Intraoperative hypotension is not associated with adverse short-term postoperative outcomes after esophagectomy in esophageal cancer patients

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Abstract

Background The effect of low systolic blood pressure and its subsequent postoperative outcome during esophagectomy for esophageal cancer is not well studied. Methods Prospective study was conducted and data were collected on patients who underwent esophagectomy and esophagogastrostomy for esophageal cancer. Intraoperative Hypotension (IOH), defined as Systolic Blood Pressure (SBP) < 90 mm Hg lasting more than 5 minutes, was 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. Mean duration of the surgery was 208 minutes. Intraoperative mean low SBP was 80mmHg while the lowest record was 55 mmHg. IOH occurred in 51.2% (n=29) of patients; of these, 7.4% (n=4) had anastomotic leak (OR 1.2, 95% CI 0.26-6.3; p=0.76), mortality was 5.5% (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). Over all anastomotic leak rate was 13% (n=7). The 30 days operative mortality was 9.2% and 55% (30) of patients had prolonged hospital stay. Multivariate analysis (logistic regression model) showed SBP < 90mmHg for more than 5 min during surgery has not significantly associated either with individual or composite outcomes of mortality, anastomotic leak and prolonged hospital stay (AOR 1.06, 95% CI 0.98-1.14; p=0.16). Conclusion In patients undergoing esophagectomy for esophageal cancer, a systolic blood pressure < 90 mm Hg for greater than 5 min during surgery has no significant statistical association either with individual or composite adverse outcomes of mortality, anastomotic leak and prolonged hospital stay.

Introduction

Globally esophageal cancer is on the rise being the 8th most common cancer and 6th most common cause of death from cancer1. It is, particularly, increasing in Sub-Saharan Africa with higher incidence rates in Eastern and Southern African Sub-regions2. It is also the leading cause of elective cardiothoracic admissions to the surgical ward for procedures performed at our university hospital3. Esophageal cancer results in severe multifaceted insults to the physiology and cardiorespiratory reserve. Not only does it cause homeostatic derangements due to cachexia as in other malignancies, but the dysphagia and subsequent dehydration further confounds their clinical status4. The presenting symptoms of esophageal cancer usually signify locally advanced disease, distant metastases, or both, irrespective of histologic type; even in cases with “early” diagnosis5,6. Hence, patients tend to have an overall poor performance status, a state of depleted intravascular volume, and hypoalbuminemia at the time of diagnosis resulting in higher risk of postoperative morbidity and mortality.

Esophagectomy, the mainstay of management in esophageal cancer, is a major and complex surgery involving the abdomen, chest, and / or neck. It is commonly associated with significant blood loss7–10. Manipulation of the mediastinum during surgery often leads to decreased preload, vagal stimulation and arrhythmia11,12, thereby worsening the state of hypovolemia and hypo perfusion. It is estimated up to
75% of esophagostomies are associated with intra operative hypotension\textsuperscript{13}. There is, however, paucity of data on the relationship of intraoperative low Systolic Blood Pressure (SBP) and postoperative outcomes during esophagectomy particularly from a low resource, high volume centers.

We, therefore, prospectively studied the effect of intraoperative hypotension during esophagectomy and adverse short term postoperative outcomes among patients operated for esophageal cancer.

**Patients And Methods**

**Study design and data collection**

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

**Inclusion criteria**

All male and female patient’s older than 18 years of age who underwent standard esophagectomy were included in the study.

**Exclusion Criteria**

Patients who had exploration only, patients with feeding gastrostomy or jejunostomy tube insertion without esophagectomy due to unresectable disease, 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 ascites ...etc. were excluded.

**Sample size and sampling technique**

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

**Data collection data collection tool**

Data were 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 were documented. Modified Takita’s grading 1 -6\textsuperscript{14} was used for the assessment of dysphagia. American Society of Anesthesiology (ASA) physical status classification system I-IV\textsuperscript{15} for preoperative anesthesiology evaluation, BMI (Body Mass Index) based on body weight and height (kg/m\textsuperscript{2}),Eastern Cooperative Oncology Group (ECOG) performance classification (0-4)\textsuperscript{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\(^\text{17}\).

**Definitions**

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

Anastomotic leak was defined by 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 performed in 51.0% (n=26) of cases. McKeown’s esophagectomy was preferred for mid and upper thoracic esophageal cancers which are at T4 stage and performed in 15.7% (n=8) of the cases. Ivor – Lewis procedure was performed for 3.9% (n=2) patients while 29.6% (n=16) patients had Left thoracotomy approach as it was preferred for gastro esophageal junction and proximal gastric cancers. All esophago-gastric anastomosis were done via the anatomical esophageal bed and with hand sewn techniques.

