Immediate Post-Operative Outcomes of Stapled and Hand Sewn Techniques during Oesophagogastronomy: A Randomized Clinical Trial

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Abstract

Background: Oesophagogastronomy is a very crucial surgical management. Objective: The purpose of the present study was to observe the immediate post-operative outcomes of stapled and hand sewn techniques during oesophagogastronomy. Methodology: This single centre, parallel randomized clinical trial was conducted in the Department of Thoracic Surgery at National institute of Diseases of the Chest and Hospital, Dhaka, Bangladesh from January 2011 to December 2011 for a period of one year. Prior to commencement of this study the study protocol was approved by the thesis committee of NIDCH. Patients were purposefully selected from different surgery ward of NIDCH irrespective of age and sex of patients for the study. Patients were divided into two groups designated as group A and B. Stapled oesophago gastric anastomosis was performed in group A and hand sewn anastomosis was done in group B. Immediate post-operative complication were recorded. Result: A total of 60 patients of oesophageal or gastric cardia carcinoma were recruited for this study. Of them 32 cases were assigned to Stapler method and 28 cases to Hand-sewn method of oesophagogastronomy. The mean age of the patients of group A and group B were 56.1±12.7 years and 55.3±8.3 years respectively. Regarding blood loss during operation, the table shows that in group A mean + SD were 430.4±63.2 ml and in group B mean + SD were 529.6±86.9 ml. In one stage operation in group A it was mean + SD i.e. 362.2±38.3 ml and in group B it was mean + SD 529.6±86.9 ml. In two stage operation in group A it was mean 466.2±39.7 ml and in group B it was mean ± SD 585.6±62.2 ml. Respiratory complication developed in 9.4% of the patients in group A and 17.9% patients in group B. Cardiac complication developed in 3.1% of the patients in group A and 7.1% of patients in group B. Wound infection developed in 12.5% of the patients in group A and 10.7% of the patients in group B. Conclusion: In conclusion most of the immediate anastomotic complications are less in stapled anastomotic technique than hand sewn technique. [Journal of National Institute of Neurosciences Bangladesh, 2020;6(1):43-47]

Keywords: Immediate; post-operative outcomes; stapled and hand sewn techniques; oesophagogastronomy

Introduction

Surgical excision was previously considered as the main method for treating gastrointestinal (GI) tumors¹. Anastomotic procedure is one of the key factors determining surgical success. Hand-sewn and stapled sutures comprise the major anastomotic methods in clinical practice of GI surgeries. Oesophagogastronomy is performed for different surgical conditions of oesophagus². There are different methods of oesophagogastronomy. In transhiatal method, extirpation of the intrathoracoic esophagus is done without a thoracotomy, and advancement of the oesophageal substitute, usually a greater curvature gastric tube is performed to the neck for reconstruction³. The standard transthoracic oesohagogastrctomy is

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the most widely performed operation for cancer of the oesophagus worldwide\(^6\). This procedure can be carried out by a right or left thoracotomy depending on the preference of the surgeon and the localization of the tumour within the oesophagus. Generally a right thoracotomy is required for adequate exposure of tumours in the middle or upper third that are anatomically intimately related to the membranous trachea or the arch of the aorta. Tumours located at the gastrooesophageal junction or in the lower third of the oesophagus can usually be approached through a left thoracotomy incision combined with a left phrenotomy or, alternatively, with a left thoracoabdominal incision\(^7\).

The surgical treatment of esophageal cancer remains controversial\(^8\). For example, various reconstructive options are available after esophagectomy for esophageal cancer. These options depend on the reconstructed organ (stomach, colon, or small intestine), characteristics of the esophageal conduit (whole stomach or thin gastric roll, jejunum or ileum, or left or right colon), location of anastomosis (cervical or thoracic), anastomotic method (hand-sewn or stapled), route of reconstruction (antethoracic, retrosternal, or postmediastinum). Of these factors, the anastomotic technique is obviously one of many variables that can affect the operative morbidity or postoperative course. In fact, hospital deaths after esophagectomy are related to postoperative impediments, such as pulmonary complications and anastomotic leakage\(^9\). Therefore, much effort has been devoted to reducing the occurrence of anastomotic leakage. This present study was undertaken to observe the immediate post-operative outcomes of stapled and hand sewn techniques during oesophagogastrostomy.

