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Stapled versus hand-sewn cervical esophagogastric anastomosis in patients undergoing esophagectomy: A Retrospective Cohort Study

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HIGHLIGHTS

- We analyzed & compared the outcomes of cervical esophagogastric anastomosis between hand sewn and partial side to side stapled technique.
- Both hand sewn and stapled techniques are equally effective way of performing a cervical esophagogastric anastomosis.
- Anastomotic leak results in anastomotic stricture more often with hand-sewn anastomosis than stapled.

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ABSTRACT

Introduction: Anastomotic leak is one of the main causes of morbidity following esophageal resection for carcinoma of the esophagus and gastroesophageal junction. We compared hand sewn and stapled cervical esophagogastric anastomotic techniques in terms of postoperative complications.

Methods: All patients who underwent esophagectomy with cervical esophagogastric anastomosis at a single academic center from 2004 to 2014 were included in the study. Both early and late complications were analyzed.

Results: 153 patients underwent resection for carcinoma of the esophagus and gastroesophageal junction. Of these 140 patients had esophagectomy with cervical esophagogastric anastomosis. 66 patients underwent a hand sewn anastomosis and 74 patients had a side-to-side stapled anastomosis fashioned. Both groups were comparable with respect to preoperative characteristics. There was no difference in the operative blood loss and T and N stage of the disease. The overall morbidity and mortality was 32.8% and 6.4%, respectively. Overall leak rate was 17%. There was no difference in the leak rates among two groups (12 in the hand-sewn group & 12 in the Stapled stapled group; $p = 0.82$). The rate of anastomotic stricture was significantly higher for the hand sewn group (16.1% vs 4.3%; $p = 0.03$) at median follow up of 30 months.

Conclusion: Both hand sewn and stapled anastomotic techniques are equally effective way of performing a cervical esophagogastric anastomosis. However, patients having anastomotic leak develop anastomotic stricture more often in those having hand-sewn anastomosis compared to stapled anastomosis.

1. Introduction

Surgery is the mainstay of treatment for patients with carcinoma of the esophagus and gastroesophageal junction. Anastomotic leak is one of the main cause of morbidity and mortality following esophageal resection [1,2]. Despite being reported to have higher leak [3] and stricture rate [4], cervical esophagogastric anastomosis (CEGA) is preferred because of better tumor eradication [3] (especially for middle and proximal tumors) and reduced mortality and morbidity associated with anastomotic leakage [1,2]. Recent meta-analysis suggested higher leak with CEGA but showed similar complication rate compared to thoracic anastomosis [5]. Studies on factors associated with anastomotic leaks suggest that both local and systemic factors are responsible [4,6]. Patient related risk factors include pre-existing diabetes mellitus, cardiovascular disease, smoking history and neoadjuvant chemoradiotherapy that may result in reduced tissue micro perfusion [7]. Over the years

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surgical technique of preparing the gastric conduit has been standardized to reduce gastric tip ischemia. However, the method of anastomosis-hand sewn or stapled (total stapled or partial stapled); remains as issue of contention. Among the hand sewn anastomosis, single layer anastomosis is the most commonly used technique [8,9]. The reported leak rate varies from 10 to 15% [4,6,10]. Early reports using staplers showed no difference in leak rate but higher incidence of stricture [11,12]. This was probably related to the use of circular staplers and it subsequently led to the introduction of the side to side stapled technique [13]. Orringer et al. [14] reported a leak rate below 3% following side-to-side stapled anastomosis along with a lower rate of anastomotic stricture and improved satisfaction in swallowing compared to the hand sewn technique. Subsequent studies [15–17] have not demonstrated consistent results with stapled anastomosis. In these studies, the leak rate ranged between 10–15%, prompting most surgeons to fashion an anastomosis based on their experience and preference.

Consequently, the aim of this study was to analyze & compare the outcomes of cervical esophagogastric anastomosis between hand sewn and partial side to side stapled technique.

