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Advanced lymph node stage is associated with adverse short term postoperative outcomes in esophagectomy for esophageal cancer patients

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Abstract

Background: Factors affecting short term adverse postoperative outcomes in esophagectomy for Esophageal cancer in low resource center are not well studied.

Methods: A prospective study was conducted and data were collected on patients who underwent esophagectomy and esophagogastrostomy for esophageal cancer. Pre-operative and Intraoperative factors (including IntrOperative hypotension: IOH) were recorded. Patients' 30 days post-operative composite outcome of mortality, anastomotic leak and prolonged hospital stay were analyzed as outcome variables.

Result: A total of 54 patients underwent esophagectomy for esophageal cancer during the study period. The mean age was 54 years. The mean duration of the surgery was 208 minutes. Intraoperative mean low SBP was 80 mmHg while the lowest record was 55 mmHg. IOH occurred in 51% (n=29) of patients. Anastomotic leak occurred in 7% (n=4) (OR 1.2, 95% CI 0.26-6.3; p=0.76). In-hospital mortality was 5% (n=3) (OR 1.44, 95% CI 0.22- 9.3; p=0.7) and 33 % (n=18) had prolonged hospital stay (OR 0.53, 95% CI 0.14- 1.9; p=0.34). The overall anastomotic leak rate was 13% (n=7). The 30 days operative mortality was 9% and 55% (30) of patients had prolonged hospital stay. Multivariate analysis (logistic regression model) Intraoperative N3 Lymph node stage was associated with composite adverse short term out comes of mortality, Anastomotic leak and Prolonged hospital stay (AOR=0.04, 95% CI: 0.01, 0.97) p=0.048.

Conclusion: In patients undergoing esophagectomy for esophageal cancer, Intraoperative N3 Lymph node stage is statistically associated with an increased composite adverse short term out comes of mortality, anastomotic leak and prolonged hospital stay.

Keywords

Esophageal cancer; Esophagectomy; Lymph node stage; Mortality; Anastomotic leak; Prolonged hospital stay.

Abbreviations

AJCC: American Joint Committee on Cancer; ASA: American Society of Anesthesiology; AOR: Adjusted Odds Ratio; BMI: Body Mass Index; CI: Confidence interval; COR: Crude Odds Ratio; ECG: Electrocardiogram; ECOG: Eastern Cooperative Oncology Group; IOH: Intraoperative hypotension; LN: Lymph Node; OR: Odds Ratio; RBBB: Right Bundle Branch Block; SBP: Systolic Blood Pressure; TNM: Tumor Lymph node Metastasis; THE: Trans Hiatal Esophagectomy.

Background

Over all Esophageal cancer is on the rise being the 8th most common cancer worldwide and 6th most common cause of death from cancer. It is, in particular, on the increase in the Sub-Saharan Africa and it is exclusively higher in the Eastern and Southern African Sub-regions [1]. It is also the leading diagnosis of elective admission for surgery performed at our University hospital [2]. Esophageal Cancer has an effect of multifaceted severe insult in the physiology and cardiorespiratory reserves of the subjects as it does not only put the patient at significant imbalance due to cachexia as other malignancies do but it also confounds the situation by dysphagia and subsequent dehydration [3]. The presenting symptoms of esophageal cancer usually signify locally advanced disease or distant metastases or both irrespective of histologic type even in developed nations with “early “diagnosis [4,5]. Hence patients tend to have an overall poor performance status, a state of depleted intravascular volume hypoalbuminemia at the time of diagnosis that may lead to a high risk of postoperative mortality and morbidity. This state of diagnosis is worse in a set up like ours.

Esophagectomy, which is the main stay of management in esophageal cancer, is a major and complex surgery, involving the abdomen the chest and/or the neck and associated with significant blood loss [6-9]. Manipulation of the mediastinum during surgery may often lead to decreased preload, vagal stimulation and arrhythmia [10,11], hence worsening the state of hypovolemia and shock. As there are multiple factors contributing to morbidity and mortality following esophagectomy for esophageal cancer we prospectively studied association of pre and intraoperative factors on postoperative adverse short-term outcomes for patients undergoing esophagectomy for esophageal cancer, especially from a low resource high volume centers.

