

International Journal of Cardiology Sciences



ISSN Print: 2664-9020
ISSN Online: 2664-9039
Impact Factor: RJIF 5.42
IJCS 2023; 5(2): 29-39
www.cardiologyjournals.net
Received: 16-04-2023
Accepted: 25-05-2023

Mehede Hasan Sawon
Registrar, Department of
Thoracic Surgery, Dhaka
Medical College Hospital,
Dhaka, Bangladesh

Md. Kamrul Alam
Professor and Head,
Department of Thoracic
Surgery, Dhaka Medical
College, Dhaka, Bangladesh

Syed Aminul Haque
Associate Professor,
Department of Thoracic
Surgery, Dhaka Medical
College, Dhaka, Bangladesh

Mohammad Serajus Salekin
Assistant Professor,
Department of Thoracic
Surgery, Dhaka Medical
College, Dhaka, Bangladesh

Mehdi Rafique Al Islam
Assistant Registrar,
Department of Thoracic
Surgery, Dhaka Medical
College Hospital, Dhaka,
Bangladesh

Debashish Das
Resident Surgeon, Department
of Thoracic Surgery, Dhaka
Medical College Hospital,
Dhaka, Bangladesh

Golam Mursalin
Registrar, Department of
Thoracic Surgery, Dhaka
Medical
College Hospital, Dhaka,
Bangladesh

Corresponding Author:
Mehede Hasan Sawon
Registrar, Department of
Thoracic Surgery, Dhaka
Medical College Hospital,
Dhaka, Bangladesh

Early Outcome of Stapler versus Hand-Sewn Intrathoracic Esophagogastric Anastomosis for Carcinoma Esophagus

**Mehede Hasan Sawon, Md. Kamrul Alam, Syed Aminul Haque,
Mohammad Serajus Salekin, Mehdi Rafique Al Islam, Debashish Das
and Golam Mursalin**

DOI: <https://doi.org/10.33545/26649020.2023.v5.i2a.36>

Abstract

Background: Esophagogastrectomy with Esophagogastrostomy is the mainstay of treatment for operable carcinoma esophagus patient. After gastric fashioning and conduit preparation, esophagogastric anastomosis is done either by hand-sewn or by mechanical circular stapled device but which method has better outcome regarding operating time, anastomotic time, anastomotic leakage, bleeding and pulmonary complications remain still a matter of debate.

Objective: To compare the early outcome between hand-sewn and stapled esophagogastrostomy for carcinoma esophagus.

Study design: Comparative cross-sectional study setting and period: Conducted in the Department of Thoracic Surgery, Dhaka Medical College, Hospital, Dhaka from 01st July 2022 to 30th June 2023. Participants: Total 44 patients, who underwent esophagogastrectomy with esophagogastrostomy for carcinoma esophagus, divided in two groups (Group A having 20 hand-sewn patients and Group B having 24 stapled patients) were selected for the study.

Methods: Patients who underwent esophagogastrectomy with esophagogastrostomy for carcinoma esophagus were included in the study. Twenty (20) hand-sewn anastomotic patients and twenty-four (24) stapled anastomotic patients were interviewed by using a structured questionnaire. Epidemiological, clinical and histopathological data of the patients were collected prospectively and analyzed.

Results: The mean total operating time for hand-sewn group and stapled group were 220.3±20.42 minutes and 205.0±25.70 minutes respectively (p=0.38). Anastomotic time for hand-sewn group and stapled group were 29.2±3.38 minutes and 19.04±2.73 minutes respectively (p<0.001), per-operative bleeding for hand-sewn group and stapled group were 248.8±71.7 ml and 196.7±59.2 ml respectively, (p=0.012) and pulmonary complications for hand-sewn group and stapled group were 25% vs.4.2% respectively (p=0.045). All these findings were statistically significant. But no statistically significant difference was found in terms of anastomotic leakage (10% vs.4.2% respectively, p=0.445), cardiac complications (35% vs.16.7% respectively, p=0.162), postoperative hospital stay (10% vs.20.8% respectively, p=0.328) and in hospital mortality (5% vs.8.3% respectively, p=0.662).

Conclusion: Although stapled intrathoracic esophagogastric anastomosis had less operating time, anastomotic time, per-operative bleeding and pulmonary complications but regarding anastomotic leakage, hospital stay, cardiac complications and inhospital mortality, both procedures had similar early postoperative outcomes.

Keywords: Outcome, stapler, hand-sewn, intrathoracic, esophagogastric anastomosis

Introduction

Esophageal cancer is the eighth most commonly diagnosed cancer and is the sixth leading cause of cancer death worldwide [1]. The burden of this malignant tumor is significantly high in least developed countries, where almost 80% of all cases occur. Approximately 70% of cases occur in men, and there is a 2- to 5-fold difference in incidence and mortality rates between the sexes. In addition, esophageal cancer is higher in middle-aged and elderly populations and the chance of getting it increases with age [2]. In Bangladesh, by the year 2020 among 156775 cancer patients, new cases of esophageal cancer are 21745 with 20319 total deaths [3].

