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Comparative Study on Early Postoperative Outcome between Linear Cutting Stapling Device Gastro-Jejunostomy &Amp; Traditional Hand Sewn Gastro-Jejunostomy for Gastric Cancer

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Abstract

Background: Gastric cancer (GC) is a heterogeneous, multifactorial disease. It endangers human physical and psychosocial wellbeing, causing a significant public health and economic burden in developed and developing countries. To compare the early postoperative outcome between linear cutting stapling device gastro-jejunostomy & traditional hand sewn gastro-jejunostomy for gastric cancer. **Material & Methods:** The study was a Prospective observational study which was conducted in Department of Surgery, Dhaka Medical college & Hospital, over Six months period after approval of protocol using a semi-structured questionnaire through face to face interview. Data were analysed using a computer programme SPSS 24.0 version. **Results:** Total 40 patients were enrolled in this study among them 20 patients underwent traditional hand sewn gastro-jejunostomy (Group-A) and 20 patients underwent Linear Cutting Stapling Device gastro-jejunostomy (Group-B). The mean age of the total participants was 57.45±7.04 years where in Group A mean age was 57.30±7.14 years and in Group B mean age was 57.60±6.83 years. The overall mean BMI of the patients was 21.94±1.61 kg/m2. Among all the respondents 25% had comorbidity. Operation time and time for anastomosis were significantly higher in Group A than Group B but no significant difference was found in relation to hospital stay and post-operative blood loss. About 15% had Anastomotic hemorrhage, 10% had Anastomotic leak, 5% had Intra-abdominal abscess and 5% had bowel obstruction in Group A beside 5% had Anastomotic hemorrhage, 5% had Anastomotic leak and 5% had SSI in Group B. Among all 10% needed blood transfusion in Group A and 5% needed blood transfusion in Group B. No significant difference has been found with post-operative complications between both groups. **Conclusion:** Observed advantages of Linear Cutting Stapling Device Gastro-Jejunostomy in this study were the significantly reduced operation time and anastomosis time.

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Keywords:- BMI, DM, HTN, SSI.

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INTRODUCTION

Gastric cancer (GC) is a heterogeneous, multifactorial disease. It endangers human physical and psychosocial wellbeing, causing a significant public health and economic burden in developed and developing countries.[1] It is estimated to be one of the most leading causes of all deaths worldwide. The incidence and mortality vary widely according to geographic areas, socio-cultural and economic entities.[2] The prevalence rates in developing Asian countries such as Bangladesh, India, Thailand, and Vietnam have been incredibly high at 92%, 81%, 74%, and 75%, respectively.[3] About one million new GC cases were estimated to have been diagnosed annually, making it the fourth most common malignancy in the world. More than 70% of GC cases occur in developing countries, with half the world's total cases occurring in Eastern Asia.[4] Although the incidence of GC is decreasing, The initial diagnosis of gastric carcinoma often is delayed because up to 80 percent of patients are asymptomatic during their early stages.[5] The majority of GC shows distant metastasis at the time of diagnosis, characterized by poor prognosis with a reported 5-year survival rate of less than 30% in most series.[6] Treatment strategy of gastric cancer has dramatically changed during the last decades, mainly due to advances in chemotherapy. However, surgery remains the main and only curative treatment option for GC. Survival rates after corrective surgery vary depending on several factors, but the stage of the disease and the quality of surgery are the two most important predictors.[7] The type of gastrectomy relies on the primary tumor site with the resection margin aimed at a 5 cm minimum from the palpable edge of the tumor. The anastomotic procedure is one of the key factors determining surgical success.[8] Currently, two methods are being used for anastomosis; the first one is a hand-sewn method, while the second one involves a surgical stapling device, known as the EEA stapler. The choice of anastomotic technique is influenced by diameter of the bowel ends, accessibility, edema and site of anastomosis, available time and equipment, contamination, and underlying pathology.[9] However, the most essential factor in performing particular anastomosis depends on individual surgeons' experience and personal preference. The single-layer simple interrupted suturing pattern using absorbable monofilament suture material and it was considered the best end-to-end anastomosis pattern among the hand-sewn methods of the anastomosis.[10] The newer stapling devices for anastomosis has provided an alternative option to perform the rapid anastomosis. The various types of staplers which are being used for the purpose of anastomosis include circular ligators, clip appliers, endoscopic staplers, etc.[11] Generally, the stapler is used for resection and transection of organs or tissues. linear cutting stapler is available in sizes ranging from 55 mm to 100mm (effective length of the anastomosis and transection).[12] Two staples' heights are available for each size of the stapler, which facilitate anastomosing of thick and thin tissues. The linear cutting stapler is loaded with two double staggered rows of titanium staples and simultaneously cuts and divides tissue between the two double.[13] The surgical staplers are preferred because of their convenient use and rapid application. They favor the blood flow across the anastomosis; provoke less injury, necrosis and edema.[14]

