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Low-Cost Single-Port (LoCoSP) Device for a Transcervical Approach in Minimally Invasive Transhiatal Esophagectomy

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TITLE:

Low-Cost Single-Port (LoCoSP) Device for a Transcervical Approach in Minimally Invasive Transhiatal Esophagectomy

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SUMMARY:

Here, we describe a step-by-step description of transhiatal esophagectomy and the development of a low-cost single-port device for a transcervical approach in a minimally invasive transhiatal esophagectomy.

ABSTRACT:

Esophagectomy remains the preferred option to achieve curative treatment in advanced esophageal cancer, but the choice of surgical approach remains controversial. A transthoracic approach may improve lymph node dissection, but it has considerable morbidity and respiratory complications. Transhiatal access has been demonstrated as an efficient means of minimizing post-operative complications. Minimally invasive transhiatal esophagectomy may reduce operative trauma and morbidity as well as enhance postoperative recovery with no compromise in cancer recurrence or survival. Nevertheless, it has a technical limitation in terms of cervical esophagus dissection. Thus, a low-cost single-port device was developed to complete upper mediastinal dissection by a transcervical approach during minimally invasive transhiatal esophagectomy. This device uses a nasogastric tube, a number-eight sterile glove, a sterile sponge, and 3 permanent 5-mm trocars. The step-by-step process of transhiatal esophagectomy and the development of this device are described. This technique allows for the dissection of the upper mediastinum, as well as the esophagus over the aortic arch and behind the superior portion of the trachea. The harvesting of lymph nodes along the left recurrent laryngeal nerve and paratracheals was improved.

INTRODUCTION:

There are multiple options for the treatment of esophageal cancer, which involve endoscopy,

surgery[1], neoadjuvant, and definitive treatment with chemoradiotherapy[2]. Esophagectomy is the most important element in the curative treatment of patients with advanced esophageal cancer[3], and the two main approaches currently used for surgical treatment are transthoracic esophagectomy (TTE) and transhiatal esophagectomy (THE). However, the choice of approach remains controversial. Since TTE requires pulmonary collapse during surgery, more frequent pulmonary complications are to be expected than in a transhiatal approach. Minimally invasive techniques are used to reduce access trauma to the lungs and others structures of the thorax, but they do not decrease the morbidity in comparison to THE. Thus, minimally invasive THE has become a more attractive option; however, the upper esophagus and upper mediastinum are difficult areas to dissect due to blind areas, and cervical incision might be not enough to allow a safe dissection of the upper part.

Laparoscopic THE reduces morbidity[4] and enhances postoperative recovery with no compromise in cancer recurrence or survival[5]. THE has been shown to decrease the hospital stay, hospital mortality, surgical time, and blood loss. Furthermore, TTE has a higher risk of pulmonary complications. The patient's stay in the intensive care unit is significantly longer after transthoracic resection, and hospital stay is also significantly prolonged.

However, there is an issue with THE regarding the lymph node dissection, particularly in the upper mediastinum, which is a blind area. This results in a risk of tracheal and vascular lesions during the surgery. Tokairin[6] et al. and Fujiwara et al. described a single-port mediastinoscopic method for upper mediastinal dissection in esophageal cancer surgery. This technique enabled clear visualization of the structures around the aortic arch and safe lymphadenectomy[7]. A low-cost single-port device was developed to improve upper mediastinal dissection using a left transcervical mediastinoscopic approach, which was used to improve the visibility and dissection in the upper mediastinum around the aortic arch. The aim of this project is to describe the step-by-step process of a laparoscopic THE completed using a mediastinoscopy cervical approach with a low-cost single-port device in a rendezvous technique.

PROTOCOL:

The surgical procedure and the protocol were explained to the patients, and they signed a consent form. This study was approved by the local ethics committees of the institutional review board and informed consent were collected from patients, register number 1688/20. Patients who underwent transhiatal esophagectomy were included in the protocol, while those patients who underwent a transthoracic approach were excluded.