The management of esophageal cancer (EC) is complex and highly variable which includes surgery, neoadjuvant therapy followed by surgery or neoadjuvant & adjuvant therapy in combination with surgery. In case of inoperable cases, palliative chemotherapy, radiotherapy, targeted therapy, brachytherapy, laser therapy, endoscopic stenting or other modalities of palliation are applied. Among them, surgery plays the mainstay of treatment for operable patient [4]. Patients with carcinoma esophagus are usually diagnosed in advanced stage with progressive dysphagia and significant weight loss [5]. After proper staging and pre-operative evaluation of the patient, esophagogastrectomy with esophagogastrostomy with lymph node dissection is the standard treatment for EC. The most important technical factor for a successful esophageal surgery is a well healed anastomosis without complications. Transthoracic esophagectomy (TTE) with gastric conduit and intrathoracic or neck anastomosis is the procedure practiced in most high volume centers. The technique of esophagogastric anastomosis (EGA) following esophagogastrectomy is crucial and is closely correlated with the patient's outcome because early complications, such as leakage, and late complications, such as stricture, cause significant morbidity and mortality. EGA can be carried out either by sutures or by using surgical mechanical circular staplers [6]. As the surgical resection is the mainstay of treatment for esophageal cancer for operable patient, so after gastric fashioning and conduit preparation esophagogastric anastomosis is done either by hand sewn or by mechanical circular device [7]. Depending on location of the tumor, esophagogastrectomy with esophagogastrostomy is done by variable approaches including Ivor-Lewis, Sweet and McKeon procedure [6, 7]. In general, for intrathoracic anastomosis, Ivor Lewis procedure is done for carcinoma involving middle third of the esophagus and sweet procedure is done for carcinoma involving lower third of the esophagus and gastro esophageal junction [8]. After conduit preparation, appropriate site was selected on the anterior wall of the gastric conduit away from the stapled line and approximately 3 cm below the highest point of the organ to ensure good vascularity. For hand-sewn anastomosis, an end-to-side EGA is performed using single-layer full thickness interrupted 3-0 absorbable polyglactin suture. A Ryle's tube is passed into the gastric conduit for decompression of the conduit [7, 9, 10]. For stapled anastomosis, an end-to-side anastomosis is performed in the thoracic cavity using endoluminal circular stapler of 26 to 31 mm size. A Ryle's tube is then passed inside the stomach conduit for post-operative stomach decompression [5, 7]. End to end anastomotic (EEA) stapling circular device size corresponds to its outer lumen diameter in millimeter. These devices are in different diameter sizes to accommodate the variety of bowel lumen diameters encountered clinically. The effect of circular stapler lumen diameter (not staple size) on outcomes is still a matter of debate. Lower sizes are associated with gastric stasis and anastomotic stricture. Higher sizes are associated with reflux esophagitis. So, EEA size should be determined clinically at the time of surgery by the native esophageal diameter [8]. The advantages of stapled anastomosis lie in its security, accuracy and speed. Aim of this technique is to reduce the anastomotic time, esophageal injury during anastomosis, per-operative & post-operative bleeding, risk of anastomotic leak. It allows the uniformity of the anastomosis and a shorter operating time.

However, it increases costs and the incidence of anastomotic stricture [11-13]. The hand-sewn depends more on the surgeon's expertise and certainly is cheaper than stapled anastomosis [14, 15]. Post-operative anastomotic leak and stricture are common complications that cause increased morbidity and mortality. For this reason, it is important to evaluate the best way to perform the anastomosis. The anastomotic leak decreases the patient quality of life, prevent early feedings, requires laborious local care, needs reopen with re-anastomosis, prolongs hospitalization and increases mortality [11]. Although hand-sewn anastomosis is initially cost effective but if anastomotic leakage occurs then it prolongs the post-operative hospital stay with raised treatment cost and it actually exceeds the total cost of the operation compared to stapled anastomosis cost [15]. In Bangladesh, esophageal surgery is well established only in couple of government and private centers. Over the years, general practice was hand sewn anastomosis in our country. In past few years, stapled anastomosis has got popularity due to its easy availability and time saving property. But, due to limited resources still a good number of anastomoses is performed by hand sewn. But so far known, no study has been conducted in our country to compare the two procedures. The purpose of this study is to compare the early outcomes of hand-sewn and stapled intrathoracic esophagogastric anastomosis after esophago gastrectomy for carcinoma of esophagus.

Materials and Methods

Study design: Comparative cross-sectional study.

Place of study: Department of Thoracic Surgery, Dhaka Medical College and Hospital (DMCH), Dhaka, Bangladesh.

Period of study: 1st July 2022 to 30th June 2023.

Study population: Patients with carcinoma esophagus admitted in the Department of Thoracic Surgery, Dhaka Medical College and Hospital, Dhaka, Bangladesh.

Sampling size calculation:

$$N = \frac{7.84 \times 9170.06}{361} = 25.4018 \approx 25$$

According to this formula minimum sample size for each group 25.

Due to short duration of study period finally targeted sample in each group at least 20. Group A - Hand-sewn anastomosis (20), Group B - Stapled anastomosis (24).

Inclusion criteria

- Patients of carcinoma esophagus underwent for surgery.

Exclusion criteria

- Patients of carcinoma esophagus with any features of metastasis found per-operatively
- Patients of carcinoma esophagus with locoregional invasion like bronchus, pericardium and aorta.
- Patients with severe comorbid conditions like uncontrolled diabetes mellitus, decompensated heart failure, uncontrolled COPD.

Procedures: After pre-operative evaluation regarding operability and fitness, all the cases of carcinoma esophagus that fulfilled the inclusion criteria were enrolled in this study

at our department. As a part of review work up, we recorded detailed history including age, sex, address, smoking habits, significant comorbid condition and all the necessary laboratory hematological and radiological investigations. Proper optimization of patient was done to correct hemoglobin (>10 gm/dl) and serum albumin level (>3.5gm/dl). Serum electrolytes was also corrected accordingly. Patients were divided into two groups. Group A for Hand-sewn and Group B for Stapled. This grouping was non-randomized depending on the patient's ability to bear the cost and surgeons preference. Patients were kept nil by mouth for 24 hours prior to the procedure. In selected cases, we advised 03 days standard preparation. Esophagogastrectomy with esophagogastrostomy were done by the different thoracic surgeons of similar skills and experiences. For general anesthesia, patients were intubated by a suitable double lumen endotracheal tube depending on the surgical approach. Patients vital parameters such as pulse, blood pressure, and oxygenation were monitored continuously throughout the procedure. In every case, stomach conduit preparation was done by linear cutter stapler. For Ivor-Lewis procedure, patients were made to lie in supine position for laparotomy then left lateral position for thoracotomy. During laparotomy stomach mobilization, hiatalysis, fashioning done with careful preservation of right gastroepiploic and right gastric arteries. In left lateral position after esophagus mobilization, esophagogastrostomy was done by either handsewn or circular End to end anastomotic (EEA) stapler of appropriate size. For Sweet procedure, in right lateral position anterolateral thoracotomy was done by left 7 th intercostal space, mobilization of stomach was done after a radial incision through the diaphragm. After esophagus mobilization, stomach conduit preparation and fashioning, esophagogastrostomy was done by either hand-sewn or circular End to end anastomotic (EEA) stapler. For hand-sewn group, end to side anastomosis was done by single layer full thickness interrupted anastomosis taking two stay sutures on each side. The anastomosis was started in the posterior layer using a 3-0 polyglactin suture and ended anteriorly. Before completion of anastomosis anteriorly, Ryle's tube was washed and placed in stomach up to hiatus. Care was taken to ensure the patency of the lumen during anterior anastomosis. For stapled group, end to side anastomosis was done by circular End to end anastomotic (EEA) stapler, size ranging from 26 mm to 31 mm determined per-operatively depending on the esophageal lumen diameter. Feeding jejunostomy was done in 24 Ivor-Lewis cases depending on the patient's comorbidity and surgeons'