**Methodology**

**Study Population and Settings:** This single centre, parallel randomized clinical trial was conducted in the Department of Thoracic Surgery at National institute of Diseases of the Chest and Hospital, Dhaka, Bangladesh from January 2011 to December 2011 for a period of one year. Prior to commencement of this study the study protocol was approved by the thesis committee of NIDCH. All patients were informed about the study. Patients were purposefully selected from different surgery ward of NIDCH irrespective of age and sex of patients for the study. All the patients having carcinoma of oesophagus at the lower two third irrespective of age and sex undergoing surgery were included as study population. Patients having carcinoma in upper one third of oesophagus or having advanced stage (i.e. inoperable) of carcinoma of oesophagus were excluded from this study.

**Randomization and Blinding:** Patients were divided into two groups by computer generated simple random sampling technique into two groups designated as group A and B.

**Allocation:** Stapled oesophago gastric anastomosis was performed in group A and hand sewn anastomosis was done in group B. One-stage operation was carried out for the lesions in the lower third of oesophagus and at the oesophagogastric junction. Two-stage operation was carried out for the lesions in the middle third of oesophagus. The linear stapler was used to resect the diseased portion of the stomach and at the same time to anastomose the cut margins of it. The circular one was used for anastomosis between the oesophagus and the anterosuperior surface of the stomach.

**Follow up and Outcome Measures:** Approximate blood loss was also measured in both groups of patients in the two separate techniques and recorded. Techniques used for measuring blood loss were traditional methods. The methods were weighing swabs (mops and gauges) before and after soaking by blood. Lost blood in the operative field was sucked into a measuring jar and amount of blood was measured in this way.

**Statistical analysis:** Collected data were expressed as mean ± SD and mean ± SE. The effect of variables were analyzed using standard statistical method using SPSS. Data were recorded including patient's demographic details, hospital resource utilization, length of stay and other measures of variables. Student pair (t) test was used. A value of ‘p’ is equal to or <0.05 was considered to be significant.

**Results**

A total of 60 patients of oesophageal or gastric cardia carcinoma were recruited for this study. Of them 32 cases were assigned to Stapler method and 28 cases to Hand-sewn method of oesophagogastrostomy. The mean age of the patients of group A and group B were 56.1 ± 12.7 years and 55.3 ± 8.3 years respectively (Table 1).
esophagogastrectomy is performed for different surgical conditions of oesophagus. Stapled sutures comprise the major anastomotic technique for reconstruction.

Introduction

Surgical excision was previously considered as the mainstay of treatment for cancer of the oesophagus. Two-stage operation was carried out by a right or left thoracotomy depending on the location of the tumour. This operation was associated with a high mortality rate, with causes such as complications related to the thoracic cavity. The one-stage operation has been carried out traditionally by a median sternotomy, and ileal interposition was performed in the case of a very low thoracic tumour. The most widely performed operation for cancer of the oesophagus is oesophagogastrectomy with oesophagogastrostomy. This operation is considered to be superior to the other types of surgery, but it is associated with a high rate of anastomotic leakage and postoperative pulmonary complications. Many studies have been carried out to determine which of the methods is more effective, but the results are contradictory.

In group A, one stage operation was performed in 34.4% and two stage operation was performed in 65.6% cases. In group B, it was 42.9% and 57.1% for one stage and two stage operation respectively (Table 2).

Regarding blood loss during operation, the table shows that in group A mean ± SD were 430.4 ± 63.2 ml and in group B mean ± SD were 529.6 ± 86.9 ml. In one stage operation in group A it was mean ± SD i.e. 362.2 ± 38.3 ml and in group B it was mean ± SD 529.6 ± 86.9 ml. In two stage operation in group A it was mean 466.2 ± 39.7 ml and in group B it was mean ± SD 585.6 ± 62.2 ml. Duration of operation shows that in group A mean ± SD were 204.6 ± 39.3 min. In group B it was mean ± SD 251.7 ± 36.3 min. In group A (one stage) mean ± SD were 167.2 ± 9.9 min while in group B it was mean ± SD were 212.5 ± 8.6 min. In group A (two stage) mean ± SD were 224.3 ± 26.1 min while in group B it was 281.2 ± 12.7 min. (Table 3).

