.5%), anal incontinence to feces (12.5% vs 13.5%) and flatus (12.5% vs 19.2%), sexual dysfunction (14.6% vs 15.4%) and pelvic pain (12.5% vs 9.6%) of variable severity in both the groups. These neither have any affection on anastomotic technique nor the result showed any significance after chi-square testing.

Deep dissection for low and ultra-low anterior resection with or without intersphincteric intervention and prolonged intraoperative anal retraction²¹ are potential factors for nerve and sphincteric muscle injury. Lukkonen and Jarvinen²² showed their study on complication and functional outcome after restorative proctocolectomy and ileoanal anastomosis. They found 30% and 28% reduction in resting anal pressure respectively in both groups and no difference in use of either single or double stapling device. Kim²³ recorded frequency of stool after ultra-low anterior resection and showed the rate of motion as 6.1/day after 3 months, 4.4/day after 1 year and 3.1/day after 2 years. Mortality, in this study, was 4.2% in stapled and 5.8% in hand-sewn group. It was very difficult to detect absolute anastomosis related death rate in this study. All deaths were within 6 months follow-up period. Cochrane review¹⁷ revealed the specific mortality of 2.4% and 3.6% in stapled and hand-sewn group which was comparable to this study rate. After statistical analysis and significance testing of outcome variables stapled anastomosis was found to be significantly less time consuming (18.17 min vs 26.85 min) which have direct implication on postoperative recovery. Though hemorrhage from anastomotic line (4.2% vs 5.8%), clinical anastomotic leakage (8.3% vs 13.5%), ileus or obstruction (10.4% vs 13.5%) and wound dehiscence (10.4% vs 13.5%) were much less in stapled than hand-sewn group they lack statistical power. The use of stapler in distal rectal resection and anastomosis encourages sphincter preservation and holds the drive of colorectal surgeons in favor of using this device. Considering postoperative complications and paying respect to analysis, it is critical to make definitive comment on this small study.

CONCLUSION

Stapled anastomosis, though not overall but at least to some extent, is safer than hand-sewn anastomosis and in user perspective, it is superior to hand-sewn technique in colorectal surgery. However, to strengthen the comment, more standardized and randomized control trial is required.

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