preferences. At the end of the anastomosis by both procedure, quality of anastomosis was evaluated visually by its uniformity, integrity, intervening tissue and bleeding. Anastomosis was covered by available omental tissue. All the tissue sample including enbloc resected growth, esophageal doughnut, lymph nodes were collected in jar containing preservative and labelled properly and sent to pathological laboratory for histopathology. Wound closure was done in a standard fashion with a 28/32F chest drain tube keeping in situ. All patients were extubated immediately after surgery. All patients were advised for 2 hourly NG suction, propped up position and respiratory physiotherapy. Patients were kept nil by mouth for 7 days. During this period vitals were monitored, also ICU stays, post-operative bleeding, cardiac complications, pulmonary complications, wound infection and features of anastomotic leakage were observed and noted. Nutritional status was maintained as per departmental protocol either by total parenteral nutrition or by enteral feeding through feeding jejunostomy tube or by both. All patients were given test feed on 7th POD and monitored for any extravasation of dye in chest drain bag. ICT was removed on the same day if no leakage was found. All patients were followed up to 01 month following the procedure for any features of morbidity such as leakage, anastomotic stricture, wound infection or death.

Data Processing and Analysis: The statistical package for the social sciences program (SPSS version 29.1) was used to evaluate all data. The numerical data obtained from the study were analyzed and significance of difference was estimated by using appropriate statistical methods. Continuous variables were expressed as mean values \pm standard deviation and compared using Student's t-test. Categorical variables were expressed as frequencies with percentages and compared using Chi-square test when and where appropriate. $p < 0.05$ was considered as significant. The summarized data were presented in the form of tables.

Results

Total 44 carcinoma esophagus patients who underwent esophagogastric anastomosis either by hand-sewn or circular stapler. Twenty (20) cases were in the hand-sewn group labelled as group A and 24 cases were in the stapled group labelled as group B, respectively. Demographic and clinical outcome variables between the two groups were stated below with relevant statistical analysis.

Table 1: demographic characteristics of the study subjects between Group A (Handsewn) and Group B (Stapled) (N=44)

Age group (years)	Group A (Hand-sewn) (n=20)	Group B (Stapled) (n=24)	p-value
40-49	3(15.0%)	6(25.0%)	0.180 ^{ns}
50-59	5(25.0%)	6(25.0%)	
60-69	8(40.0%)	9(37.5%)	
70-79	4(20.0%)	3(12.5%)	
Total	20(100.0%)	24(100.0%)	
Mean \pm SD	60.9 \pm 7.5	57.3 \pm 9.47	
Sex			
Male	15(75.0%)	15(62.5%)	0.375 ^{ns}
Female	5(25.0%)	9(37.5%)	
Total	20(100.0%)	24(100.0%)	
Occupation			
Service holder	1(5.0%)	5(20.8%)	0.283 ^{ns}
Housewife	3(15.0%)	6(25.0%)	

Farmer	11(55.0%)	8(33.4%)	
Others	5(25.0%)	5(20.8%)	
Total	20(100.0%)	24(100.0%)	
Educational level			
Never went to school	8(40.0%)	5(20.8%)	0.314 ^{ns}
Primary	5(25.0%)	12(50.0%)	
Secondary	5(25.0%)	4(16.7%)	
Higher secondary	2(10.0%)	3(12.5%)	
Total	20(100.0%)	24(100.0%)	
Monthly income (Tk.)			
<50,000	19(95.0%)	22(91.6%)	0.650 ^{ns}
50,000-1,00,000	1(5.0%)	1(4.2%)	
>1,00,000	0(0.0%)	1(4.2%)	
Total	20(100.0%)	24(100.0%)	

Data were expressed as frequency and percentage and mean \pm SD, Unpaired student t-test was performed to compare between two groups, ns = not significant

Table-1 shows the age distribution of the subjects between Groups A (Handsewn) and Group B (Stapled). The results indicate that both groups had similar age distributions, with no significant difference in mean age between the two groups (Group A: 60.9 \pm 7.5, Group B: 57.3 \pm 9.47, p=0.180). In both groups, the majority of participants were in the 60-69 age group (40.0% and 37.5%, respectively). Shows that in Group A, 75.0% of the subjects are male, while in Group B, 62.5% of the subjects are male. For females, 25.0% of the subjects are in Group A, while 37.5% are in Group B. There is no significant difference in the sex distribution between the two groups (p=0.375). Majority of subjects in Group a (55.0%) are farmer, while in Group B, the largest group of subjects (25.0%) are housewives. Only 5.0% of subjects in Group A are involved in service, while 20.8% are in Group B. There is no significant difference in the distribution of subjects by occupation between the two groups (p=0.283). Shows that in Group A, 40.0% subject never went to school, 25.0% had a primary education, 25.0% had a secondary education, and 10.0% had a higher secondary education. In Group B, 20.8% subject never went to school, 50.0% had a primary education, 16.7% had a secondary education, and 12.5% had a higher secondary education. There is no significant difference in the distribution of subjects by educational level between the two groups (p=0.314). Group A, the majority (95.0%) had a monthly income below 50,000 TK. while a small proportion (5.0%) had an income between 50,000-100,000 TK. In Group B, a similar pattern was observed, with 91.7% having an income below 50,000 TK. One patient in Group B (4.2%) had a monthly income falling in the 50,000-100,000 TK. income range and another patient (4.2%) had a monthly income above 1,00,000 TK.