Methods

Study Design and Data Collection

This is a prospective observational cohort study on patients who underwent esophagectomy for esophageal cancer from August 1, 2017, to March 30, 2020. Diagnosis was based on clinical presentation; endoscopic evaluation, biopsy, and radiologic study (contrast x-rays and/or CT scan).

Inclusion Criteria

All male and female patients older than 18 years of age who underwent standard esophagectomy were included in the study. Standard esophagectomy is defined as a subtotal resection of the esophagus which is reconstructed using one of the following conduits Stomach, Colon, or Jejunum with one of the following four surgical approaches: Trans Hiatal, Transthoracic (Ivor- Lewis), McKeown's Esophagectomy or Left Thoracotomy.

Exclusion Criteria

Patients with poor pre-operative performance status, patients with cervical esophageal cancer, and patients who had signs indicative of advanced disease state such as hoarseness of voice, malignant ascite, etc. were excluded.

Sample Size and Sampling Technique

The sample size was calculated using statistical software Epinfo with a power of 80 and a CI of 95%. Consecutive patients used in sampling technique.

Data Collection and Data Collection Tool

Data collected prospectively in a structured and pretested data collection format. Socio-demographics, clinical information on preoperative and intraoperative variables, as well as postoperative morbidity, mortality, and post-op stay documented. Modified Takita's grading 1-6 [14] was used for the assessment of dysphagia. American Society of Anesthesiology (ASA) physical status classification system I-IV [15] for preoperative anesthesiology evaluation, BMI (Body Mass Index) based on body weight and height (kg/m^2), Eastern Cooperative Oncology Group (ECOG) performance classification (0-4) [16], serum albumin, serum creatinine, serum electrolytes, and liver enzyme tests were recorded. Preoperative ECG, echocardiography, and radiologic characteristics from barium swallow and CT studies were also recorded. AJCC 8th edition Esophageal Cancer staging was used for clinical staging [17].

Definitions

As one of the frequently used thresholds identified in a systematic review done by Bijker et al [18], SBP <90 mmHg, and duration of more than 5 min [18,19] was used to define Intra Operative Hypotension (IOH).

Anastomotic leak was defined by a clinically diagnosed leak, and prolonged hospital stay was defined as hospital stay more than 7th post-op day.

Intraoperative blood loss, intraoperative events including arrhythmias, need for blood transfusion, need for inotropic, and/or vasopressor support were documented.

Trans Hiatal esophagectomy was preferred for mid and distal thoracic esophageal cancers and per-

formed in 51% (n=26) of cases. McKeown's esophagectomy was preferred for mid and upper thoracic esophageal cancers which are at T4 stage and performed in 16% (n=8) of the cases. Ivor – Lew is procedure was performed for 4% (n=2) patients while 30% (n=16) patients had Left thoracotomy approach as it was preferred for gastroesophageal junction and proximal gastric cancers. In all cases stomach was used as a substitute conduit for esophagogastric anastomosis which were done via the anatomical esophageal bed and with hand-sewn techniques.

End Point

The primary endpoint was the composite outcome of anastomotic leak, mortality of any cause, and prolonged postop hospital stay. Patients were followed for 30 days post-operatively.

Data Quality Assurance

Data completeness checked by reviewing data collection format and Patient medical records regularly.

Ethical Consideration

An approval from the Institutional ethics review board (Addis Ababa University College of Health Sciences: Protocol Number 084/17/Surg.) was acquired and written consent was obtained from the patients

Statistical Analysis

IBM SSPS 23 software package used for statistical data analysis. Descriptive statistics used for describing the data, results are presented in percentage, and simple frequency, mean (SD), and median were used for other data. Factors with a possible influence on perioperative morbidity and mortality were calculated using multivariate regression analysis. A p-value of <0.05 was considered statistically significant.

Socio-Demographic Characteristics

A total of 54 patients were included in the study. Mean age was 54 (SD ±12.08) years and 61% (n=33) were females. The mean body weight of the study participants was 49.04 (SD ±9.74) Kg and the mean BMI was 18.6 (SD ± 2.85). Thirty-three (62%) of the patients were from a rural area and 30% (n=16) of the study participants were from esophageal cancer endemic localities of the country (Table 1).