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Increased cost and less familiarity with its usage are the main drawbacks of stapling devices. However, the clinical efficacy of stapled side-to-side anastomosis for reducing the risk of delayed gastric empting and its superiority over conventional hand-sewn end-to side anastomosis is uncertain. Thus the aim of the study is to compare the early postoperative outcome between linear cutting stapling device gastro-jejunostomy & traditional hand sewn gastro-jejunostomy for gastric cancer.

MATERIAL AND METHODS

The study was a Prospective observational study which was conducted in Department of Surgery, Dhaka Medical college & Hospital, over Six months period after approval of protocol. Patients Age: >18 years of age, histologically diagnosed as gastric carcinoma, fit for surgery and willing to participate were included in the study and Patients having evidence of distant metastasis, Severely ill patients not fit for surgery and Patients having severe co-morbid conditions were excluded from the study. Maintaining all formalities face to face interview was taken by using pre-tested questionnaire with Purposive convenient sampling type of sampling technique. Total 40 patients were enrolled in this study among them 20 patients underwent traditional hand sewn gastro-jejunostomy (Group-A) and 20 patients underwent Linear Cutting Stapling Device gastro-jejunostomy (Group-B).The detail of the study was explained to each eligible respondent and consent was taken. After collection, the data were checked and cleaned, followed by editing, compiling, coding and categorizing according to the objectives and variable to detect errors and to maintain consistency, relevancy and quality control. Collected data were edited and analyzed according to the objectives and variables by IBM software- Statistical package for Social Science (SPSS 23) version. Ethical clearance was taken from the IRB of the institution.

RESULTS

This was a prospective observational study conducted in department of Surgery, Dhaka Medical college & Hospital. Total 40 patients were enrolled in this study among them 20 patients underwent traditional hand sewn gastro-jejunostomy (Group-A) and 20 patients underwent Linear Cutting Stapling Device gastro-jejunostomy (Group-B).

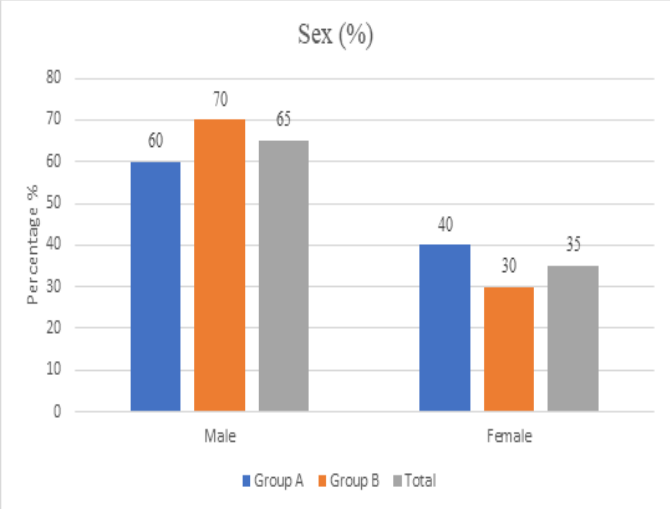

Figure 1: Distribution of the respondents by Sex (n=40)

Bar chart shows that majority (65%) of the patients were male with 60% in Group A and 70% in Group B (70%). No significant difference has been found between both groups (p=0.371).