Table 3: Distribution of the study subjects by pre-operative risk factors between Group A (Hand-sewn) and Group B (Stapled) (N=44)

Risk factors	Group A (Hand-sewn) (n=20)	Group B (Stapled) (n=24)	p-value
Smoking	13(65.0%)	11(45.8%)	0.204 ^{ns}
White tobacco	3(15.0%)	3(12.5%)	0.810 ^{ns}
Betel nut	15(75.0%)	17(70.8%)	0.757 ^{ns}
Betel leaf	11(55.0%)	15(62.5%)	0.845 ^{ns}
Hot food	7(35.0%)	4(16.7%)	0.162 ^{ns}
Alcohol consumption	0(0.0%)	1(4.2%)	0.356 ^{ns}
Family history of malignancy	1(5.0%)	2(8.3%)	0.662 ^{ns}

Data were expressed as frequency and percentage, Chi-square was performed to compare between two groups, ns = not significant

Table-3 shows the distribution of study subjects by their personal habits was compared between Group A (Hand-sewn) and Group B (Stapled). In Group A, 13 subjects (65.0%) were smokers, 3 subjects (15.0%) used white

There is no significant difference in terms of monthly income between the two groups (p=0.650).

Table 2: Distribution of the study subjects by area of residence between Group A (Hand-sewn) and Group B (Stapled) (N=44)

Division's	Group A (Hand-sewn) (n=20)	Group B (Stapled) (n=24)	p-value
Dhaka	6(30.0%)	6(25.0%)	
Chittagong	1(5.0%)	1(4.2%)	
Rajshahi	2(10.0%)	1(4.2%)	
Mymensingh	1(5.0%)	1(4.2%)	
Sylhet	3(15.0%)	5(20.8%)	0.814 ^{ns}
Khulna	2(10.0%)	4(16.6%)	
Barishal	2(10.0%)	5(20.8%)	
Rangpur	2(10.0%)	0(0.0%)	
Cumilla	1(5.0%)	1(4.2%)	
Total	20(100.0%)	24(100.0%)	

Data were expressed as frequency and percentage, Chi-square was performed to compare between two groups, ns = not significant

Table-2 shows that in Group A, the largest proportion of subjects resided in Dhaka (30.0%), followed by Sylhet (15.0%), Khulna (10.0%), Barisal (10.0%), and Rangpur (10.0%). The remaining areas had smaller percentages ranging from 5.0% to 10.0%. In Group B, the highest proportion of subjects resided in Dhaka (25.0%), followed by Sylhet (20.8%), Barisal (20.8%), Stapled (16.6%), and Chittagong (4.2%). Rajshahi, Mymensingh, Comilla, and Rangpur had only one subject each (4.2% or 0.0%). There is no statistically significant difference in the distribution of study subjects by area of residence between the Hand-sewn (Group A) and Stapled (Group B) groups.

tobacco, 15 subjects (75.0%) consumed betel nut, 11 subjects (55.0%) used betel leaf, and 0.0% reported alcohol consumption, 5.0% had a family history of malignancy. and 7 subjects (35.0%) consumed hot food. In Group B, 11

subjects (45.8%) were smokers, 3 subjects (12.5%) used white tobacco, 17 subjects (70.8%) consumed betel nut, 15 subjects (62.5%) used betel leaf, and 4.2% reported alcohol consumption, 8.3% had a family history of malignancy and 4 subjects (16.7%) consumed hot food. The choice of hand-

sewn or stapled methods does not appear to be significantly associated with personal habits of smoking, white tobacco use, betel nut consumption, betel leaf use, consumption of hot food ($p>0.05$).

Table 4: Distribution of the study subjects by comorbid disease between Group A (Hand-sewn) and Group B (Stapled) (N=44)

Comorbid disease	Group A (Hand-sewn) (n=20)	Group B (Stapled) (n=24)	p-value
Diabetes mellitus	4(20.0%)	9(37.5%)	0.205 ^{ns}
Hypertension	3(15.0%)	2(8.3%)	0.488 ^{ns}
IHD	0(0.0%)	2(8.3%)	0.186 ^{ns}
COPD	3(15.0%)	5(20.8%)	0.617 ^{ns}

Data were expressed as frequency and percentage, Chi-square was performed to compare between two groups, ns = not significant

Table-4 shows the distribution of study subjects by comorbid diseases was compared between Group A (Hand-sewn) and Group B (Stapled). In Group A, 20.0% had diabetes mellitus, 15.0% had hypertension, 0.0% had ischemic heart disease (IHD) and 15.0% had chronic obstructive pulmonary disease (COPD) In Group B, 37.5%

had diabetes mellitus, 8.3% had hypertension, 8.3% had IHD and 20.8% had COPD. There were no significant association of study patients between Group A and Group B based on the presence of diabetes mellitus ($p=0.205$), hypertension ($p = 0.488$), IHD ($p = 0.186$) and COPD ($p=0.617$).

Table 5: Distribution of the study subjects by pre-operative histopathology findings between Group A (Hand-sewn) and Group B (Stapled) (N=44)

Histopathology findings	Group A (Hand-sewn) (n=20)	Group B (Stapled) (n=24)	p-value
Adenocarcinoma	8(40.0%)	10(41.7%)	
Squamous cell carcinoma	12(60.0%)	14(58.3%)	0.911 ^{ns}
Total	20(100.0%)	24(100.0%)	

Data were expressed as frequency and percentage, Chi-square was performed to compare between two groups, ns = not significant

Table-5 shows that in Group A, 40% of the subjects were diagnosed with adenocarcinoma, while 60% were diagnosed with squamous cell carcinoma. In Group B, the respective percentages were 41.7% for adenocarcinoma and 58.3% for

squamous cell carcinoma. There was no significant association between the two groups in terms of histopathology findings ($p=0.911$).

Table 6: Distribution of the study subjects by pre-operative anatomical site of involvement between Group A (Hand-sewn) and Group B (Stapled) (N=44)

Involved part	Group A (Hand-sewn) (n=20)	Group B (Stapled) (n=24)	p-value
Middle third	12(60.0%)	14(58.3%)	
Lower thirds	6(30.0%)	7(29.2%)	0.967 ^{ns}
Gastroesophageal junction	2(10.0%)	3(12.5%)	
Total	20(100.0%)	24(100.0%)	

Data were expressed as frequency and percentage, Chi-square was performed to compare between two groups, ns = not significant

Table-6 shows that in Group A, the majority of subjects had the site of growth in the middle third (60.0%), followed by the lower thirds (30.0%) and the gastroesophageal junction (10.0%). Similarly, in Group B, the majority had the site of growth in the middle third (58.3%), followed by the lower thirds (29.2%) and the gastroesophageal junction (12.5%). There was no significant difference in the distribution of anatomical sites between the two groups ($p=0.967$). Shows the distribution of study subjects by the surgical approach between Group A (Hand-sewn) and Group B (Stapled), comprising a total of 44 individuals.