2. Patients and methods

The records of all patients admitted from 2004 to 2014 for management of carcinoma the esophagus or gastroesophageal junction in the Department of Gastrointestinal Surgery at Govind Ballabh Pant Hospital (GB Pant) and Maulana Azad Medical College were evaluated from the prospectively maintained database.

Inclusion criteria: All patients undergoing esophagectomy with cervical esophagogastric anastomosis (CEGA) were included in the study.

Exclusion criteria: a) Patients with locally advanced unresectable disease b) metastatic disease c) patients with inoperable cancers at work up d)refuse to treatment e) patients found to upper third tumors f) Patients undergoing esophagectomy with intrathoracic anastomosis and those requiring total gastrectomy with intra abdominal anastomosis were excluded.

2.1. Diagnostic work up and preoperative preparation

The diagnostic work-up included upper gastrointestinal (UGI) endoscopy and biopsy and Contrast enhanced computed tomography (CT) scan from the neck to the pelvis. Positron Emission Tomography was performed in the last forty four cases. Bronchoscopy was performed in patients with tumors at or above the carina. Neoadjuvant chemoradiotherapy was introduced as a protocol from 2011 onwards & given in all patient with tumor stage T3 & above and or nodal disease. EUS was not performed in any of our patients.

2.2. Preoperative preparation

Nutritional support was maintained by enteral feeding either orally or through a nasogastric tube depending upon grade of dysphagia. Oral hygiene was maintained by povidone iodine gargles. Chest physiotherapy by incentive spirometry and steam inhalation was started in all patients beginning from the first encounter in the outpatient department. Smokers were instructed to stop smoking prior to surgery. The compliance rate was 90%. Bronchodilators were used to improve the pulmonary status as required.

2.3. Operative technique

After preoperative anesthetic clearance and consent, surgery was performed either through a transhiatal approach or through a right posterior thoracotomy. From July 2011 thoracoscopic mobilization replaced posterior thoracotomy approach.

The gastric conduit based on the right gastric and right gastroepiploic vessels was prepared. Pyloromyotomy and pyloroplasty were not done. The gastric conduit was constructed using a linear cutter stapler along the lesser curvature. The stomach was brought up into the left side of the neck through posterior mediastinal route. The CEGA was done either by a partial side-to-side stapled technique (EZ45 Endoscopic Linear Cutter, Endopath, EndoGIA, Ethicon surgical, Delhi) or end-to-side hand-sewn technique using single layer interrupted 3-0 vicryl suture. All anastomosis were performed by one of the two surgeons in the department. One surgeon routinely performed hand-sewn anastomosis and all anastomosis were done by him or under his supervision. The second surgeon performed stapled anastomosis as a routine and all anastomosis were done by him or under his supervision. An average of 8 vicryl sutures was required to complete the hand sewn anastomosis. After hemostasis, the neck wound was closed loosely with interrupted 3-0 vicryl sutures over a 14F suction drain and the skin approximated with skin staplers. Bilateral Chest tubes were placed in all cases. A Feeding jejunostomy (Witzel's type) with 12F Ryles tube was performed in all patients for postoperative nutrition.

2.4. Cervical esophagogastric anastomosis

2.4.1. Hand sewn technique

An 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. The stomach was then opened transversely approximately 3 cm long. Mucosa to mucosa anastomosis was performed using 3.0 vicryl in a full thickness interrupted sutures. A 14F nasogastric tube was then placed across the anastomosis into the intra thoracic stomach. The anterior wall of the anastomosis was completed in a similar manner.

2.4.2. Stapled technique

We performed Collard's modification of the stapled esophagogastric anastomosis (Partial stapled partial hand sewn anastomosis) [13]. The gastric conduit was placed posterior to the esophagus in such a way that the esophagus overlapped the stomach for about 3–5 cm. Three interrupted seromuscular sutures were taken between the posterior wall of the esophagus and anterior wall of stomach well away from the gastric staple line to secure the organs in position. The gastrotomy was made 5 cm distal to stapled tip on anterior aspect of conduit. Endo GIA 45 blue was then passed with one limb in stomach and other in esophagus and then fired. Hemostasis was achieved and then a 14–16 Fr nasogastric tube was passed in the conduit. Anterior layer was closed with interrupted 3-0 vicryl suture.