Clinical Presentation

Fifty patients (93%) presented with a chief complaint of dysphagia and the mean duration of dysphagia was 7 months (SD ±.5.2). Grade III and IV dysphagia were more common presentations than other grades of dysphagia 32 % (n=17) and 35 %(n=19) respectively. No patient had pre-operative neoadjuvant treatment. No supraclavicular lymph node was appreciated clinically in 93% (n=50) cases at presentation (Table 2).

Table 1: Socio-demographic characteristics of the study participants.

Variable	Number (%)
SEX	
Male	21(39)
Female	33(61)
Residence	
Urban	20 (38)
Rural	34 (62)

Table 2: Clinical parameters.

Variable	Number (%)
Presence of dysphagia	
Yes	50 (93)
No	4 (7)
Degree of dysphagia	
Complains but can still swallow (I)	1(2)
Requires liquid to swallow (II)	6(11)
Can swallow semisolids but not solids (III)	17(32)
Can swallow liquids but not semisolids (IV)	19(35)
Can swallow saliva but not semisolids (V)	9(17)
Can't even swallow saliva (VI)	2(4)
Presence of Supraclavicular lymph node (LN)	
Yes	2(4)
No	50(92)
Missed data	2(4)

Preoperative Risk Assessment

Fifty-two (96 %) of the patients were in a good performance state with ECOG class 2 or less. There was no patient in ECOG class 4. Fifty percent (n=27) were in ASA class 1 classification and 89% (n=48) had no known comorbidity. Cardiovascular disease (mostly hypertension) was the commonest comorbidity found in 4 (7%) of patients. Only 7% (n=4) had a history of smoking.

Investigation Results

Mean preoperative hematocrit was 38.41% (SD ±8.14) and mean WBC was 6674.2 (SD: ± 2058). Mean serum albumin was 3.92 (SD: ±0.85) g/dl and median serum K+ was 4.00 (IQR: 3.60 -4.50) meq /L. Mean serum creatinine was 1.04 mg/dl and 89% (n=48) patients had no derangement of liver enzyme tests. Minor abnormal ECG was noted in 23% (n= 12) patients and 8% (n=4) cases had evidence of old ischemic changes.

CT imaging was done for 86% (n= 44) of the cases 24% (n=10) and 4.7% (n=2) had a loss of fat plane between the aorta and esophagus and between the tracheobronchial tree and esophagus respectively. Mean length of malignant strictures on barium swallow study and CT imaging was 4.94 (SD ±2.11) cm. Fifty-two (96%) had upper GI Endoscopy evaluation. The mean location of the tumor from incisors was at 32cm (SD: ±4.67). Biopsy results have revealed Squamous cell carcinoma in 72% (n=39) and Adenocarcinoma in 19 % (10). There were 9% (5) patients with no Biopsy result.

Intraoperative Findings and Events

Thirty-nine (72%) patients were in clinically stage III disease and 9% (n=5) patients were in stage IV. More than 90% of the patients were found to have T3 or advanced tumor stage during surgery. Three (6%) patients had an invasion of unresectable structures such as the aorta. All patients had lymph node involvement with N1 and N2 stage involvements being the commonest. Five patients had signs of gross

metastasis. Omental wrap was used in 51% (n=24) of the cases.

Mean duration of surgical procedures was 208.6 minutes (SD ±65.89) and the mean duration of anesthesia was 238 minutes (SD ±75.65). Mean estimated blood loss was 741 ml and the median estimated blood loss of the procedure was 500.00 (IQR: 300.00-695.00) ml. One (2%) patient who had significant

Table 3: Intraoperative findings and events.