1. Production of low-cost single-port device

1.1. Use a nasogastric tube, a sterile number-eight glove, a sterile sponge, 3 permanent 5-mm trocars and surgical suture materials.

1.2. Make one cylinder with the sterile sponge.

1.3. Use three glove fingers to triangulation the trocars: little finger, middle finger and thumb

1.4. Use the three trocars to pierce the sponge and perform a triangulation (**Figure 1** and **Figure 2**).

1.5. Make one ring with the nasogastric tube.

1.6. Place the sponge, the trocars and the glove between the ring to seal the air leak during mediastinoscopy and to stabilize the structures.

1.7. Use the glove to cover all the structures to prevent air leak again.

2. Laparoscopic and transhiatal procedure

2.1. Put the patient under general anesthesia in a supine position.

2.2. Insert an orotracheal, a central venous and an invasive arterial pressure catheter respectively in the trachea, jugular vein and radial artery.

2.3. Create a pneumoperitoneum using a Veress needle. Insert the needle in the midline above the umbilical scar.

2.4. Place laparoscopic trocars in the following positions: one 12-mm trocar in the supraumbilical area, two 10-mm trocars in the left and right hypochondrium, and two 5-mm trocars in the right hypochondrium and the epigastrium.

2.5. Perform abdominal cavity inventory to search for peritoneal or liver metastasis.

2.6. Examine the gastroepiploic arcade from the right gastroepiploic artery to the short gastric vessels.

2.7. Open up the gastrocolic ligament to the pilorus to gastric fundus while preserving the gastroepiploic arcade.

2.8. Perform the posterior gastric wall release. Lift up the posterior aspect of the stomach and dissect using an ultrasonic harmonic scalpel to free it from the retroperitoneum. Identify the pancreas, left gastric vessels, and celiac trunk.

2.9. Make a gastric tube with a stapler. Start stapling in the antrum by the lesser curvature and move towards the greater curvature. Make a slim gastric tube to create an anastomosis in the cervical esophagus and empty it properly.

2.10. Perform dissection and ligation of the left gastric vessels at the origin to harvest the appropriate lymph nodes. Perform the dissection cranially to the origin of the left gastric vein and the left gastric artery.

2.10.1. Use one clip proximally and other distally in the left gastric vein before sealing it. Use two hemolocks proximally and one distally in the left gastric artery before sealing it.

2.11. Sequentially dissect all the lymph nodes and connective tissue along the left gastric artery (7), common hepatic artery (8a), celiac trunk (9), proximal splenic artery (11p), lesser curvature (3), and the esophago gastric junction (1) and reflect toward the stomach.

2.12. Perform dissection of the esophageal hiatus. Enlarge the hiatus anteriorly to facilitate dissection and mobilization of the thoracic esophagus and the other mediastinal structures.

2.13. Identify the aorta and dissect the posterior wall of the esophagus from the descending aorta with a harmonic scalpel.

2.14. Continue the dissection of the esophagus in a paraesophageal plane in the lower mediastinum under pneumomediastinum. In the middle to upper portion of the mediastinum, however, this dissection is normally performed blindly and may lead to tracheal lesions or hemorrhage from tearing of the larger vessels.

2.15. Stop the dissection in the transition of the middle to upper mediastinum up to the carina and started with a single-port mediastinoscopic cervical approach using a rendezvous technique (this technique is described below).

3. Transcervical procedure

3.1. Make an oblique incision along the anterior border of the left lower sternocleidomastoid parallel to the clavicle.

3.2. Identify the sternocleidomastoid muscle and divide.

3.3. Mobilize the cervical esophagus and initiate the dissection of the cervical lymph nodes along the left recurrent laryngeal nerve.

3.4. Insert the single-port device into the cervical wound (**Figure 3**) and create a pneumomediastinum by carbon dioxide insufflation (8 mmHg). Use a 5-mm Otic and a Harmonic Scalpel for esophagus dissection along with a laparoscopic grasper.

3.5. Dissect the esophagus over the aortic arch and behind the superior portion of the trachea. Perform the dissection of the lymph nodes along the left recurrent laryngeal nerve and trachea.