2.5. Postoperative management

Patients were managed in the intensive care unit. Jejunostomy feeding was started with 500 ml of normal saline usually on postoperative day (POD) 2 or 3. A contrast study with Gastrografin was done on the seventh postoperative day unless there was a clinically obvious anastomotic leak. If test showed no leak, the nasogastric tube was removed, and oral feeding was initiated with soft diet. The neck drain was removed on the seventh postoperative day after the

contrast study. If a leak was identified, the cervical wound was opened to establish external drainage of any collection. Regular dressing with normal saline soaked gauze was done. If there was radiological leak, patients were managed conservatively without opening the cervical wound.

2.6. Follow up

All the patients were followed up for a minimum of 12 months post surgery or till death of the patient. The follow up protocol include out patient department visit after one week and after one month. After that patients were followed up after every 3 months for next 2 years and then every six months. Routine clinical examination, hemogram and chest X-ray were done in all patients. Patients who had difficulty in swallowing underwent a thin barium swallow and esophagoscopy with biopsy to rule out anastomotic recurrence. Anastomotic strictures were dilated endoscopically as per dilatation protocol.

2.7. Outcome measures

The primary outcome measure was anastomotic leak. The secondary outcome measures included operative time, and occurrence of anastomotic stricture. Anastomotic leak was assessed by radiographic contrast (gastrografin) study performed on POD7. Leaks were labeled 'minor' when the leak was minimal, healed spontaneously without stoppage of oral feeding and without prolonging the hospital stay beyond 14 days. All leaks causing neck wound dehiscence, copious discharge of saliva/refluxed bile, requiring stoppage of oral feeding and prolongation of hospital stay beyond 14 days were labeled 'major'.

Anastomotic stricture was defined as anastomotic narrowing requiring dilatation to relieve postoperative dysphagia or failure to pass the esophagoscope through the anastomosis. Those patients who died in hospital or developed malignant recurrence at the anastomotic site were excluded from the analysis for anastomotic stricture.

The surgical procedure details, operating time, blood loss, post operative complications, duration of hospital stay and operative mortality were reviewed from the hospital record. Operative mortality included all patients who died within 30 days of the procedure or during the same hospital admission. Peri-operative complications included all complications occurring within 30 days of procedure or during the same hospital admission.

2.8. Statistical analysis

Continuous variables were reported as mean with Standard deviation (SD). Categorical variables were reported as proportions. Student's t test and Fisher's exact test were used, where appropriate, for comparison between groups. A p value of 0.05 or less was regarded as significant. All calculations were performed with the Statistical Package for the Social Sciences (SPSS Inc, Chicago, Illinois) program.

3. Results

Two hundred and seventeen patients with carcinoma esophagus and gastroesophageal junction were admitted in the Department of Gastrointestinal Surgery, Govind Ballabh Pant hospital and Maulana Azad Medical College from 2004 to 2014. Sixty four patients had either unresectable or inoperable disease due various reasons (Fig. 1) and were treated either with chemoradiotherapy or palliative stenting. One hundred and fifty three underwent curative resection. Thirteen patients who underwent Ivor Lewis (n = 4) or total gastrectomy with esophagojejunostomy (n = 9) were excluded from the study. Remaining one hundred and forty patients, who underwent resection with cervical esophagogastric anastomosis (CEGA), were included in the study. There were 66 patients with Hand sewn anastomosis (Group A) and 74 patients with Stapled anastomosis (Group B). The two groups were comparable with respect to demographic and preoperative clinical and biochemical profile (Table 1).

The mean age of patients was 53 (range 23–77) years. There were 79 males and 61 females. The tumor was located in the upper third esophagus in 2 patients, middle third esophagus in 61 patients, lower third esophagus in 62 patients and gastroesophageal junction in 15 patients. Majority of patients had squamous cell carcinoma (n = 116). 98 patients underwent transhiatal esophagectomy, 27 patients had transthoracic esophagectomy & 11 patients underwent hybrid (Thoracoscopic + Laparotomy) esophagectomy. Four patients undergoing transhiatal esophagectomy were converted to transthoracic operation. In 2 patients there was bleeding from an esophageal arterial branch while in other two patients there was difficulty in obtaining R0 resection from transhiatal route.