In Group A, the majority of subjects had Ivor-Lewis procedure (60.0%), followed by the sweet procedure (40.0%). Similarly, in Group B, the majority had Ivor Lewis procedure (58.3%), followed by sweet procedure (41.7%). In Ivor Lewis procedure, 10 out of 12 patients (83.3%) in Group A underwent feeding jejunostomy while in Group B all patients (100%) underwent feeding jejunostomy. No patient in sweet procedure underwent feeding jejunostomy irrespective of Group A or Group B. Based on the surgical approaches, there were no significant differences between Group A and Group B ($p>0.05$).

Table 7: Comparison of operating time and anastomotic time for Ivor Lewis and Sweet procedure in between Group A (Hand-sewn) and Group B (Stapled) (N=44)

Procedure specific timing	Group A (Hand-sewn) (n=20)	Group B (Stapled) (n=24)	p-value
Ivor-Lewis procedure			
Operating time (min)	225.8±13.6	205.7±23.5	0.015 ^s
Anastomotic time (min)	29.1±3.48	19.6±3.0	<0.00 ^s
Sweet procedure			
Operating time (min)	197.5±16.0	179.5±12.3	0.016 ^s
Anastomotic time (min)	29.4±3.46	18.2±2.15	<0.001 ^s

Data were expressed as mean ± SD, Unpaired t-test was performed to compare between two groups, s = significant

Table-7 shows that in Group A, the operating time for Ivor-Lewis procedure and sweet procedure was reported as 225.8±13.6 minutes and 197.5±16 minutes respectively while in Group B, it was 205.7±23.5 minutes and 179.5±12.3 minutes respectively. Operating time was significantly lower in Group B compared to Group A ($p=0.015$ & 0.016). For the anastomotic time, Group A had

a mean time of 29.1±3.48 minutes for Ivor-Lewis procedure and 29.4±3.46 minutes for sweet procedure respectively, while Group B had a significantly lower mean anastomotic time of 19.6±3 minutes for Ivor Lewis procedure and 18.2±2.15 minutes for sweet procedure respectively. The anastomotic time was significantly shorter in Group B compared to Group A ($p<0.001$).

Table 8: Distribution of the study subjects by early post-operative outcomes and tumor resection margin findings between Group A (Hand sewn) and Group B (Stapled) (N=44)

Early postoperative outcomes	Group A (Hand- sewn) (n=20)	Group B (Stapled) (n=24)	p-value
ICU stay	0(0.0%)	0(0.0%)	-
Pneumonia/atelectasis	5(25.0%)	1(4.2%)	0.045 ^s
Wound infection	4(20.0%)	5(20.8%)	0.946 ^{ns}
Anastomotic leakage	2(10.0%)	1(4.2%)	0.445 ^{ns}
Prolong hospital stay	2(10.0%)	5(20.8%)	0.328 ^{ns}
Cardiac arrhythmia (AF/SVT)	7(35.0%)	4(16.7%)	0.162 ^{ns}
Starting of feeding through feeding jejunostomy			
3rd POD	8(90.0%)	11(78.6%)	0.795 ^{ns}
4th POD	2(10.0%)	3(21.4%)	
Chest drains removal			
7th POD	17(85.0%)	18(75.0%)	
8th POD	2(10.0%)	4(16.7%)	
10th POD	0(0.0%)	1(4.2%)	0.500 ^{ns}
21st POD	1(5.0%)	0(0.0%)	
28th POD	0(0.0%)	1(4.2%)	
Incomplete tumor margin resection	0(0.0%)	0(0.0%)	-
In-hospital mortality	1(5.0%)	2(8.3%)	0.662 ^{ns}

Data were expressed as frequency and percentage, Chi-square was performed to compare between two groups, ns = not significant, s = significant

Table-8 shows the early postoperative outcome between Group A (Hand sewn) and Group B (Stapled). In terms of ICU stay, none of the subjects in either group required ICU admission. Regarding specific postoperative outcomes, Group A had a higher incidence of pneumonia/atelectasis (25.0% vs. 4.2% in Group B) ($p=0.045$). However, there were no significant differences in the rates of wound infection, anastomotic leakage, or prolonged postoperative hospital stay between the two groups. Cardiac arrhythmia (AF, SVT) was findings 35.0% cases in Group A and 16.7% in Group B. No significant difference between two groups

regarding cardiac arrhythmia ($p=0.162$). For the starting of feeding through feeding jejunostomy, the proportions on the 3rd and 4th postoperative days (POD) were similar between Group A and Group B, with no statistically significant differences. In terms of chest drain removal, there were no significant differences in the timing of removal between the two groups. Both groups had no cases with incomplete histopathological tumor clearance. The in-hospital mortality rate was 5.0% in Group A and 8.3% in Group B, with no significant difference between the two groups.

Table 9: Comparison of per-operative and post-operative bleeding between Group A (Hand-sewn) and Group B (Stapled) (N=44)

Bleeding	Group A (Hand- sewn) (n=20)	Group B (Stapled) (n=24)	p-value
Per-operative bleeding (ml)	248.8±71.7	196.7±59.2	0.012 ^s
Postoperative bleeding (ml) (ICT+NG tube)	230.0±78.1	197.7±69.3	0.154 ^{ns}

Data were expressed as mean ± SD, Unpaired t-test was performed to compare between two groups, s = significant, ns = not significant

Table-9 shows that in terms of per-operative bleeding, Group A had a mean bleeding volume of 248.8±71.7 ml, while Group B had a significantly lower mean bleeding volume of 196.7±59.2 ml. Regarding postoperative bleeding, Group A had a mean bleeding volume of 230.0±78.1 ml, while Group B had a slightly lower mean

bleeding volume of 197.7±69.3 ml. Based on the analysis, Group B (Stapled) showed significantly lower preoperative bleeding compared to Group A (Hand-sewn) ($p=0.012$). However, there was no significant difference observed in postoperative bleeding between the two groups ($p=0.154$).