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Table 1: Distribution of the respondents by Age group (n=40)

Age group	Group A (n=20)	Group-B (n=20)	Total (n=40)	p value
>50 years	16 (80)	15 (75)	31 (77.5)	*0.50
≤50 years	4 (20)	5 (25)	9 (22.5)	
Mean±SD	57.30±7.14	57.60±6.83	57.45±7.04	**0.893
Total	20 (100)	20 (100)	40 (100)	

Values are presented as mean±SD or frequency (%). Percentage expressed according to column. P value was determined by *Chi-square test and **Independent sample t test

[Table 1] shows that mean age of the total participants was 57.45±7.04 years where in Group A mean age was 57.30±7.14 years and in Group B mean age was 57.60±6.83 years. Among all majority (77.5%) of the respondents were more than 50 years.

Table 2: Distribution of the respondents by BMI (n=40)

BMI (kg/m^2)	Group A (n=20)	Group-B (n=20)	Total (n=40)	P value
Below normal (>18.5 kg/m^2)	3 (15)	2 (10)	5 (12.5)	*0.720
Normal (18.5 to 24.99 kg/m^2)	15 (75)	17 (85)	32 (80)	
Above normal (≥25 kg/m^2)	2 (10)	1 (5)	3 (7.5)	
Mean±SD	21.80±1.95	22.07±2.72	21.94±2.61	**0.744
Total	20 (100)	20 (100)	40 (100)	

Values are presented as mean±SD or frequency (%). Percentage expressed according to column. P value was determined by *Chi-square test and **Independent sample t test, BMI= Body Mass Index

[Table 2] shows the overall mean BMI of the patients was 21.94±1.61 kg/m2. Where majority (80%) of the respondents had normal BMI followed by 12.5% had below the normal level and 7.5% had above the normal level of BMI.

Table 3: Distribution of the respondents by Comorbidities (n=40).

Comorbidities	Group A (n=20)	Group-B (n=20)	Total (n=40)	P value
	n(%)	n(%)	n(%)	
Absent	14 (70)	16 (80)	30 (75)	*0.358
Present	6 (30)	4 (20)	10 (25)	
DM	2 (10)	1 (5)	3 (7.5)	
HTN	3 (15)	2 (10)	5 (12.5)	
Liver disease	1 (5)	1 (5)	2 (5)	

P value was determined by *Chi-square test. Percentage expressed according to column, DM= Diabetes Mellitus
HTN= Hypertension
[Table 3] shows among all the respondents 25% had comorbidity. Among them 12.5% had HTN. 7.5% had DM and 5% had liver disease. In Group A 30% of the respondents had comorbidity where 10%

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had DM, 15% had HTN and 5% had liver disease and in Group B 20% respondents had comorbidity where 5% had DM, 10% had HTN and 5% had liver disease. No significant difference has been found between both group with comorbidities.

Table 4: Distribution of the study population by Tumor characteristics (n=40)

Tumor characteristics	**Group A (n=20)**	**Group-B (n=20)**	**Total (n=40)**	**P value**
	n (%)	**n(%)**	**n(%)**	
Tumor Location				**0.331
Lower	2 (10)	4 (20)	6 (85)	
Middle	18 (90)	16 (80)	34 (15)	
Histological type				**0.903
Well differentiated	4 (20)	5 (25)	9 (22.5)	
Moderately differentiated	8 (40)	9 (45)	17 (42.5)	
Poorly differentiated	6 (30)	4 (20)	10 (25)	
Signet ring cell	2 (10)	2 (10)	4 (10)	
T stage				**0.496
T1a	9 (45)	10 (50)	19 (47.5)	
T1b	8 (40)	8 (40)	16 (40)	
T2	1 (5)	2 (10)	3 (7.5)	
T3	2 (10)	0 (0)	2 (5)	
N stage				**0.348
N0	17 (85)	19 (90)	36 (90)	
N1	0 (0)	0 (0)	0(0)	
N2	2 (10)	1 (5)	2 (5)	
N3	1 (5)	1 (5)	2 (5)	

Percentage expressed according to column. *p value was determined by *Independent sample t-test and **Chi-square test.