Table 3: Distribution of patients by type of operation performed

| Type of Operation | Group A | Group B | P value |
|-------------------|---------|---------|---------|
| One stage         | 11(34.4)| 12(42.9)|         |
| Two stage         | 21(65.6)| 16(57.1)| 0.500   |
| Total             | 32(100.0%) | 28(100.0%)|         |

In the present study, 60 patients of the oesophageal cancer patients in Bangladesh are considered. Nelson14 studied a total of 113 cases with a diagnosis of carcinoma oesophagus and carcinoma cardia. Later, Kabir 13 carried out a study in NIDCH where it has been demonstrated that the age at the time of surgery may be different for carcinoma oesophagus. This is in line with the findings of the present study which showed that the age at the time of surgery was 55.3 ± 8.3 years in group A and 55.3 ± 8.3 years in group B. In the current series, the lowest and highest ages were 25 years and 65 years, respectively. All of these were consistent with the age distribution of the observed patient population.

Wound infection developed in 12.5% of the patients in group A and 10.7% of the patients in group B. Anastomotic leakage developed in 3.1% and 10.7% of the patients in group A and group B respectively. Reoperation for bleeding was done in one (3.6%) patients in group B. The average hospital stay was 13.4 days in group A and 13.7 days in group B (p = 0.696). Two patients in each group died during their hospital stay (Table 4).

Table 4: Distribution of patients by in-hospital complications between groups

| Variables of morbidity | Group A | Group B | P value |
|------------------------|---------|---------|---------|
| Respiratory complication* |         |         |         |
| Yes                    | 3(9.4)  | 5(17.9) | 0.280   |
| No                     | 29(90.6)| 23(82.1)|         |
| Cardiac complication*  |         |         |         |
| Yes                    | 1(3.1)  | 2(7.1)  | 0.449   |
| No                     | 31(96.9)| 26(92.9)|         |
| Anastomotic leakage*   |         |         |         |
| Yes                    | 1(3.1)  | 3(10.7) | 0.257   |
| No                     | 31(96.9)| 25(89.3)|         |
| Re-operation for bleeding* |       |         |         |
| Yes                    | 0(0.0)  | 1(3.6)  | 0.467   |
| No                     | 32(100.0)| 27(96.4)|         |
| Hospital stay# (days)  |         |         |         |
| 13.4 ± 3.5             |         |         |         |
| Mortality before discharge* |     |         |         |
| Yes                    | 2(6.3)  | 2(7.1)  | 0.641   |
| No                     | 30(93.7)| 26(92.9)|         |

*Data were analysed using Fisher’s Exact Test.

Discussion

Oesophageal cancers are highly lethal neoplasm having a poor prognosis. Despite advances in multimodality therapy, 5 year survival generally remains less than 10% cases. But in spite of the operative risks, surgery remains the primary mode of therapy for carcinoma of the oesophagus & oesophagogastrointestinal junction because of the poor cure rate and persistence of symptoms after therapy with other modalities.

In Bangladesh there are some studies regarding oesophageal carcinoma which have been done previously but unfortunately there is no study regarding comparison of outcome of oesophagogastrostomy after oesophagogastrectomy between stapler and hand sewn techniques.
tumors. Anastomotic procedure is one of the key surgical methods in clinical practice of GI surgeries. Stapled sutures comprise the major anastomotic surgical conditions of oesophagus. There are advancement of the oesophageal substitute, usually a transhiatal method, extirpation of the intrathoracic oesophagus worldwide. This procedure can be performed for the lesions in the lower third of the oesophagus and cardia. The blood loss in our study is almost equal in stapling group but little less in hand sewn group than that of the above mentioned study.

In this study, the mean age of the subjects was 56.1±12.7 years in group A and 55.3±8.3 years in group B. The lowest and highest ages were 25 years and 71 years respectively. A total of 41 patients (68.3%) were in between 51 to 60 years. Bruni and Nelson studied a total of 113 cases with a diagnosis of carcinoma of the esophagus and cardia and it showed that most of them were between 50 to 70 years of age. More recently Karl et al collected data of 143 patients who underwent oesophageal resection for cancer of the esophagus and oesophagogastric junction and demonstrated that the age at the time of surgery averaged 63.7 years, ranging from 33 years to 83 years. All of these were consistent with the age distribution of the current series.