Variable	Number (%)
Clinical (Intra Operative) Tumor Staging	
T stage	
T1 (invasion of Submucosa)	0(0)
T2 (invasion of Muscularis propria)	5(9)
T3 (invasion of adventitia)	25(46)
T4A (invasion of resectable adjacent Structures)	21(39)
T4B (invasion of unresectable adjacent Structures)	3(56)
N Stage	
N0 (No LN invasion)	0(0)
N1 (1-2 regional LN involvement)	19(35
N2 (3-6 regional LN involvement)	23(43)
N3 (≥7 regional LN involvement)	12(22)
M stage	
M0 (No Metastasis)	49(91)
M1 (Distant Metastasis)	5 (9)
Ascites	2 (4)
Liver metastasis	2 (4)
Lung metastasis	1 (2)
Clinical Stage	
I	0(0)
II	10 (19)
III	39 (72)
IV	5 (9)
Omental Wrap Use	
Yes	24(44)
No	23(43)
Missing data	7 (13)
Operative Complications*	
Tumor Perforations	3 (6)
R2 resection	3 (6)
Chylothorax	1(2)
Recurrent laryngeal Nerve Injury	1(2)
Others~	4(7)
No Complication	42(78)
Need for intraoperative blood transfusion	
Yes	10(19)
No	43(81)
Missing data	1(2)
Need for intraoperative inotropic support	
Yes	15(28)
No	32(59)
Missing data	7(4)

**: Includes complications observed both Intra op and Post-op*

~: includes Persistent air leak from Right, pleural breach, Pyothorax, Splenic injury (splenectomy) gall bladder injury (cholecystectomy)

bleeding of approximately 1000 ml. Mean total duration of SBP < 90 mmHg was 18.3 (SD ±28.5) minutes. Mean SBP during IOH was 80 mmHg (SD ±12.4) while the lowest record was SBP of 55 mmHg. The median lowest SBP was 80.00 (IQR: 73.50-90.00) mmHg. IOH occurred in 51% (n=29) of the time. Most IOH episodes were corrected by boluses of crystalloids infusion. IOH occurring due to mediastinal manipulations resolved with an intermittent withdrawal of the surgeon's hand. Ten (19%) patients needed an intraoperative blood transfusion and ten patients (19%) required intraoperative inotropic and or vasopressor support. Epinephrine and Phenylephrine were inotropic and vasopressor support drugs of choices. No patient had an epidural catheter in place (Table 3).

Postoperative Care and Outcomes

Most Patients 45 (83%) were extubated on the OR table and observed in a Post Anesthetic Care Unit for the first 6 hrs immediate post-op before deemed stable enough to be transferred to the general ward. Nine Patients (17) patients were transferred to ICU and subsequently extubated the next immediate hours to the first post-op day. Ten patients (19%) who needed inotropic and or vasopressor support were transferred to the ICU until they were weaned off inotropic and or vasopressor support and deemed stable enough to be transferred to their respective wards as well.

The 30 days operative mortality was 9% (n=5). Among the in-hospital deaths, 4% (n=2) were attributed to anastomotic leak. One (2%) patient died after discharge within the study period of 30 post-op days from an unknown cause. There were 13% (n=7) cases of anastomotic leak. Six (12%) patients underwent reoperations such as feeding jejunostomy tube insertion for complications (anastomotic leak). Mean post-op hospital stay was 12 days. Thirty (55%) of patients had a prolonged hospital stay. Fifteen (29%) and 5(10%) patients needed a postoperative blood transfusion and postoperative inotropic support respectively. On 30th-day post-op 57 %(n=31) of the patients were ambulatory in more than 50% of waking hours and capable of all self-care (ECOG 3) (Table 4).

Outcome of Patients and Associated Factors

Four (7%) patients with anastomotic leak (OR 1.2, 95% CI 0.26- 6.3; p=0.76), 3(5%) patients who died (OR 1.44, 95% CI 0.22-9.3; p=0.7) and 18 (33%) with prolonged hospital stay (OR 0.53, 95% CI 0.14,-1.9 p=0.34) had experienced IOH (Table 5).

Multivariable binary logistic regression analysis showed SBP < 90 mmHG for > 5 min was not significantly associated with composite outcomes of anastomotic leak, mortality, and prolonged hospital stay (AOR 1.06, 95% CI 0.98-1.14; p=0.16).

Patients who had N3 (≥7 LN) clinical intraoperative tumor stage were 96% less likely to have good composite outcome compared to those patients who had N1 (<3 LN) clinical intraoperative tumor stage (AOR 0.04, 95% CI 0.01-0.97; p=0.048) (Table 6).

Table 4: Postoperative care and outcomes.