3.6. After this stage, completely mobilize the esophagus, and reach the region that was dissected using a transhiatal approach. Divide the cervical esophagus, and remove the esophagus with the tumor by an abdominal incision.

3.7. Perform cervical anastomosis with gastric tube and esophageal stump.

REPRESENTATIVE RESULTS:

The LoCoSP device is a useful tool for safely dissecting the structures of the upper mediastinum. Direct visualization of the cervical and upper thoracic esophagus allows for safe dissection with less risk of tracheal injury and hemorrhage from tearing of the larger vessels, in addition to improving the lymphadenectomy of the left recurrent laryngeal and paratracheal nodes.

From 2018 to 2020, 12 patients with distal esophageal carcinoma (2 squamous cell carcinoma and 10 adenocarcinoma) were submitted to laparoscopic transhiatal esophagectomy with transcervical access to cervical esophagus dissection and lymphadenectomy. The median age was 62 (60 ± 85) years old, only one patient was female. There was no chordal palsy, bleeding, tracheal damage related to the transcervical access. One anastomotic fistula occurred with no clinical complications, spontaneous drainage through the cervical incision. The median operation time was 360 min (300 ± 420 min), and the operation time of the transcervical dissection of the cervical esophagus was 60 min (40 ± 110 min). The median hospital stay was 10 days (9 ± 12 days). All cases were performed with the LoCoSP device (**Table 1**).

FIGURE AND TABLE LEGENDS:

Figure 1: Low-cost single-port device

Figure 2: Low-cost single-port device (note the triangulation of the three trocars)

Figure 3: Low-cost single-port device into the cervical wound

Table 1: Surgery results using low cost single-port device

DISCUSSION:

The LoCoSP device allows for safer surgery using a transcervical approach in minimally invasive THE. This is accomplished by improving the recognition and dissection of the esophagus, trachea, and the aortic arch under magnified vision. The advantages of THE are amplified. In addition to allowing surgery with less morbidity and fewer pulmonary complications, this technique can improve the dissection of left paratracheal and recurrent lymph nodes. Another advantage of this technique is that it is possible to reduce the risk of tracheal and vascular injury during THE.

Damage of the posterior wall of the trachea or the main bronchi rarely occurs during esophagectomy, and the reported rates are 1.35%[8] to 1.8%[9]. However, when it does happen, the prognosis is unfavorable[10]. Dissection with a single-port mediastinoscopic cervical approach allows for direct visualization of the upper esophagus and the trachea, which could possibly

decrease the chances of injury to the airways. Finally, the production of the LoCoSP device is easy, and it can be reproduced in other centers. The device is produced using cheap and widely available instruments in any operating room. An important limitation of the technique is the leakage of air through the cervical wound, during the dissection of the upper mediastinum. Nevertheless, the method is still an experimental method, and the real benefit of using the LocOSP device must be studied and analyzed in a greater number of patients.

ACKNOWLEDGMENTS:

None.

DISCLOSURES:

There are no disclosures.