Comparison of operative and peri-operative data between two groups is shown in Table 2. The operative blood loss was comparable among the two groups (hand-sewn 289 ± 179 ml vs stapled 296 ± 182 ml; p = 0.81). The duration of surgery was significantly more in hand sewn anastomosis compared to stapled group (352 ± 95 min vs 297 ± 93 min; p = 0.001). Histopathological examination showed that both groups were comparable with respect to T and N stage. Overall leak rate was 17.1%. There was no difference in the leak rates in both the groups (hand-sewn n = 12, Stapled n = 12; p = 0.82). None of the patients developed gastric tip necrosis. There was no difference in serum albumin levels in those with a leak compared to those without a leak in both the stapled (3.64 ± 0.34 g/dl vs 3.69 ± 0.53 g/dl; p = 0.75) and hand-sewn group (3.57 ± 0.35 g/dl vs 3.74 ± 0.36 g/dl; p = 0.14).

The overall mortality rate was 6.4%. The operative mortality among the stapled group was comparable to hand sewn group (4/66 vs 5/74, p = 1). Four patients died within the first week (myocardial infarction n = 2, arrhythmia = 1, respiratory complication n = 3) while 5 patients died later (thoracic duct injury n = 2, respiratory failure n = 3).

The overall morbidity was 32.8%. Major post-operative complications included respiratory complications (n = 19), cardiac (n = 7), thoracic duct injury (n = 8), and anastomotic leak (n = 12 each). Among the 8 patients with thoracic duct injury, only two had anastomotic leak, suggesting that it did not influence the leak rate. The leak rate among patients with thoracic duct injury was not significantly different from those without it (2/8 vs 22/132; p = 0.62). The leak rate was also not significantly different among patients received neoadjuvant chemoradiotherapy from those undergone upfront surgery (4/26 vs 20/114; p = 1.00). The complication rates was comparable among the two groups (p = 0.32). The hospital stay was also comparable (hand-sewn: 12.6 ± 7.3 days, Stapled: 11.8 ± 6.3 days; p = 0.5).

Overall two patients in the stapled group with a neck leak died. In both the patients, the leak was not directly responsible for deaths. One patient had thoracic duct injury and underwent thoracic duct ligation. She subsequently died because of respiratory complication on day 45. The second patient also died of chest infection on day 24. Among the other 22 patients with leak, 9 had a minor leak (stapled,n = 4, hand sewn,n = 5). All these patients were managed conservatively and were discharged by day 14. The leak did not have any significant impact on the postoperative hospital stay in these patients. Thirteen patients (stapled n = 6, hand sewn n = 7) had major leaks. They were managed conservatively with