**End Point**

The primary end point was the individual outcome variables or 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 was 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 was used for statistical data analysis. Descriptive statistics was used for describing the data and results are presented in percentage and simple frequency, mean (SD) and median are 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.

Results

1. Socio demographic characteristics

A total of 54 patients were included in the study. Mean age was 54 (SD ±12.08) years and 61.1% (n=33) were females. Mean body weight of the study participants was 49.04 (SD ±9.74) Kg and mean BMI was 18.6 (SD ± 2.85). Thirty-three (62.3%) of the patients were from rural area and 16 29.6% (n=16) of the study participants were from esophageal cancer endemic localities of the country. (Table 1)

Table 1: Socio-demographic characteristics of the study participants

| Variable       | Number (%) |
|----------------|------------|
| SEX            |            |
| Male           | 21(38.9)   |
| Female         | 33(61.1)   |
| Residence      |            |
| Urban          | 20 ( 37.7) |
| Rural          | 34 (62.3)  |

2. Clinical presentation

Fifty patients (92.6 %) presented with compliant 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 31.5 % (n=17) and 35.2 %( n=19) respectively. No supraclavicular lymph node was appreciated clinically in 92.6% (n=50) cases at presentation. (Table 2)

3. Preoperative risk assessment

Fifty two (96 %) of the patients were in 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 88.9% (n=48) had no known comorbidity. Cardiovascular disease (mostly hypertension) was the commonest comorbidity found in 4 (7.4 %) of patients. Only 7.4% (n=4) had history of smoking.

Table 2: Clinical parameters
| Variable                                      | Number (%) |
|----------------------------------------------|------------|
| **Presence of dysphagia**                    |            |
| Yes                                          | 50 (92.6)  |
| No                                           | 4  (7.7)   |
| **Degree of dysphagia**                      |            |
| Complains but can still swallow               | (I)        |
| Requires liquid to swallow                    | (II)       |
| Can swallow semisolids but not solids         | (III)      |
| Can swallow liquids but not semisolids        | (IV)       |
| Can swallow saliva but not semisolids         | (V)        |
| Can't even swallow saliva                     | (VI)       |
| Yes                                          | 1(1.9)     |
| 6(11.1)                                      |
| 17(31.5)                                     |
| 19(35.2)                                     |
| 9(16.7)                                      |
| 2(3.8)                                       |
| **Presence of Supra clavicular lymph node(LN)** |          |
| Yes                                          | 2(3.8)     |
| No                                           | 50(92.6)   |
| Missed data                                  | 2(3.8)     |

4. **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 88.9% (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 86.3% (n= 44) of the cases 23.8% (n=10) and 4.7% (n=2) had 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 on CT imaging was 4.94 (SD ±2.11) cm. Fifty two (96.3%) had upper GI Endoscopy evaluation. The mean location of tumor from incisors was at 32cm (SD: ±4.67). Biopsy results have revealed Squamous cell carcinoma in 72.2% (n=39).

5. **Intraoperative findings and events**
Thirty nine (72.2 %) patients were in clinically stage III disease and 9.2 % (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 (5.5%) patients had invasion of unresectable structures such as the aorta. All patients had lymph mode involvement with N1 and N2 stage involvements being the commonest. Five patients had signs of gross metastasis. Omental wrap was used in 51.1% (n=24) of the cases.

Mean duration of surgical procedures was 208.6 minutes (SD ±65.89) and mean duration of anesthesia was 238 minutes (SD ±75.65). Mean estimated blood loss was 741ml. Mean total duration of SBP < 90mmHg was 18.3 (SD ±28.5) minutes. Mean low SBP below 90 mmHg was 80 mmHg (SD ±12.4) while the lowest record was SBP of 55 mmHg. IOH occurred in 51.2 % (n=29) of the time. Ten (18.9%) patients needed intraoperative blood transfusion and ten patients (18.9%) required intraoperative inotropic or vasopressor support. (Table 3.)