Variable	Number (%)
Need for postoperative blood transfusion	
Yes	15(28)
No	37 (68)
Missing data	2 (4)
Need for Postop Inotropic/vasopressor Support	
Yes	5(9)
No	47(87)
Missing data	2(4)
Anastomotic leak	
Yes	7(13)
No	47(87)
Reoperation for complication	
Yes	6(11)
No	48(89)
30 days Mortality	6 (11)
In hospital	5 (9)
Post-discharge, within 30 days post-op	1 (2)
Probable cause of death attributed to anastomotic leak	2 (4)
Probable cause of death not attributed to anastomotic leak	
MI	1 (2)
Stroke	1 (2)
Chylothorax (sepsis, hypotension)	1 (2)
ECOG Performance status 30th Postoperative day	
0: Fully active	2 (4)
1: Restricted in physically strenuous activity but ambulatory	10(19)
2: Ambulatory and capable of all self-care but unable to carryout any work activities; up and about > 50% of waking hours	19(35)
3: Capable of only limited self-care; confined to a bed or chair > 50% of waking hours	18(33)
4: Completely disabled; cannot carry on any self-care; totally confined to bed or chair	0(0)
Missing data*	4(7)

**Excluding one death post-discharge*

Table 5: Intraoperative hypotension and Outcome variables.

Endpoint		No Intra op hypotension N (%)	Intra op hypotension N (%)	OR 95% CI	P-value
Hospital stay	≤7 days	5(9)	7(13)	0.53 (0.14-1.9)	*p*=0.34
	>7 days	24(44)	18(33.3)		
Anastomotic leak	Yes	3(5)	4(7)	1.28 (0.26- 6.3)	*p=0.76*
	No	23(43)	24(44)		
Death	Yes	2(4)	3(5)	1.44 (0.22-9.3)	*p*=0.70
	No	24(44)	25(46)		

Table 6: Composite outcome and perioperative factors.

Variables	COR (95% CI)	p-value	AOR** (95% CI)	p-value
N Stage				
N1 (<3 LN)	1		1	
N2 (3-7 LN)	0.53 (0.13, 2.23)	0.388	0.27 (0.05, 1.43)	0.125
N3 (>7 LN)	0.13 (0.12, 1.01)	0.051	0.04 (0.01, 0.97)	0.048*
SBP <90 mmHg >5 min SBP <90 mmHg	1.06 (0.99, 1.12) 2.36 (0.7, 7.93)	0.056 0.166	1.06 (0.98, 1.14) 1.07(0.16,6.99)	0.160 0.945
Lowest SBP	0.96 (0.91, 1.01)	0.135	0.98 (0.93, 1.03	0.423
Pre op ECOG performance				
Level 0 and 1	0.41 (0.11, 1.51)	0.181	0.46 (0.08, 2.73)	0.394
Level 2 and 3	1		1	

**Statistically significant*
***AOR: Adjusted for Mortality, Anastomotic leak, and Prolonged Hospital stay*

Discussion

The rates of morbidity and mortality following esophagectomy for esophageal cancer are improving [20]. In a 1980 review article, operative mortality for esophageal resection was 29% [20]. In mid-2000s operative mortality decreased to 10-11% [9,21,22]. While multiple works of literature suggested tumor stage, histologic subtype, performance status, age, type of surgical approach, intraoperative blood loss, and blood transfusion as risk factors, few have also addressed the effect of intraoperative hypotension on postoperative morbidity and mortality of patients undergoing esophagectomy for esophageal cancer [9,10,21-27].

Even though Gockel and colleges [9] in their study involving 424 patients suggested that tumor characteristics, e.g. TNM classification, were of no influence on the postoperative course our study, however, found that N3 stage, hence stage III disease, is significantly associated with adverse short term postoperative outcomes (AOR 0.04 (0.01- 0.97 p= 0.048). This result is in agreement with other risk analysis studies, which suggest that those with stage III or IV disease have a higher postoperative mortality [30,31].

In our study, we found that neither intraoperative hypotension, SBP < 90 mmHg for more than 5 min (OR 1.06, 95% CI 0.98- 1.14; p= 0.160) nor the lowest SBP (OR 1.07, 95 % CI 0.16- 6.99; p= 0.945) were associated with adverse composite outcomes of mortality, anastomotic leak or prolonged hospital stay.

