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Evaluation of the outcome of linear stapler anastomosis in comparison to hand-sewn anastomosis in elective loop transverse colostomy closure in children: a study in a tertiary care hospital, Dhaka, Bangladesh

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ABSTRACT

Background: Conventional hand suture technique of intestinal anastomosis has been in vogue for decades. Staplers which developed to simplify surgery began to have significant impact. Objective were to see outcome of linear stapler anastomosis in comparison to hand-sewn anastomosis in elective loop transverse colostomy closure in children.

Methods: This prospective interventional study was carried out in the department of pediatric surgery, Dhaka medical college hospital, Dhaka from January 2018 to December 2019 over a period of 2 years. Forty-seven patients who underwent loop transverse colostomy closure were included in this study. Patients were allocated by purposive sampling into two groups, group A (linear stapler anastomosis) and group B (hand-sewn anastomosis).

Results: Mean age of the patients were 5.79 ± 3.23 years and 4.21 ± 3.13 years in linear stapler anastomosis group and hand-sewn anastomosis group respectively. Male to female ratio was 1.2:1 in linear stapler anastomosis group and 5.25:1 in hand-sewn anastomosis group. The mean duration of return of bowel movements (passage of flatus after surgery) in linear stapler method was 32.82 ± 6.04 hours and in hand sewn method was 40.56 ± 5.35 hours (p<0.05). Oral feeding was started earlier in patients who underwent linear stapler anastomosis (3.18 ± 0.39 days), as compared to hand-sewn anastomosis (4.16 ± 0.37 days) (p<0.001). The mean cost in linear stapler method was Tk. 4072 ± 158 and in hand sewn method was Tk. 1440 ± 362 . Anastomotic leakage was lower (4.5%) in linear stapler anastomosis than that in hand-sewn anastomosis (20.0%) (p>0.05).

Conclusions: Stapling technique can be used safely and effectively as a part of modern Surgeon's armory and one should be equally expert with stapler guns as with needle holders and sutures.

Keywords: Linear stapler, Anastomosis, Hand-sewn anastomosis, Elective loop transverse, Colostomy closure

INTRODUCTION

Gastrointestinal anastomosis is a commonly performed surgical procedure to establish communication between two formerly distant portions of the bowel since the era of Sushruta, The great Indian surgeon' who described the use of black ants during the suturing of intestinal anastomosis.¹ Prior to nineteenth century, intestinal surgeries were limited to exteriorization by means of a stoma or closure of simple lacerations. Lembert then described his seromuscular suture technique in 1826,

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while Senn advocated a two-layer technique for closure. Kocher's method utilized a two-layer anastomosis, first a continuous all-layer suture using catgut, then an inverting continuous seromuscular layer suture using silk.2 Numerous surgical conditions require the resection of bowel segments and the creation of reliable anastomosis. Restoring intestinal continuity after complete/partial and/or colectomy central enterectomy is gastrointestinal surgery. Anastomosis may be created between two segments of bowel in a multitude of ways. It may be end-to-end, side-to-side, or end-to-side. The submucosal layer of the intestine provides the strength of the bowel wall and must be incorporated in the anastomosis to assume healing.³

The evolution of mechanical sutures by stapler devices is a technological advancement which helps anastomosis of bowel loops with less tissue injury and decreased time duration of procedure. It also decreases the anastomotic leak complication.⁴ Most of these devices are disposable and relatively expensive, but their cost is offset by the saving of operative time and the potential increase in the range of surgery possible.² The modern era of mechanical staplers was launched when American surgeon Mark Ravitch observed a Russian surgeon in Keiv operating with a stapler on the lung.⁵ The basic instruments are the LDSTM (Ligates and divides to save), TA 30TM (thoracoabdominal), TA 55TM, TA 90TM, GIATM (gastrointestinal anastomosis) and the EEATM (end-to-end) surgical staplers. The LDS is employed in dividing mesentery, mesocolon and omentum. Although ingenious has been the least successful of the stapling instruments. The GIA, TA 30, TA 55, and the TA 90 are used for opening, closure, resection and anastomosis.⁶ The evolution of mechanical sutures by means of stapler use has become a real technological advancement, as it has represented the concept of a new product with the combination of new functions that have resulted in improvements and effective gains of quality or productivity in the handicraft suture process that has been done by surgeons for centuries.7