**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(9.2)     |
| T3 (invasion of adventitia )                                           | 25(46.3)   |
| T4A (invasion of resectable adjacent Structures)                       | 21(38.8)   |
| T4B (invasion of unresectable adjacent Structures)                     | 3(5.5)     |
| **N Stage**                                                            | 0(0)       |
| N0 (No LN invasion)                                                    | 19(35.2)   |
| N1 (1-2 regional LN involvement)                                       | 23(42.6)   |
| N2 (3-6 regional LN involvement)                                       | 12(22.2)   |
| N3 (≥7 regional LN involvement)                                        |            |
| **M stage**                                                            | 49(90.7)   |
| M0 (No Metastasis)                                                     | 5 (9.2)    |
| M1 (Distant Metastasis)                                                | 2 (3.7)    |
| Ascites                                                                | 2 (3.7)    |
| Liver metastasis                                                       | 1 (1.8)    |
| Lung metastasis                                                        |            |
| **Clinical Stage**                                                     | 0(0)       |
| I                                                                      | 10 (18.5)  |
| II                                                                     | 39 (72.2)  |
| III                                                                    | 5 (9.2)    |
| IV                                                                     |            |
| **Omental Wrap Use**                                                   |            |
| Yes                                                                    | 24(44.4)   |
| No                          | 23 (42.6) |
|-----------------------------|-----------|
| Missing data                | 7 (12.9)  |

**Operative Complications***

| Tumor Perforations          | 3 (5.5)   |
|-----------------------------|-----------|
| Part of Tumor Left over     | 3 (5.5)   |
| Chylothorax                 | 1 (1.8)   |
| Recurrent laryngeal Nerve Injury | 1 (1.8) |
| Others~                     | 4 (7.4)   |
| No Complication             | 42 (77.7) |

**Need for intraoperative blood transfusion**

| Yes                        | 10 (18.9) |
|----------------------------|-----------|
| No                         | 43 (81.1) |
| Missing data               | 1 (1.8)   |

**Need for intraoperative inotropic support**

| Yes                        | 15 (27.7) |
|----------------------------|-----------|
| No                         | 32 (59.2) |
| Missing data               | 7 (3.9)   |

* Includes complications observed both intra op and Post op

~ Includes Persistent air leak from Right, pleural breach, Pyothorax, Splenic injury (splenectomy) GB injury (cholecystectomy)

**Table 4**: Postoperative care and outcomes
| Variable                                      | Number (%) |
|----------------------------------------------|------------|
| Need for postoperative blood transfusion     |            |
| Yes                                          | 15 (27.7)  |
| No                                           | 37 (68.5)  |
| Missing data                                 | 2 (3.7)    |
| Need for Postop Inotropic/vasopressor Support|            |
| Yes                                          | 5 (9.2)    |
| No                                           | 47 (87)    |
| Missing data                                 | 2 (3.7)    |
| Anastomotic leak                             |            |
| Yes                                          | 7 (13)     |
| No                                           | 47 (87)    |
| Reoperation for complication                 |            |
| Yes                                          | 6 (11.1)   |
| No                                           | 48 (88.8)  |
| 30 days Mortality                            |            |
| In hospital                                  | 5 (9.2)    |
| Post discharge, within 30 days post op       | 1 (1.8)    |
| Probable cause of death attributed to anastomotic leak | 2 (3.7) |
| Probable cause of death not attributed to anastomotic leak | 1 (1.8) |
| MI                                           | 1 (1.8)    |
| Stroke                                       | 1 (1.8)    |
| Chylothorax (sepsis, hypotension)            | 1 (1.8)    |
| ECOG Performance status 30th Postoperative day |        |
| 0: Fully active                              | 2 (3.7)    |
| 1: Restricted in physically strenuous activity but ambulatory | 10 (18.5) |
| 2: Moderately limited activity               | 19 (35.1)  |
2: Ambulatory and capable of all self-care but unable to carry out any work activities; up and about > 50% of waking hours

3: Capable of only limited self-care; confined to bed or chair > 50% of waking hours

4: Completely disabled; cannot carry on any self-care; totally confined to bed or chair

Missing data*

*excluding one death post discharge

6. Postoperative care and outcomes

The 30 days operative mortality was 9.2% (n= 5). Among the in hospital deaths, 3.7% (n=2) were attributed to anastomotic leak. One (1.8%) patient died after discharge within the study period of 30 post op day form unknown cause. There were 12.9% (n=7) cases of anastomotic leak. Six (12.2%) 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 prolonged hospital stay. Fifteen (28.8%) and 5(9.6%) patients needed postoperative blood transfusion and postoperative inotropic support respectively. On 30th day post op 57.4 % (n=31) of the patients were ambulatory in more than 50% of waking hours and capable of all self-care (ECOG 3). (Table 4)