Table10: Comparison of per-operative and post-operative bleeding in Ivor-Lewis and Sweet procedure in between Group A (Hand-sewn) and Group B (Stapled) (N=44)

Bleeding related to specific surgical approach	Group A (Hand- sewn)(n=20)	Group B (Stapled) (n=24)	p-value
Per-operative bleeding(ml)			
Ivor-Lewis procedure	262.1±66.1	195.7±53.0	0.009 ^s
Sweet procedure	228.8±79.5	198.0±70.1	0.396 ^{ns}
Postoperative bleeding (ml)			
Ivor-Lewis procedure	230.8±70.5	212.5±78.8	0.541 ^{ns}
Sweet procedure	228.8±93.6	177.0±49.9	0.151 ^{ns}

Data were expressed as mean ± SD, Unpaired t-test was performed to compare between two groups, s = significant, ns = not significant

Table-10 shows that in Group A, the Per-operative bleeding (ml) for Ivor-Lewis procedure and sweet procedure was reported as 262.1±66.1 ml and 228.8±79.5 ml respectively while in Group B, it was 195.7±53.0 ml and 198.0±70.1 ml respectively. Per-operative bleeding (ml) was significantly lower in Group B compared to Group A for Ivor-Lewis procedure ($p=0.009$). Peroperative bleeding for sweet procedure and post-operative bleeding for both procedure between group A and group B were not statistically significant ($p>0.05$).

Discussion

Esophagogastrectomy with esophagogastrostomy is the mainstay of treatment for operable esophageal cancer patient. So, after gastric fashioning and conduit preparation esophagogastric anastomosis is done either by hand-sewn or by mechanical circular device. The hand-sewn depends more on the surgeon's expertise and certainly is cheaper than stapled anastomosis^[11]. In our study, we presented the data of 44 patients who underwent surgery for carcinoma esophagus with intrathoracic anastomosis in Group A, we included 20 hand-sewn patients and in Group B, we included 24 stapled patients. Patients were grouped on the basis of surgeons preferences and patients ability to bear the cost. Age of the patients in our study population ranged 40 to 79 years with a mean age of 60.9±7.5 for group A and 57.3±9.47 years for Group B, which was not statistically significant ($p=0.180$) and similar to other studies^[14,16]. This may be related to the fact that carcinoma esophagus is more common in elderly patients. In our study the male predominates in both groups. In hand-sewn group, 75.0% of the patients were male, while in stapled group, 62.5% of the patients were male. For females, 25.0% of the patients were in hand-sewn group, while 37.5% were in stapled group. So, in hand-sewn group and stapled group, male-female ratio was statistically insignificant ($p=0.375$). In another study in northeast India in 2021 found that among 45 patients who underwent carcinoma esophagus surgery 75% were male and 25% were female in hand-sewn group and 73% were male and 27% were female in stapled group^[6]. The majority of cases were male patients (88% males and 12% females) in another study by Borggreve, A.S *et al.* 20 these data correlate with our study. In our study, majority of patients were farmer in both group, 11 (55%) & 08 (33%) respectively. Next occupation was housewife, 03 (15%) & 06 (25%) respectively. There was no significant difference ($p=0.283$) in the distribution of patients by occupation between the two groups. Different epidemiological study suggest squamous cell carcinoma of esophagus is the diseases of poor socioeconomic status people of least developed countries^[1, 17]. In our study, largest proportion of patients were resided in Dhaka division (30% and 25% respectively) and next were Sylhet (15% and 20.8% respectively) and Barisal (10% and 20.8% respectively). There was no statistically significant difference ($p=0.814$) in the distribution of patients by area of residence between the two groups. In our study, majority of patients (40%) never went to school in hand-sewn group, on the other hand, majority of patients (50%) receive primary education in stapled group. There was no statistically significant difference ($p=0.314$) between the two groups considering educational level. Majority of the patient's monthly income was below 50,000 taka, 95% and 91.6% in hand-sewn group and stapled group, respectively. Only one patient from each

group, monthly income ranged 50000 to 100000 taka. One patient in stapled group, monthly income exceeds one lac taka. There was no statistically significant difference ($p=0.650$) in terms of monthly income between the two groups. These data indicate that we dealt with lower- and middle-income group of patients in our hospital. It also indicates that carcinoma of esophagus is the diseases of poor socio-economic status people. In our study, in hand-sewn group, 13 patients (65.0%) were smokers, 3 patients (15.0%) used white tobacco, 15 patients (75.0%) used betel nut, 11 patients (55.0%) used betel leaf, and 7 patients (35.0%) used hot food. In stapled group, 11 patients (45.8%) were smokers, 3 patients (12.5%) used white tobacco, 17 patients (70.8%) used betel nut, 15 patients (62.5%) used betel leaf, 1 patient reported alcohol consumption and 4 patients (16.7%) consumed hot food. Consumption of tobacco and other related products are independent risk factors for carcinoma esophagus^[18, 19].

In our study, these findings were not statistically significant in between the two groups. One patient from hand-sewn group and 02 patients from stapled group had family history of malignancy. These findings were not statistically significant between the two groups. Different epidemiological studies support these data as a risk factor for carcinoma esophagus^[1, 20, 17]. Among the 44 patients of both groups, 28 patients had different co-morbidities. In hand-sewn group, 04 patients had diabetes mellitus, 03 patients had hypertension, 03 patients had ischemic heart disease (IHD) and 03 patients had chronic obstructive pulmonary disease (COPD). In stapled group, 09 patients had diabetes mellitus, 02 patients had hypertension, 02 patients had IHD and 05 patients had COPD. As the carcinoma esophagus patients were mostly elderly, so the comorbid conditions were more prevalent in these patients. Different comorbid condition influence surgical outcome in elderly patients especially considering anastomotic techniques but, in our study, there were no statistically significant difference in both groups regarding comorbid conditions ($p>0.05$). Similar results were seen in a study done by Kuwano H *et al* and Grimm JC *et al*^[4, 5].

In our study, pre-operative histopathology report showed that in hand-sewn group, 08 patients were diagnosed as adenocarcinoma, while 12 patients were diagnosed as squamous cell carcinoma (40% vs 60%). In stapled group, 10 patients were diagnosed as adenocarcinoma and 14 patients were diagnosed as squamous cell carcinoma (41.7% vs 58.3%). But comparing the hand-sewn group and stapled group, there were no statistically significant difference in squamous cell carcinoma and adenocarcinoma ($p=0.911$). A study conducted by Grimm JC *et al.*, showed that squamous cell carcinoma was more prevalent (65%) than adenocarcinoma (35%) in that study^[5]. These findings were consistent with our study.