[Table 4] shows among all the study participants 85% Tumor location was in middle where majority (42.5%) of the tumor was moderately differentiated followed by poorly differentiated (25%), well differentiated (22.5%) and signet ring cell (10%). Also 47.5% had T1a stage followed by T1b (40%), T2 (7.5%) and T3 (5%) further 90% had N0 stage followed by N2 (5%) and N3 (5%). No significant difference has been found between both groups.

Table 5: Distribution of the study population by post-operative outcome

Post-operative outcome	**Group A (n=20)**	**Group-B (n=20)**	***P value**
	mean±SD	**mean±SD**	
Operating time (min)	22.6±2.9	15.8±2.4	<0.01
Time for anastomosis (min)	17.5±2.01	5.4±1.53	<0.01
Hospital stay (days)	8±1.48	7.60±1.23	0.360
Blood loss (ml)	822.50±121.90	750±162.22	0.118

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*p value was determined by Independent sample t test

[Table 5] shows that Operation time and time for anastomosis were significantly higher in Group A than Group B but no significant difference was found in relation to hospital stay and post-operative blood loss.

Table 6: Postoperative complications for both groups of patients (n=40)

Postoperative complications	**Group A (n=20)**	**Group-B (n=20)**	***P value**
	(n%)	**(n%)**	
Anastomotic hemorrhage	3 (15)	1 (5)	0.30
Anastomotic leak	2 (10)	1 (5)	0.24
SSI	0 (0)	1 (5)	0.50
Intra-abdominal abscess	1 (5)	0 (0)	0.50
Bowel obstruction	1 (5)	0 (0)	0.50
Needed blood transfusion	2 (10)	1 (5)	0.24

*p value was determined by Chi-square test. SSI= Surgical site infection

[Table 6] shows that 15% had Anastomotic hemorrhage, 10% had Anastomotic leak, 5% had Intra-abdominal abscess and 5% had bowel obstruction in Group A beside 5% had Anastomotic hemorrhage, 5% had Anastomotic leak and 5% had SSI in Group B. Among all 10% needed blood transfusion in Group A and 5% needed blood transfusion in Group B. No significant difference has been found with post-operative complications between both groups.

DISCUSSION

Present study was conducted to compare the conventional hand-sewn method of anastomosis and the stapled suturing technique to know the superior procedure in terms of safety and efficacy. Total number of the patients was 40 among them 20 patients underwent traditional hand sewn gastro-jejunostomy (Group-A) and 20 patients underwent Linear Cutting Stapling Device gastro-jejunostomy (Group-B).

In this study mean age of the total participants was 57.45±7.04 years where in Group A mean age was 57.30±7.14 years and in Group B mean age was 57.60±6.83 years. Among all majority (77.5%) of the respondents were more than 50 years old. Male was predominant constituting 65% of the participants. Stomach cancer occurs most commonly in older people and men are twice as likely to develop stomach cancer as women. Estrogen protects women from this kind of inflammation. Women with delayed menopause and increased fertility have a lower risk of gastric cancer. Many other previous study also observed among all the gastric cancer patients majority were older aged people and male was predominant in the study.[15,16] Similar findings also observed in a previous study by Seo et al. where mean age of the patients was 60.1±11.7 years in manual group and 60.4±12.0 years in stapler group and in both groups majority were male 10. Another study by Liu et al. stapled group consisted of 296 patients, where 187 was male and 109 was female patients with average age 59.05 ± 10.18 years

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and the group performed with manual procedure contained 203 cases where 136 were male and 67 were female patients with average age was 57.50 ± 10.05 years. This finding also similar to current study.[17] This study also revealed similar findings.