The overall mortality was 9% while 3 (5%) of deaths are associated with IOH. This was similar to post esophagectomy mortality rates of 3-16% reported by multiple studies [9,10,21-23,25]. In this study mortality adjusted for Trans Hiatal Esophagectomy (THE) only, was 10% which was less than the 18.7% reported in a 2012 study for THE in the same institution [7].

Anastomotic leak occurred in overall 7 patients (13%) and 4 (7%) in patients with IOH. There were no leaks from the left thoracotomy approach with left intrathoracic anastomosis while 1 patient leaked from right intrathoracic anastomosis while the remaining 6 patients had a cervical leak. As it is well known that cervical anastomosis leak rates are higher due to the tension applied to the stomach to reach the neck. This further explains why left thoracotomy approaches are very unlikely to have leaks because the tension on the stomach is very less followed by right intrathoracic anastomosis. The anastomotic leak we found in this study had no significant statistical association with intraoperative hypotension (6% Vs 7%; p=0.76). This is in contrast to the finding by Fumagall U. et al [27] where leaks were significantly more common in patients with intra-operative hypotensive episodes (p= 0.02). Their study involved a larger patient number (84), defined hypotensive episodes as SBP decreasing more than 30% of the basal value for more than 5 min, and had procedures performed in a prone position. Unlike their study, none of our study patients was operated on in a prone position.

Our anastomotic leaks accounted for 2 (4%), of the deaths and had a 2/7 (28%) mortality which is comparatively higher than a 12% mortality from anastomotic leak found in a systematic review done by Verstegenet al [28] and other recent data [30] but comparable to the 37 % mortality reported by Turkyilmaz A et al [29].

The occurrence of recurrent laryngeal nerve injury (2%), chylothorax (2%), pleural breach, splenic injury (<2%) are at acceptable level with international experiences [12,14]. There were no other major intraoperative injuries like tracheal injury and uncontrollable mediastinal hemorrhage or intra operative deaths which may be due small volume of cases and the learning curve acquired in time as we had such events in the past [17].

In their study on geriatric cancer patients undergoing surgery for solid tumors Chou et al [28] found that ECOG scale of 3-4 were associated with the highest probability of 3 month postoperative mortality. Another study by Ñamendys-Silva et al [29] of 315 patients found that ECOG score of >2 during the last month before hospitalization were associated with in-hospital mortality in postsurgical cancer patients without infection. Unlike these studies though we have neither ECOG scores of 0-1 nor scores of 2-3 0.46 (0.08, 2.73) p= 0.394 were significantly associated with adverse post op out comes. This may have resulted from the fact that our patients are relatively younger, we have looked only the 30 day operative mortality, the small sample size and no patient was in ECOG calls 4 which can be assumed to be highly associated with mortality and morbidity.

Limitations and Recommendations

In this study, we have identified certain limitations. It has a small sample size and has some missing data. The study also has not addressed. The study also hasn't addressed the association of stage sub types, different esophagectomy approaches and histologic subtypes such outcomes. In addition the study has not address the possible factors such as wound infection, pulmonary complications, etc. which may contribute to mortality, morbidity and prolonged hospital stay.

We recommend that the above limitations and association of advanced lymph node stage with long term effects such as survival, quality of life and recurrence, etc. to be future directions of study.

Conclusion

In this study, we found that an Intraoperative N3 Lymph node stage is statistically associated with an increased composite adverse short term out comes of mortality, anastomotic leak and prolonged hospital stay (AOR=0.04, 95% CI: 0.01, 0.97) p=0.048.

Declarations

Ethics approval and consent to participate: An approval from the Institutional ethics review board (Addis Ababa University College of Health Sciences: Protocol Number 084/17/Surg.) was acquired and written consent was obtained from the patients.

Consent for publication: Not applicable.

Availability of data and materials: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests: The authors have no conflict of interest to declare.

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Author's contributions: Ephraim. Teffera. Yeheyis: conceived, designed and conducted, and coordinated the study, operated cases, collected data, and wrote the manuscript.

Contributors

- Seyoum. Kassa: operated cases, and collected data
- Hiwot. Yeshitla: collected data.
- Abebe. Bekele: Mentorship, operating cases, and data collection

Contributors have read and approved the manuscript.

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