Surgical stapling devices were first introduced by Hültl in 1908; however, they did not gain popularity because instruments were cumbersome and unreliable. The development of reliable, disposable instruments over the past 30 years has changed surgical practice dramatically. With modern devices, technical failures are rare, the staple lines are of more consistent quality, and anastomosis in difficult locations are easier to perform.⁴ Recommendations for best practices in creating a GI anastomosis are 1) ensure an adequate blood supply, eliminate tension, maintain hemostasis, and handle tissues gently. Expert opinion without an explicit critical appraisal, or based on physiology, bench research or "first principles". 2) use an inverting (serosa-to-serosa), or an everting, with minimal exposed mucosa technique. 3) close mesenteric defects to avoid internal hernia. 4) consider a stapled technique for ileocolic anastomoses; elsewhere in the GI tract either a hand-sutured or stapled

anastomosis may be employed. 5) a single-layer anastomosis is an acceptable technique. 9

Accurate approximation without tension and with a good blood supply is fundamental whether suturing or stapling. For fashioning anastomosis, the factors considered are time required, restoration of function, effective hemostasis, reduction of tissue trauma, and prevention of postoperative morbidity. 10,11 Staplers have developed to fulfill most of these criteria. Staplers are capable of cutting and stapling at the same time avoiding the need for clamping. 11,12 Because the use of stapler's technical failures is a rarity, anastomosis is more consistent and can be used at difficult locations. 13 A temporary colostomy may be a primary procedure in the management of a congenital anorectal anomaly, distal obstruction as with Hirschsprung's disease, or an injury, severe inflammatory condition, or infective disease of the distal colon, rectum, or anus. It may also be a secondary procedure to protect a distal anastomosis. 14 Excellent technique in stapled anastomoses of the small and large bowel is of paramount importance to both practicing surgeons and trainees. The objective of this study to compare the outcome of hand-sewn versus linear stapler anastomosis in elective loop transverse colostomy closure in children.

Objectives

Objectives were to see the outcome of linear stapler anastomosis in comparison to hand sewn anastomosis in elective loop transverse colostomy closure in the children.

METHODS

Type of study

Prospective and interventional types of study were used.

Place of study

Study carried out at department of pediatric surgery, Dhaka medical college and hospital (DMCH).

Time of study

Study conducted from January 2018 to December 2019.

Duration of study

Study carried out for 24 months.

Inclusion criteria

Male or female subjects (between the ages of 06 months and 12 years) undergoing elective surgery requiring a large bowel anastomosis for the loop transverse colostomy.

Patient's parents or legal guardian who gives written informed consent after reviewing the informed consent document will be eligible for enrollment into the trial.

Exclusion criteria

Loop colostomy requiring resection and anastomosis due to accidental injury during dismantling.

Sample size

Statistically the following formula was used to calculate the sample size

$$n = \frac{P1(1-P1)+P2(1-P2)}{(P1-P2)^2} \times (Z\alpha + Z\beta)^2$$

Here,

n=Population size in each group

 P_1 =0.06 (Nichkaode, 2017); Proportion of patient developing outcome in group A

 P_2 =0.24 (Nichkaode, 2017); Proportion of patient developing outcome in group B

 $Z\alpha$ =Z- value (two tail) at a definite level of significance; 1.96 at 95% confidence interval

 $Z\beta$ = Z-value (one tail) at a definite power; 0.85 at 80% power

Therefore,
$$n = \frac{0.06(1-0.06)+0.24(1-0.24)}{(0.06-0.24)^2} \times (1.96+0.85)^2$$

=20.31 in each group=21 in each group

The first group was linear stapler anastomosis group-A which includes cases with loop transverse colostomy closure done with linear stapler. Second group was handsewn anastomosis group-B which include cases with loop transverse colostomy closure done with hand sewing.