Overall mean BMI of the patients was 21.94±1.61 kg/m2. Where majority (80%) of the respondents had normal BMI followed by 12.5% had below the normal level and 7.5% had above the normal level of BMI. In a previous study among 254 participants it was revealed that the different classification of BMI in Asian adults for overweight and obesity could cause a huge heterogeneity, and this might mask a real association between BMI level and risk of gastric cancer in Asian adults.[18] But in this current study BMI was found normal as a whole. Lower number of enrolled patients can be reason for different findings. However, all the patients had gastric carcinoma which was collected purposively so no significant difference has been found between both groups with BMI. Another study by Murata et al. also observed mean BMI was 20.7 kg/m2 and 20.4 kg/m2 in Group stapled anastomosis and Group Hand-sewn anastomosis respectively with no significant difference as all the enrolled patients were suffering from gastric carcinoma (p=0.06).[15] Some other studies by Seo et al, and Abellan et al. also found similar findings.[10,19]

Current study found that Among all the respondents 25% had cormorbidity. Among them 12.5% had HTN. 7.5% had DM and 5% had liver disease. In Group A 30% of the respondents had comorbidity where 10% had DM, 15% had HTN and 5% had liver disease and in Group B 20% respondents had comorbidity where 5% had DM, 10% had HTN and 5% had liver disease. No significant difference has been found between both group with comorbidities. Previously other studies also found small number of comorbidities among the patients with no significant difference between both groups.[10,19]

According to this study among the enrolled patients, in 85% of cases tumor location was in middle where majority (42.5%) of the tumor was moderately differentiated followed by poorly differentiated (25%), well differentiated (22.5%) and signet ring cell (10%). Also 47.5% had T1a stage followed by T1b (40%), T2 (7.5%) and T3 (5%) further 90% had N0 stage followed by N2 (5%) and N3 (5%). No significant difference has been found between both groups (p>0.05). In a previous study by Seo et al. also observed majority of the tumor was located in the middle and was moderately differentiated. Further T1a and T1b stage with N0 stage was most commonly found. No significant differences has been found in clinicopathologic parameters between the two groups 10. Tumor location, histologic type, T stage, N stage etc. depends on enrolled patients so these findings has no significant difference between two methods of surgery.

This study revealed that time required for operation and anastomosis were significantly higher in Group A than Group B but no significant difference has been found with hospital stay and post-operative blood loss. Seo et al. observed operation times were significantly shorter in the stapler group (P=0.004). The times required for Billroth-II anastomosis were also significantly different between the groups (P＜0.001). There were no statistically significant differences in post-

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operative hospital days 10. According to Shahazad et al. the suturing time significantly decreased through application of stapled suturing technique as compared with the conventional suturing method (P≤0.0002).[20] Singha et al. also observed 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.[21]

In this study no significant difference has been found with hospital stay, post-operative blood loss and post-operative complications such as anastomotic hemorrhage, anastomotic leak, intra-abdominal abscess, SSI bowel obstruction and blood transfusion. Previous other study also observed similar findings.[15,21]

This study found that operating time and anastomosis time was significantly shorter in stapling method than Hand-sewn method. It WAS also observed that the complication of post-operative hemorrhage was found to occur comparatively more frequently with hand-sewn method, yet, not up to a significant level. Although stapled suturing technique is an expensive method to be used however, stapled technique is more preferable than the conventional hand-sewn method because it requires less time for application which consequently reduces the surgical time. So, the economic restraints can be negotiated and the technique proves rapidly adaptable for routine clinical practice.

CONCLUSIONS

Observed advantages of Linear Cutting Stapling Device Gastro-Jejunostomy in this study were the significantly reduced operation time and anastomosis time. More frequency was observed on hand sewn groups in anastomotic bleeding, anastomotic leakage and SSI. However, further study with larger sample size is recommended.

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