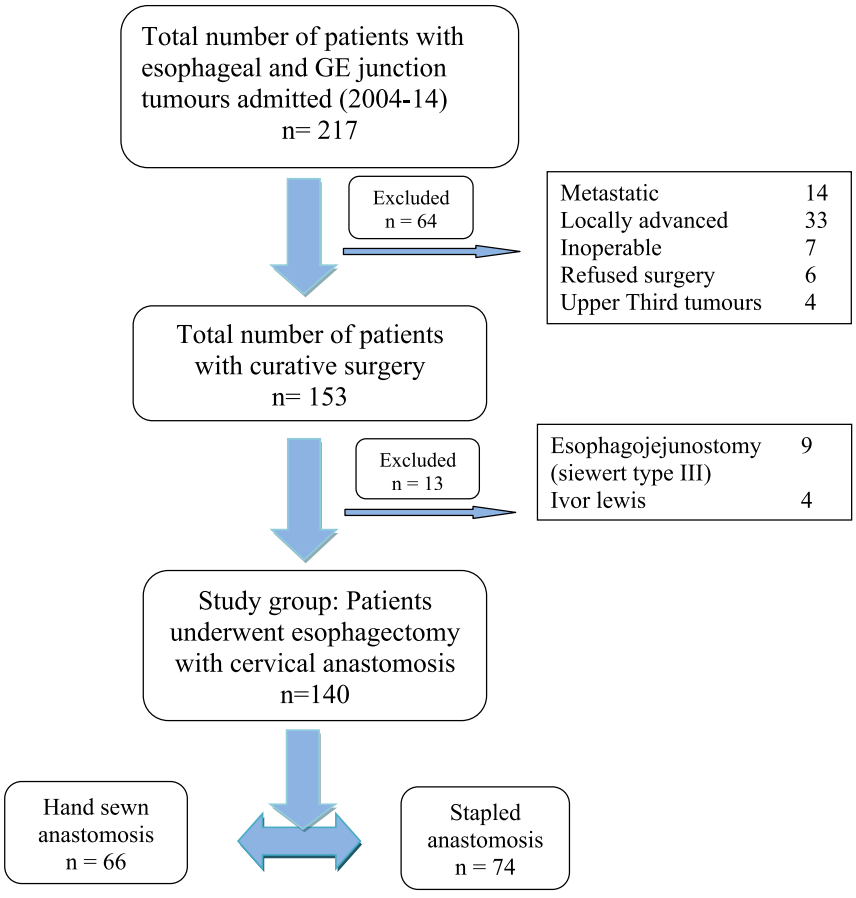

Fig. 1. Flow Diagram showing patients profile.

Table 1
Comparison of demographic, tumor and pre-operative characteristics of hand-sewn group with stapled group.

	Hand-sewn (n = 66)	Stapled (n = 74)	p value
Age (years)	52.6 ± 10.7	53.4 ± 11.3	0.68
Sex (M:F)	38:28	41:33	0.86
Grade of dysphagia	3.0 ± 0.8	3.2 ± 0.8	0.37
Duration of dysphagia (months)	4.2 ± 2.4	4.6 ± 2.5	0.29
Histology of tumor (SCC:AC)	58:8	58:16	0.18
Preoperative neoadjuvant CT RT	14	12	0.52
Hemoglobin (g/dL)	11.9 ± 1.8	12.0 ± 2.0	0.56
Albumin (g/dL)	3.71 ± 0.36	3.68 ± 0.46	0.67
Location of tumor			
Upper	1	1	1
Middle	32	29	0.30
Lower	26	36	0.30
GE junction	7	8	1
Co-morbid conditions			
Cardiac	3	3	1.0
Respiratory	7	11	0.61
Stage			
1a	1	1	1.0
1b	2	3	1.0
2a	14	14	0.83
2b	18	19	0.85
3a	12	15	0.83
3b	6	8	0.78
3c	7	8	1.0
Complete response	6	6	1.0

adequate neck drainage and dressings, antibiotics, jejunostomy feeds and gradual oral feeding after decrease in discharge. All patients with leaks resumed orally by the end of third week. The average hospital stay in patients after major leak was 21 days (17–23) in the stapled group and 27 days (17–45) days in the Hand sewn group.

Table 2
Operative and Peri-operative data in the two groups.

Factor	Hand-sewn ($n = 66$)	Stapled ($n = 74$)	P value
Operative time (min)	352 ± 95	297 + 93	0.001
Blood loss (ml)	289 ± 179	296 + 182	0.81
Anastomotic leakage	12 (18%)	12 (16%)	0.82
Minor Leak	5 (7%)	4 (5%)	
Major leak	7 (11%)	8 (11%)	
Post operative complications	19 (29%)	15 (20%)	0.32
Mortality	4 (6%)	5 (6.7%)	1.00
Hospital stay ± SEM (days)	12.9 ± 7	11 ± 6	0.09
Benign anastomotic stricture after leak	7/12	1/10	0.03
Benign anastomotic stricture without leak	3/50	2/59	0.65