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Figure1

Click here to access/download;Figure;Figure1 - final.jpg

Figure2

Click here to access/download;Figure;figure2 - final.jpg

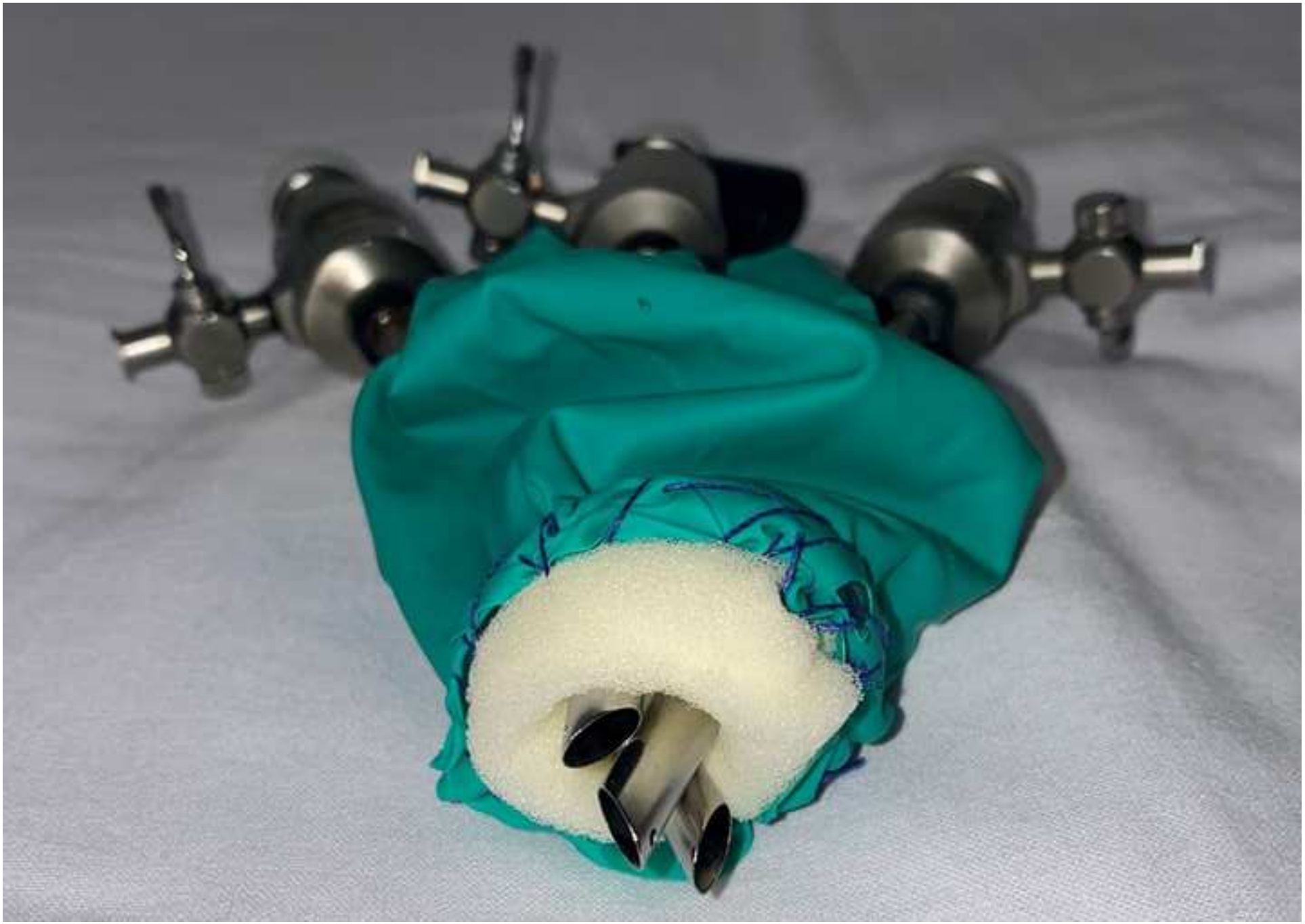
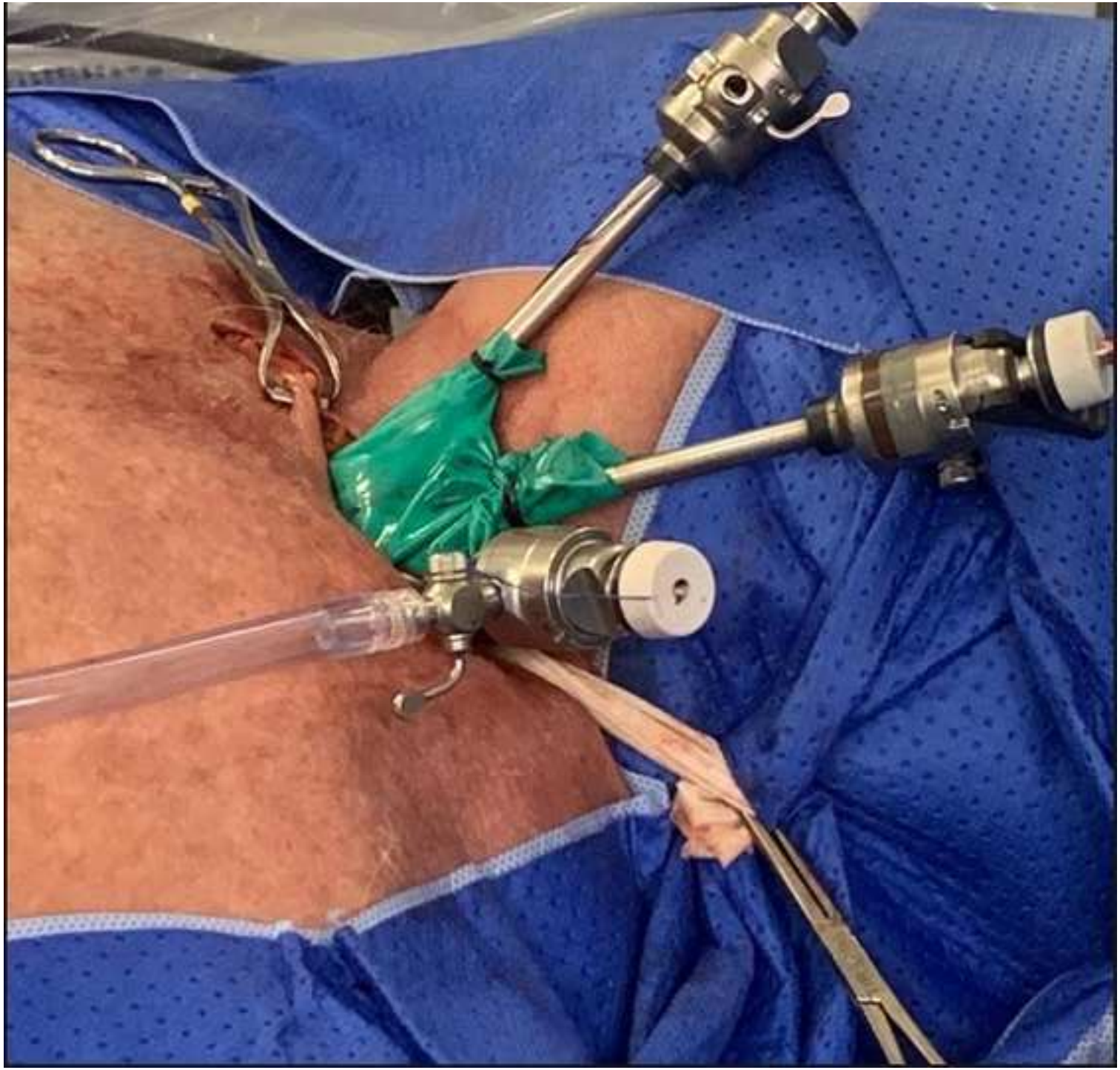