In our study, regarding the site of growth in pre-operative endoscopy, in hand sewn group, the majority of patients had the site of growth in the middle third 12 (60.0%), followed by the lower thirds 06 (30.0%) and the gastroesophageal junction 02 (10.0%). Similarly, in stapled group, the majority of patients had the site of growth in the middle third 14 (58.3%), followed by the lower thirds 07 (29.2%) and the gastroesophageal junction 03 (12.5%). Overall growth was in the middle third of the esophagus. Laterza E *et al.* showed in their study, the predominant lesion was in the middle third followed by lower third and

gastroesophageal junction (55, 30% and 5%). In their study, 10% patients' growth was in the upper third. Apart from upper third growth, other findings were consistent with our study^[16].

Surgical approach was decided by the pre-operative site of growth. Statistical analysis showed that surgical approach between the two groups were statistically insignificant ($p>0.05$). One study conducted by Wang J *et al.* and another study conducted by Feng Y *et al.*, showed that surgical approach did not affect the postoperative outcomes regarding anastomotic technique^[8,21].

In our study, we performed feeding jejunostomy only in Ivor-Lewis procedure, depending on the patient's comorbidity and to ensure enteral nutrition. In Ivor Lewis procedure, 10 out of 12 patient (83.3%) in hand-sewn group underwent feeding jejunostomy while in stapled group all patients (100%) underwent feeding jejunostomy. In Sweet procedure, we did not perform any feeding jejunostomy. In that case, we managed the patient with total parenteral nutrition and non-oral medication. Based on the feeding jejunostomy done in Ivor-Lewis procedure, there were no significant differences between two groups ($p>0.05$). In one study done by Kim MS *et al.*, suggested that feeding jejunostomy should be reserved only for the exceptionally selected cases with multiple high risk factors in patients who undergoing Ivor-Lewis procedure. Indications for feeding jejunostomy was advanced stage, malnutrition, concurrent stomach cancer and obligatory postoperative oral medication^[22].

But they did not consider the anastomotic technique in their study. In our study, in hand-sewn group, the operating time was reported as 220.3±20.42 minutes, while in stapled group, it was 205.0±25.7 minutes. Operating time was significantly lower in stapled group compared to hand-sewn group ($p=0.038$). For the anastomotic time, hand-sewn group had a mean time of 29.2±3.38 minutes, while stapled group had a significantly lower mean time of 19.04±2.73 minutes ($p<0.001$). One meta-analysis conducted by Castro *et al.*, showed that the stapled group required less operating time when compared with hand-sewn group^[7]. In another Meta-analysis of esophagogastric anastomosis by Deng XF *et al.* in China which includes Fifteen documents and 3203 patients ($n = 2027$ stapled and $n = 1176$ hand-Sewn) showed that operating time (210.3±18.42 for hand-sewn VS 202.5 ±13.42 for stapled) and anastomotic time (24.2±4.38 for hand-sewn vs 17.2±4.38 for stapled) were significantly lower in stapled group^[23].

Both study findings were similar to our study. In our study, hand-sewn group, the operating time for Ivor-Lewis procedure and Sweet procedure was reported as 225.8±13.6 minutes and 197.5±16 minutes respectively while in stapled group, it was 205.7±23.5 minutes and 179.5±12.3 minutes respectively. Operating time was significantly lower in stapled group compared to hand-sewn group ($p=0.015$ & 0.016). For the anastomotic time, hand-sewn group had a mean time of 29.1±3.48 minutes for Ivor-Lewis procedure and 29.4±3.46 minutes for Sweet procedure respectively, while stapled group had a significantly lower mean anastomotic time of 19.6±3 minutes for Ivor-Lewis procedure and 18.2±2.15 minutes for Sweet procedure respectively. The anastomotic time was also significantly shorter in stapled group compared to hand-sewn group ($p<0.001$). In a Meta-analysis of esophagogastric anastomosis by Deng XF *et al.*, in China which includes

Fifteen documents and 3203 patients ($n=2027$ stapled and $n=1176$ Hand-Sewn) showed that operating time (210.3±18.42 for hand-sewn vs 202.5 ±13.42 for stapled) and anastomotic time (24.2±4.38 for hand-sewn vs 17.2±4.38 for stapled) minutes were significantly lower in stapled group^[23]. These findings were also similar to our study. In our study, in terms of ICU stay, none of the patients in either group required ICU admission. In a study done in northeast India by Purkayastha *et al.*, showed that both groups need ICU stay, 4.25 and 2.8 days respectively. These data are not consistent with our study^[6].

Five patients in hand-sewn group and 01 patient in stapled group suffered from pulmonary complications. These findings were statistically significant ($p=0.045$). All of these cases recovered well with proper antibiotics, chest physiotherapy and supporting medications. Six primary studies by Castro *et al.* analyzed the pulmonary complications outcome. The incidence of pulmonary complications was 27, 90% in the stapled group (77 of 276 patients) and 19, 56% in the hand-sewn group (54 of 276 patients). The stapled increased the absolute risk of pulmonary complications in 8% patients^[24].

Perhaps pulmonary complications in our study were related to more operating time in hand-sewn group. In our study, 04 patients in hand-sewn group and 05 patient in stapled group suffered wound infection. But the findings were not statistically significant between the two groups ($p>0.05$). Kolokotronis *et al.* showed no significant differences in wound infection (0.2% vs 0.3%) irrespective of anastomotic techniques^[10].

In our study, regarding the anastomotic leakage, we found 02 leakages in handsewn group and 01 leakage in stapled group. All 03 leakage were suspected clinically 3rd to 6th POD and then confirmed by dye test & radiologically. From statistical points of view, there were no significant differences in the rates of anastomotic leakage between the two groups. ($p=0.445$). In a study conducted in Thailand by Luechakietisak P *et al.*, they found 04 leakages in handsewn group ($n=58$) patients, while 02 leakages in stapled group ($n=59$), which were statistically insignificant^[9].

In another study done by Deng XF *et al.* Metaanalysis of esophagogastric anastomosis revealed that there were statistically significant difference in anastomotic leakage in case of cervical anastomosis between hand-sewn group and stapled group but no differences were found in thoracic anastomotic leakage whether it was done by hand-sewn or stapled (13 anastomotic leakage in 221 stapled group patient vs 3 anastomotic leakage in 66 hand-sewn group patient)^[23]. These results were similar to our findings. According to Price *et al.*, anastomotic leakage were four types. These are radiological, clinical minor, clinical major and conduit necrosis^[25].