Sampling technique

The target population of this study was patients with loop transverse colostomy. Total 52 cases were taken as samples. By exclusion criteria total of 5 cases were excluded as non-participants. The 47 Patients were allocated by purposive sampling into two groups group-A (linear stapler anastomosis) and group-B (hand-sewn anastomosis). Group-A was treated with linear stapler anastomosis (case): 22 patients and group-B was treated with hand-sewn anastomosis (control): 25 patients.

Data collection method

Data was collected and relevant investigations were evaluated in the department of pediatric surgery, DMCH.

A Data sheet was filled up during data collection. In each case information about the patient was collected in a prescribed questionnaire after getting written consent from the parents or legal guardians. Data was collected by semi structured questionnaire.

Data analysis

Results was calculated by statistical package for social science (SPSS) version 22.0.

Ethical considerations

Informed written consent from parents or legal guardians was taken after describing the study objectives. Ethical clearance was sought from the ethical committee of Dhaka medical college.

Linear staplers' technique

After mobilizing the loop transverse colostomy, the edges were trimmed and three stays were put on the edges. Then the edges of colon were placed transversely between the two blades of linear staplers. After one minute (for hemostasis), firing of the device created an anastomosis on the anterior wall of the transverse colon.

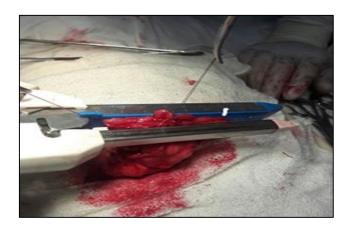


Figure 1: After mobilizing loop transverse colostomy, edges are trimmed and colon is placed transversely between the two blades of linear staplers.

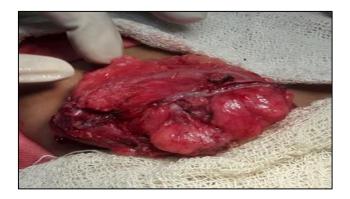


Figure 2: After firing device creates an anastomosis on the anterior wall of transverse colon.

Postoperative treatment

Nothing per oral (NPO), nasogastric decompression. Intravenous fluid (according to age and weight, fluid was changed according to electrolyte requirement). Inj. potassium: in maintenance dose from 3rd POD (1 ml inj. KT in 100 ml IV fluid) up to establishment of oral feeding. Intra venous antibiotic: Inj. ceftriaxone 100 mg/kg/day in two divided doses. Inj. metronidazole 1.5 ml/kg/dose 8 hourly. Analgesic: Inj. pthidine, I/M up to 2nd POD followed by suppository diclofenac sodium 1 mg/kg, 8 hourlies per rectally up to 5th POD. Once acceptable return of bowel function is confirmed, test feeding (sips of water) followed by establishment of oral feeding.

Post-operative follow-up

Following parameters were observed and recorded during post-operative follow up from 1st to 7th POD, body temperature, heart rate, respiratory rate.

Postoperative investigation

Complete blood count (CBC) on 2nd POD. Serum electrolytes on 2nd POD. If abdominal distension, vomiting or obstruction developed: X-ray abdomen in erect posture with both dome of diaphragm/USG of whole abdomen.

Management of postoperative complications

Patients who developed anastomotic leakage or obstruction undergone re-laparotomy. Then peritoneal toileting followed by enterostomy was done.

RESULTS

Table 1 shows mean age of the patients were 5.79±3.23 years and 4.21±3.13 years in linear stapler anastomosis group and hand sewn anastomosis group respectively. There was no significant difference in age between two groups. Unpaired t test was done to measure the level of significance.

Table 2 shows males predominant in both groups. Male to female ratio was 1.2:1 in linear stapler anastomosis group and 5.25:1 in hand sewn anastomosis group. Chisquare test was done to measure the level of significance.

Table 3 shows mean duration of anastomosis in linear stapler method is significantly shorter than that of hand sewn method. Unpaired t test was done to measure the level of significance.