In this study, 37 (61.67%) patients underwent two stage oesophagogastrectomy with oesophagogastrostomy (both group A and group B) while the rest of the patients, 23 (28.33%) cases experienced one stage operation (both groups). Type of operation performed was depended on the site of lesion. One stage operation was done for the lesion in the lower third and cardia while two stage operations was for the lesions in the middle third. Kabir in his study showed that the number of one stage operation done was 23 (48.93 %) and number of two stage operation done was 24 (51.10%) which is almost equal. However, on the contrary in our study two stage operations were done more frequently. Malcolm et al reported in their study that 61% underwent a left oesophagogastrectomy (one stage operation) and 37% cases two-stage operation. However, staging is not mandatory to be compared as most of the patients had middle third lesion and so we had to choose the two stage operations it is dependent on the site of lesion.

Blood loss during operation in one stage operation was 362.2±38.3 ml in group A while 454.9± 51.4 ml in group B. In two stage population, 466.2 ± 39.7 ml in group A and 585.6±62.2 ml in group B. In another word, average blood loss in group A is 430.6 ± 63.2 ml in comparison with 529.6±86.9 ml in group B. Shanda et al (2007) showed that an estimated blood loss in group A was 435 ±240 ml while 640=350 ml in group B. The blood loss in our study is almost equal in stapling group but little less in hand sewn group than that of the above mentioned study.

This present study demonstrates that among the post-operative complication, respiratory complication was the commonest one; i.e. in 8 patients (13.33%, n=60). Of these 3 patients (9.4%, n=32) belong to group A and 5 patients (17.9%, n=28) belong to group B. Respiratory complications include respiratory failure, pleural effusion, pneumothorax, atelectasis and pneumonitis. Out of these 8 patients, 3 patients needed ventilator support, 2 of them died (one from each group). The next common complication was found wound infection, 7 patients (11.67%, n=60) had suffered from this complication. Of these, 4 patients (12.5%, n=32) belong to group A and 3 patients (10.7%, n=28) belong to group B. The most grave complication was anastomotic leakage, 1 patient (3.1%, n=32) in group A and 3 patients (10.7%, n=28) in group B. 2 patients died (one from each group) from this complication due to intractable mediastinitis. 1 patient (3.1%, n=32) from group A and 2 patients (7.1%, n=28) from group B developed cardiac complication, who were treated conservatively but no casualty happened from this complication. Re operation had to be done in I case (3.1%, n=28) for bleeding who belongs to group B. Hospital stay for group A was 13.4±3.5 days whereas 13.7±2.2 days for group B. There was no gross difference between the groups regarding hospital stay. Mortality before discharge was 4 patients (6.7%, n=60) due to respiratory complication and anastomotic leakage which have already been discussed earlier. Two patients in each group died of these complications. In the study by Kabir, 13 (27.7%) patients had respiratory complications, 5 (10.6%) had anastomotic
leakage and 5(10.6%) had gross electrolyte imbalance. Total number in-hospital death was 11 (31.4%). Our data of respiratory complications and anastomotic leakage are almost similar to him but we had a lesser death rate. Zhang et al11 showed that anastomotic leakage in group A was 6 (2.2%) and 1 (0.4%) in group B. They also showed that 30 day post-operative mortality was 7 (2.6%) in group A and 3 (1.2%) in the group B. This finding is mildly less than that of our findings i.e. 6.25% in group A and 7.14% in group B. But in the previous study, death rate was much more than that of our study. The overall lower rates of anastomotic leaks, respiratory complications, cardiac complications are found in the group A than that of group B. But wound infection was slightly more in group A than that group B.

The rate of anastomotic leakage of the anastomosis between the remnant cervical esophagus and esophageal substitute is higher than that of other type of gastrointestinal anastomosis. To date, many studies have compared the anastomotic complication of the hand-sewn or stapled anastomosis. Zhu et al16 reviewed the major outcomes of the nonrandomized or randomized control trials of esophagogastric anastomosis after esophagectomy for esophageal cancer. In this review, several reports of nonrandomized studies described a decreased rate of anastomotic leakage with stapled anastomosis compared to hand-sewn anastomosis. However, none of the randomized control trials reported statistically significant differences in the rate of anastomotic leakage, which varied depending on the reconstructed organs, approach, or anastomotic technique.

Conclusion
In conclusion most of the immediate anastomotic complications are less in stapled anastomotic technique than hand sewn technique. Furthermore the cardiorespiratory complications are also less in number in stapled technique. Even wound infection is also few in number in stapled technique. Large scale study should be performed to see the real scenario.

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