As our all 03 anastomotic leakage cases were clinical minor variety so we treated all 3 (two in Ivor-Lewis & one in Sweet procedure) anastomotic leakage patient conservatively with total parenteral nutrition, appropriate antibiotics and chest tube drainage along with feeding through feeding jejunostomy in selected cases. However, among 3 patients, 2 died on 2st and 28th POD respectively and another one survived beyond 30 days. In our study, 02 patients in hand-sewn group and 05 patients in stapled group required hospital stay for more than 14 days. Wound infection and anastomotic leakage were responsible for this.

So, prolonged post-operative hospital stays between the two groups were statistically insignificant. ($p=0.328$). Two randomized trials by Saluja S *et al* and Zhang YS *et al.*, for esophagogastric anastomosis also found that prolonged postoperative hospital stay was not associated with anastomotic techniques [1, 26].

In the present study, 07 (35%) patients in hand-sewn group and 04 (16.7%) patients in stapled group suffered from cardiac arrhythmia (AF or SVT). No significant difference between two groups regarding cardiac arrhythmia were found ($p=0.162$). In a study, Craig, S.R *et al.*, they found cardiac arrhythmia were very common (overall incidence was 19%) in carcinoma esophagus surgery especially for lower third growth resection [27].

In another study done by Luechakiettsak P *et al.*, 16.9% hand-sewn patient suffered from cardiac arrhythmia compared to 18.9% stapled patient [23]. We treated all cardiac arrhythmia cases by careful observation of hemodynamic stability and antiarrhythmic drugs in appropriate cases. In terms of chest drain tube removal, there were no significant differences in the timing of removal between the two groups. One patient from hand-sewn group, chest drain tube removal was done in 21st POD and another patient from stapled group chest drain tube removal was done in 28th POD after their death on the respective day. Multiple study showed that chest drain tube removal was done in 7th or 8th POD after test feed irrespective of hand-sewn or stapled anastomosis [28, 29]. In our study patients, both groups had no cases with incomplete resection of tumor margin. Okuyama *et al.* showed that, tumor negative margin was strongly associated with good anastomotic outcome irrespective of anastomotic techniques [29].

In our study, the in-hospital mortality rate was 5.0% (01patient) in hand-sewn group and 8.3% (02 patients) in stapled group, with no statistically significant difference between the two groups ($p=0.662$). One patient in hand-sewn group died on 21st POD due to complications from anastomotic leakage which was diagnosed on 5th POD clinically and then by test feed. Two patients in stapled group died, 01 from sudden cardiac arrest in 1st POD during shifting to ward and another from complications of anastomotic leakage on 28th POD. In a study in Thailand, 30-day mortality was 11.8% in hand-sewn group and 10.3% in stapled group. There were no significant differences in mortality between hand sewn group and stapled group [23]. Another study showed that in hospital mortality rate was similar (0% in both group) between hand-sewn and stapled anastomotic group [29].

All these study findings were similar to our study findings. In our study, regarding per-operative bleeding, hand-sewn group had a mean bleeding volume of 248.8 ± 71.7 ml, while stapled group had a significantly lower mean bleeding volume of 196.7 ± 59.2 ml ($p=0.012$). Regarding post-operative bleeding, hand-sewn group had a mean bleeding volume of 230.0 ± 78.1 ml, while stapled group had a slightly lower mean bleeding volume of 197.7 ± 69.3 ml ($p=0.154$). In one study in Germany in 2021, they found significant differences in blood loss between two groups; average per-operative blood loss for hand-sewn group was 300ml while 200 ml for stapled group [10]. In another study in India Purkayastha M *et al.* postoperative average blood loss was

362 and 360 ml in hand-sewn and stapled groups respectively [6].

These findings are also consistent with our findings. In our study, more blood loss in hand-sewn group was related to more anastomotic time and bleeding from esophageal and gastric anastomotic margin during this period. In our study, in hand-sewn group, the per-operative bleeding for Ivor-Lewis procedure and Sweet procedure was reported as 262.1 ± 66.1 ml and 228.8 ± 79.5 ml respectively while in stapled group, it was 195.7 ± 53.0 minutes and 198.0 ± 70.1 minutes respectively. Per-operative bleeding (ml) was significantly lower in stapled group compared to hand-sewn group for Ivor Lewis procedure ($p=0.009$). This was because of two stage operation in Ivor Lewis procedure caused more bleeding. Also we did feeding jejunostomy in most of the Ivor-Lewis procedure. Per-operative bleeding for Sweet procedure and post-operative bleeding for both procedure between hand-sewn group and stapled group was not statistically significant as it is a single stage procedure. ($p=0.541$ & 0.151). STROBE compliant study which included 325 Ivor-Lewis cases and 299 Sweet procedure, done by Wang j *et al.*, they found no difference in mean bleeding between Ivor-Lewis procedure and Sweet procedure (mean bleeding 300 ml in both cases) [8]. These findings are not consistent with our study as because in STROBE compliant study anastomotic methods were not considered.

Conclusion

Hand-sewn and stapled anastomosis had no statistically significant difference in early outcomes regarding anastomotic leakage, cardiac arrhythmia, ICU stay, and post-operative hospital stay and in-hospital mortality. Only statistically significant difference was found in terms of less operating time, anastomotic time, per-operative bleeding and pulmonary complications in stapled group. So, the present study suggested that overall, both methods can be applied for esophagogastric anastomosis.

Limitations of the study

- Randomization of the sample was not done.
- Sample size was small.
- The study was conducted in a single center.
- Long-term follow-up was beyond the scope of this study.

Recommendations

- Hand-sewn and stapled anastomosis are equally effective in esophagogastric anastomosis.
- In Bangladesh with limited resources, hand-sewn anastomosis can be a good option for poor patient.
- Stapled anastomosis is quicker, safer and less time consuming so it can be done to reduce operating time and perioperative blood loss.

Funding

No funding sources.

Conflict of interest

None declared

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How to Cite This Article

Sawon MH, Alam MK, Haque SA, Salekin MS, Islam MRA, Das D, Mursalin G. Early outcome of stapler versus hand-sewn intrathoracic esophagogastric anastomosis for carcinoma esophagus. *International Journal of Cardiology Sciences*. 2023;5(2):29-39.

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