Table 5: Intraoperative hypotension and Outcome variables
### End point

| End point | No Intraop hypotension | Intraop hypotension | OR         | P value |
|-----------|------------------------|---------------------|------------|---------|
|           | N (%)                  | N (%)               | 95% CI     |         |
| Hospital stay |                     |                     |            |         |
| ≤7 days    | 5(9.2)                 | 7(12.9)             | 0.53 (0.14-1.9) | p=0.34 |
| >7 days    | 24(44.4)               | 18(33.3)            |            |         |
| Anastomotic leak |                 |                     | 1.28 (0.26-6.3) | p=0.76 |
| Yes       | 3(5.5)                 | 4(7.4)              |            |         |
| No        | 23(42.6)               | 24(44.4)            |            |         |
| Death     |                        |                     | 1.44 (0.22-9.3) | p=0.70 |
| Yes       | 2(3.7)                 | 3(5.5)              |            |         |
| No        | 24(44.4)               | 25(46.2)            |            |         |

7. **Outcome of patients and associated factors**

Four (7.4%) patients with anastomotic leak (OR 1.2, 95% CI 0.26-6.3; *p*=0.76), 3 (5.5%) 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 < 90mmHG 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 6: Composite Outcomes 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 <90mmHg >5 min          | 1.06 (0.99, 1.12)  | 0.056   | 1.06 (0.98, 1.14)  | 0.160   |
| SBP <90mmHg                 | 2.36 (0.7, 7.93)   | 0.166   | 1.07 (0.16, 6.99)  | 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

**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 literatures suggested tumor stage, histologic subtype, performance status, age, type of surgical approach, intraoperative blood loss and blood transfusion as risk factors, few have clearly addressed the effect of intraoperative hypotension on postoperative morbidity and mortality of patients undergoing esophagectomy for esophageal ca9,10,21–27. Furthermore, lack of agreed upon definitions of intraoperative hypotension (IOH) during surgical procedures, including esophageal resections has confounded the association between blood pressure deviations during surgery and mortality 15,18. The paucity of such studies makes comparison with our study challenging.

In our study we found that neither intraoperative hypotension, SBP < 90mm Hg 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 9.2 %. This was similar to post esophagectomy mortality rates of 3-16 %
reported by multiple studies. 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 but not statistically significant \( p=0.34 \).

IOH was not found to be associated with an increased perioperative mortality (5.5% vs 3.3%; OR 1.44 (0.22, 9.3) \( p=0.7 \)). This finding aligns with the retrospective cohort study on combined intraoperative blood pressure data by Monk et al which identified Systolic BP < 70 mm Hg, not higher, for \( \geq 5 \) min to be associated with increased 30-day operative mortality in non-cardiac surgery. A study by Fujisawa, A et al found that patients with intraoperative hypotension showed significantly lower 1 year cancer specific survival than patients without hypotensive episodes \( p=0.0002 \). They, however, defined intraoperative hypotension as SBP < 70mmHg and did not describe short term outcome.

The anastomotic leak we found in this study is had no significant statistical association with intraoperative hypotension (5.5% Vs 7.4%; \( p=0.76 \)). This is in contrast to the finding by Fumagall U. et al where leaks were significantly more common in patients with intra-operative hypotensive episodes \( p=0.02 \). Their study involved 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 prone position. Unlike their study, none of our study patients were operated in prone position.

Our anastomotic leaks accounted for 2(33.3%), of the deaths and had a 2/7 (28.5%) mortality which is comparatively higher than a 12% mortality from anastomotic leak found in a systematic review done by Verstegenet al and other recent data but comparable to the 37% mortality reported by Turkyilmaz A et al.

Even though Gockel and colleges 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.

**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 hasn’t addressed the effect of sustained and non-sustained IOH. Additionally, IOH was not defined and analyzed in terms of mean arterial and diastolic blood pressure on short term post op outcomes. Moreover, the study did not analyze the association and outcome of IOH with stage sub types, different esophagectomy approaches, and histologic subtypes. Furthermore, the study has not addressed other secondary end points such as wound infection, pulmonary complications...etc.

**Conclusion**
In this study, we found that a systolic blood pressure < 90 mm Hg for greater than 5 min during surgery has no significant statistical association either with individual or composite adverse outcomes of mortality, anastomotic leak and prolonged hospital stay.

**Abbreviations**

AJCC : American Joint Committee on Cancer  
AOR : American Society of Anesthesiology  
BMI : Body Mass Index  
CI : Confidence interval  
COR : Crude Odds Ratio  
ECG : Electrocardiogram  
ECOG : Eastern Cooperative Oncology Group  
IOH : Intra operative 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

**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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Authors' contributions

- T. Yeheyis: conceived, designed and conducted and coordinated the study, operated cases, collected data, and wrote the manuscript
- Kassa: conducted the study, operated cases and collected data
- Yeshitla: conducted the study and collected data.
- Bekele: Mentorship, operating cases and data collection, revised and edited the manuscript

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