All patients were followed up to evaluate the occurrence of benign anastomotic stricture. At median follow up of 30 months (range, 12–78), 9.9% (13/131) developed benign anastomotic strictures. Ten patients (16.1%) with hand-sewn anastomosis had stricture compared to three patients (4.3%) with stapled anastomosis ($p = 0.03$). 7 of 12 patients with anastomotic leak in hand sewn group developed anastomotic stricture compared to 1 of 10 patients in the stapled group ($p = 0.03$). Among the patients with major leak, 6/7 in hand sewn group and 1/6 patient in stapled group developed anastomotic stricture $p = 0.029$. Thus major leak was predictor for development of stricture in the hand sewn group. All 13 patients (stapled-3 and hand sewn-10) with anastomotic stricture underwent endoscopic dilatation as per schedule. None of the patients required surgical intervention.

4. Discussion

Following esophagectomy restoration of alimentary tract is usually performed by gastric transposition and esophagogastric anastomosis. However, it is associated with both early and late complications. Among the early complications, anastomotic leak is a significant cause of morbidity and even mortality [12]. The leak rates reported in the literature vary from 10 to 15% [4,6,10].

Causes of anastomotic leak are multi factorial and include both patient and surgery related factors [4,6,7]. Proper preoperative preparation and peri-operative care also help in reducing the risk related these factors and achieving a good outcome.

Although patient related factors can be modified to a limited extent, it is the surgery related factors which, if modified, can further potentially reduce the post-operative leak rate. Preparation of gastric conduit and anastomotic technique are two major surgery related factors. Various gastric tubes have been proposed to maintain the blood flow at the gastric tip. Use of a broad tip preserving sufficient tissue for maintaining submucosal vascular communication between gastric tip and right gastric vessels, while achieving adequate surgical margin rather than narrow tube has been advocated by Collard, Bardini and Akiyama [9,18,19]. The routine usage of this technique to prepare gastric tube enabled us to study the role of anastomotic technique on leak rate.

Other groups have reported that despite using various forms of hand-sewn anastomosis (single layer vs double layer; continuous vs interrupted absorbable vs non absorbable sutures) the leak rate after esophagogastric anastomosis varied between 10 and 15% [14]. We used a single layer, interrupted, mucosa to mucosa anastomosis and found leak rate of 17%. These were comparable with other reports in literature.

Staplers have been introduced in order to reduce the incidence of anastomotic leak. Proposed benefits of stapled technique over hand sewn anastomosis include a water tight anastomosis along with minimal tissue trauma by less tissue handling and quicker anastomosis. A wider anastomosis by the stapled technique would decrease the chance of anastomotic stricture especially after anastomotic leak. Earliest use of a stapler to do end to side anastomosis was reported by Steichen [20]. Subsequently a circular stapler was used to perform these end to end anastomosis. The various randomized trial and subsequent meta analysis comparing hand-sewn and this stapled anastomotic technique showed no difference in leak rate but an increased incidence of stricture rate [11,12]. These results lead to use of side-to-side stapled anastomosis (functional end to end) first reported by Collard [13] and later modified by Orringer. Although Orringer et al. [14] showed a reduction in leak rates from 14% to 2.7% using this technique, gastric tip necrosis and radiological leaks were excluded from this analysis. If the radiological leaks and conduit tip necrosis are included then the leak rate in their study would increase to 7%. Although Ercan et al. [21] reported higher leak rates following hand sewn anastomosis (11%) compared from modified Collard's technique of stapled anastomosis (4%) but the difference was not statistically significant. Saluja et al. [17] reported the first randomized trial comparing hand sewn with side to side partial stapled technique which showed no difference in leak rate (16% vs 18%). In our study, leak rate (17%) was similar to reported in the literature with no difference between the hand sewn and stapled group. Both the groups in our study were comparable. Santos et al. [15] showed that total stapled anastomosis had leak rate of 7%, which was significantly less than the hand sewn/partial stapled technique (23%). Another recent trial by Nakata K et al. [22]showed zero leak rate along 4.4% stricture after cervical end-to-side triangulating esophago-gastric anastomosis using linear stapler. A randomized trial may be necessary to support these results as it may further increase the cost of treatment.