Table 4 shows comparison of mean duration of return of bowel movements (passage of flatus after surgery) between linear stapler anastomosis and hand sewn anastomosis. Mean duration of return of bowel movements in linear stapler method is significantly earlier than that of hand sewn method. Unpaired t test was done to measure the level of significance.

Table 5 shows mean oral feeding starting day in linear stapler method is significantly earlier than that of hand sewn method. Unpaired t test was done to measure the level of significance.

Table 6 shows mean cost in linear stapler method was significantly higher than that of hand sewn method. Unpaired t test was done to measure level of significance.

Table 1: Distribution of the study subject according to age in linear stapler anastomosis and hand sewn anastomosis, (n=47).

Age (In years)	Linear stapler anastomosis (n=22), n (%)	Hand sewn anastomosis (n=25), n (%)	P value
≤2	3 (13.6)	9 (36.0)	
2-5	9 (40.9)	10 (40.0)	0.087
5-10	8 (36.4)	4 (16.0)	0.087
10-14	2 (9.1)	2 (8.0)	
Mean ± SD	5.79±3.23	4.21±3.13	

Table 2: Distribution of the study subject according to gender in linear stapler anastomosis and hand sewn anastomosis, (n=47).

Gender	Linear stapler anastomosis, (n=22), n (%)	Hand sewn anastomosis, (n=25), n (%)	P value
Male	12 (54.5)	21 (84.0)	0.028
Female	10 (45.5)	4 (16.0)	0.028

Table 3: Comparison of duration of anastomosis between linear stapler anastomosis and hand sewn anastomosis, (n=47).

Variable	Linear stapler anastomosis (n=22), mean ± SD	Hand sewn, anastomosis (n=25), mean ± SD	P value
Duration of anastomosis (mins)	6.82±0.91	25.72±3.39	< 0.001

Table 4: Comparison of duration of return of bowel movements between linear stapler anastomosis and hand sewn anastomosis, (n=47).

Variable	Linear stapler, anastomosis (n=22), mean ± SD	Hand sewn anastomosis (n=25), mean ± SD	P value
Return of bowel movements (hours)	32.82±6.04	40.56±5.35	< 0.001

Table 5: Comparison of oral feeding starting day between linear stapler anastomosis and hand sewn anastomosis, (n=47).

Variable	Linear stapler anastomosis (n=22), mean ± SD	Hand sewn anastomosis (n=25), mean ± SD	P value
Oral feeding starting day (POD)	3.18±0.39	4.16±0.37	< 0.001

Table 6: Comparison of cost between linear stapler anastomosis and hand sewn anastomosis, (n=47).

Variable	Linear stapler anastomosis (n=22), mean ± SD	Hand sewn anastomosis, (n=25), mean ± SD	P value
Cost (Taka)	4072±158	1440±362	< 0.001

Table 7: Comparison of anastomotic leakage between linear stapler anastomosis and hand sewn anastomosis, (n=47).

Variables	Linear stapler anastomosis, (n=22), n (%)	Hand sewn anastomosis, (n=25), n (%)	P value
Yes	1 (4.5)	5 (20.0)	0.194
No	21 (95.5)	20 (80.0)	0.194

Table 7 shows anastomotic leakage is lower in number in linear stapler method than that of hand sewn method but statistically not significant. Chi-square test was done to measure the level of significance.

DISCUSSION

Numerous surgical conditions require the resection of bowel segments and the creation of reliable anastomosis. As such, anastomotic techniques have been central to the development of modern surgical practice. Traditionally, a wide variety of suture materials have been used to create hand sewn anastomosis. Although, surgical stapling devices have existed since the early 20th century, their use in routine gastrointestinal surgery has not been widespread until approximately 30 years ago, when their design became much more efficient and convenient. Today, stapled anastomosis is an integral part of most major abdominal operations. After the stapled anastomosis was initiated, the hand-sewn was only used in incidences of a misfired staple, technically difficult to use stapler due to anatomical considerations, or if there was not enough gastric conduit to overlap the anastomosis sufficiently for the stapler. Numerous studies have compared the clinical and laboratory features of hand sewn and stapled anastomotic techniques. However, the use of such stapling devices, in the closure of single (anterior) wall of transverse colon-a common stoma in pediatric surgical practice yet not found in literatures which are reviewed.