In our study operative time was lesser in patients undergoing stapled anastomosis as compared to those undergoing handsewn anastomosis (297 ± 93 min vs 352 ± 95 min, $p = 0.001$). However, the difference in operative time cannot be attributed to anastomotic technique alone as separate anastomosis time was not recorded.

Overall mortality in our study was 6.4% which is comparable to the rates reported in the current literature (5%). Only two patients with a neck leak died and the leak was not directly responsible for the death. There was no difference in hospital stay among both the groups. Most other studies have shown higher hospital stay in the hand sewn group. This may be due to the fact that most studies with stapled anastomosis used historical controls for comparison. Thus length of post operative stay in hand sewn patients might be higher [16]. The hospital stay is increased in patients with a neck leak. It did not vary with type of anastomosis but was related to the type of leak (i.e. major or minor).

The most important long term sequel of anastomotic leak is development of stricture. It is important because it results in dysphagia. Therefore it impairs the quality of life and is an important indicator of successful esophagectmy. Incidence of the stricture currently varies from 26 to 42% [4,23,24]. Various studies have

confirmed anastomotic leak as a significant risk factor for post operative benign stricture [23,25,26]. Other risk factors include associated comorbidities like diabetes mellitus, cardiac disease and neoadjuvant chemoradiotherapy. The circular stapler has been shown to be associated with higher anastomotic stricture rate compared to hand sewn anastomosis [11,12]. However, with formation of a wide anastomosis using the linear stapler, this ratio seems to be changing with higher rates of stricture following Hand-sewn anastomosis compared to stapled anastomosis. Harustaik et al. [27] in their retrospective analysis showed lower leak rate and restricture rate in patients with stapled intrathoracic esophagogastric anastomosis. At the same time meta-analysis by Deng XF et al. [28] showed similar leak rate in intra-thoracic anastomosis but less leak rate in cervical esophagogastric anastomosis in patients with linear stapled anastomosis. They also found less stricture rate after stapled anastomosis. We found higher stricture rate in patients with hand sewn anastomosis especially after leak (7/12 with Hand-sewn compared to 1/10 with stapled) and this was statistically significant ($p = 0.03$). Major leak was found to be predictor for development of anastomotic stricture in the hand sewn group. Moreover the number of dilatations were less for patients with stapled anastomosis compared to hand sewn anastomosis. Finally, it is important to note that in the absence of a leak, the rate of anastomotic strictures were similar. There are few limitations of this study. Though the data analyzed is from a prospective data base, study is of retrospective nature and has inherent bias despite best efforts to avoid bias. Secondly Although the operative time was less in stapled group, separate anastomosis time were not recorded which could have more direct impact. Thirdly the number of patients with neoadjuvant protocol were less. This may have impact on anastomostic leak rate when we have larger number of patients undergoing chemoradiotherapy.

At the same time the strengths of our study are that all consecutive patients were included in the study and surgical protocols were standardised. Both surgeons had adequate experience in esophageal surgeries, did single type of anastomosis and the procedures were standardised. Recent advances in esophageal cancer like minimally invasive surgery and neoadjuvant protocol were adopted in the study group and results were similar in both groups.

5. Conclusion

Both hand sewn and stapled anastomotic techniques are an equally effective way of performing a cervical esophagogastric anastomosis. Stapled anastomosis reduces the operative time and the incidence of postoperative anastomotic stricture especially after a neck leak.

Ethical approval

Written informed consent was obtained from all patients for publication of this retrospective study.

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Author contribution

Sundeep Singh Saluja and Pramod Kumar Mishra designed the study. Sundeep Singh Saluja and Nikhil Gupta wrote the paper. Vaibhav Kumar Varshney, Nilesh Sadashiv Patil, Harsh Shah and Amit Jain contributed equally in data collection and analysis. Pramod Kumar Mishra also helped in editing the paper.

Conflicts of interest

We don't Have any conflicts of interest.

Trial registry number

Not applicable.

Guarantor

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Disclosure

The authors declare no conflict of interest.

Consent

Written informed consent was obtained from all patients for publication of this study.

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