In this study, 22 patients had linear stapler anastomosis and 25 patients had hand sewn anastomosis. Mean age of

the patients were 5.79±3.23 years and 4.21±3.13 years in linear stapler anastomosis group and hand sewn anastomosis group respectively. Most of the patients were ≤5 years old. There was no significant difference in age between two groups. Males were predominant in both groups. Male to female ratio was 1.2:1 in linear stapler anastomosis group and 5.25:1 in hand sewn anastomosis group. Males were predominant in the studies. 16-18 Mean time required for anastomosis in linear stapler method was 6.82±0.91 minutes which was significantly shorter than that of hand sewn method (25.72±3.39 minutes). The overall difference between two groups (18.9 minutes) was more than that of which was 14 minutes (14.3 vs 28.1 min) and far more than who revealed mean difference 9.5 minutes (5.7 vs 15.2 minutes) who found mean difference 8.6 minutes (18.2 vs 26.8 minutes). 18,19,24 Mean time required for anastomosis in linear stapler method was 6.82±0.91 minutes which was significantly shorter than that of which was 14.3 minutes which was 18.2 minutes as in this study we only transversely closed the anterior wall of transverse colon by linear staplers. 19,24

Mean duration of return of bowel movements (passage of flatus after surgery) in linear stapler method was 32.82 ± 6.04 hours and in hand sewn method was 40.56 ± 5.35 hours. Difference was statistically significant. Mean time to return of bowel sounds was 2.86 days in hand sewn group and 2.14 days in stapler method (p<0.05). In the study mean time required for return of bowel sounds was 5.83 ± 0.75 days in hand sewn group compared to 4.85 ± 0.69 days in the stapler group (p<0.05). With reduced operating time and less tissue trauma due to less tissue handling by linear staplers'

method, which enhanced early restoration gastrointestinal function and encouraged resumption of oral feeding. Oral feeding was started earlier in patients underwent linear stapler anastomosis (3.18±0.39 days), as compared to hand sewn anastomosis $(4.16\pm0.37 \text{ days})$ (p \leq 0.001) which consistent with. ^{16,20} In the study of, the mean time to take oral feeding was 4 days in hand sewn group and was 2.5 days in stapler group (p=0.014)and in the study, oral feeding was started earlier in patients who underwent stapler anastomosis 4.0±1.0 days, as compared to handsewn anastomosis 5.0 ± 0.83 days (p=0.001). ^{16,20} In the sutured group, the resumption of oral feeding was after 5.58 days, in the stapled group it was 4.45 days.⁷ Anastomotic leak rates vary widely among institutions, with rates reported from 0% to 53%. 21,22 This may in part be due to the broad range of definitions of anastomotic leak in use.²³

In this study, we found that stapling technique had reduced the time for anastomotic procedure significantly. With reduced operating time and less tissue trauma due to less tissue handling, there was early restoration of gastrointestinal function and resumption of oral feeding. Anastomotic leakage also found lower in number in linear stapler method than hand sewn method. On the other hand, we found that hand sewn anastomosis has required more operating time, more repeated use of emergency operation theaters for re-laparotomy and more hospital stay than stapling method. For that, it causes extra financial burden to patient's family, government and extra working burden to health care providers.

Limitations

Sample size was small. This study was single-centered study. Patients were allocated by purposive sampling.

CONCLUSION

The stapler anastomosis had significant less operating time, early recovery of bowel function, early starting of oral feeds and less number of anastomotic leakage, so stapling technique can be used safely and effectively as a part of modern Surgeon's armory and one should be equally expert with stapler gun as with needle holder and sutures.

Recommendations

As anastomosis with linear staplers is better than handsewn anastomosis, for widespread use of stapler devices following initiatives may be taken: Cost of the staplers' device have to be reduced to make it more cost-effective. Proper training is required to the new surgeons for sound knowledge about where to use staplers or not.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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