Figure3

Click here to access/download;Figure;figure3.jpg



Total Patients	12
Median Age (years)	62
Number Anastomotic fistula	1
Median operation time (minutes)	360
Median operation time transcervical dissection (minutes)	60
Median Hospital stay (days)	10

Thanks for the comments and expertise from the editorial team.

We submitted the revised manuscript: Low-Cost Single-Port (LoCoSP) Device for a Transcervical Approach in Minimally Invasive Transhiatal Esophagectomy.

The changes made are described below.

Best Regards,

Flavio Takeda, MD, PhD

Editorial and production comments:

Changes to be made by the Author(s) regarding the written manuscript:

1. Please take this opportunity to thoroughly proofread the manuscript to ensure that there are no spelling or grammar issues. - **Thank you for your comments. We thoroughly proofread the manuscript**
2. For in-text formatting, corresponding reference numbers should appear as numbered superscripts after the appropriate statement(s). There should only be one set of numerical reference numbering (1, 2, 3, etc.) - **Thank you for your comments. We review the corresponding reference numbers**

3. Please include an ethics statement before the numbered protocol steps, indicating that the protocol follows the guidelines of your institution's human research ethics committee.- **Thank you for your comments. We included the ethic statement and the register number**
4. Please revise the text to avoid the use of any personal pronouns (e.g., "we", "you", "our" etc.). **Thank you for your comments. We revise the text and delete any personal pronouns**

5. Please ensure that all text in the protocol section is written in the imperative tense as if telling someone how to do the technique (e.g., "Do this," "Ensure that," etc.). The actions should be described in the imperative tense in complete sentences wherever possible. Avoid usage of phrases such as "could be," "should be," and "would be" throughout the Protocol.- **Thank you for your comments. We ensure that all text in the protocol section is written in the imperative tense**

6. Please add more details to your protocol steps. Pleaseensure you answer the "how" question, i.e., how is the step performed? **Thank you for your comments. We add more details to the protocol, mainly how to produce the low cost single port device.**

7. What are the patient inclusion/exclusion criteria? - **Thank you for your comments. We add th epatient inclusion and exclusion criteria: "Patients who underwent transhiatal esophagectomy were included in the protocol, while those patients who underwent a transthoracic approach were excluded"**

8. Line 78: How is the Pneumoperitoneum created? Please provide all details and surgical tools used. - **Thank you for your comments. We add more details about how to creat pneumoperitoneum**

9. Line 93: How is the dissection and ligation done?-**Thank you for your comments. We tried to explain better how the dissection and ligation of the structures are made**

10. Line 110-116: When is this done? It should be placed at the beginning of the protoco-**Thank you for your comments. We place "Production of Low-Cost Single-port Device" at the beginning of the procol.**

11. Please provide more details on the patient before and after care. Was anesthesia used? How? **Thank you for your comments. We provide more details on the patient before and after the surgery. We use general anesthesia**

12. Please provide a Figure or Table summarizing the results. **Thank you for your comments. We provide a table summarizing the results**

13. As we are a methods journal, please revise the Discussion to explicitly cover the following in detail in 3-6 paragraphs with citations:
a) Critical steps within the protocol
b) Any modifications and troubleshooting of the technique
c) Any limitations of the technique
d) The significance with respect to existing methods
e) Any future applications of the technique
Thank you for your comments. We tried to explicitly the applications of this technique: "can improve the dissection of left paratracheal and recurrent lymph nodes. Another advantage of this technique is that it is possible to reduce the risk of tracheal and vascular injury". An important limitation of the technique is the leakage of air through the cervical wound, during the dissection of the upper mediastinum with a low-cost single-port device.

14. Please ensure that the references appear as the following: [Lastname, F.I., LastName, F.I., LastName, F.I. Article Title. Source. Volume (Issue), FirstPage – LastPage (YEAR).] For more than 6 authors, list only the first author then et al. - **Thank you for your comments. We review all references**

Changes to be made by the Author(s) regarding the video:
1. Please increase the homogeneity between the video and the written manuscript. Ideally, the narration is a word for word reading of the written protocol.
Thank you for your comments. We tried to increase the homogeneity between the video and the written manuscript. We focus more on the creation of their device

2. Video

• Video resolution is 720x480, minimum resolution is 960x720. • Few transitions are used. Consider using cross-dissolve transitions to smooth out edits. - • Fade up from black at beginning of video
• Fade to black at end of video
Thank you for your comments. We change the video resolution and we used more transitions in the film.

3. Audio
• Audio is low quality and has occasional ""drop-outs"", making some words difficult to hear. Consider re-recording at higher quality.
• 02:27 - Beginning of word ""then"" is cut-off
• 04:39 - Beginning of word ""then"" is cut-off
Thank you for your comments. We improved the audio.

4. Text
• Title card must have author names and affiliations **Thank you for your comments. We review the title card**

• Human ethics card required after introduction statements **Thank you for your comments. We add a human ethics card**

• chapter title edit needed - ""Dissection of the esophagus in the lower mediastinum"" **Thank you for your comments. We edited the chapter title**

• chapter title edit needed - ""Fabrication of the Low-Cost Single-port (LoCoSP) device""
Thank you for your comments. We edited the chapter title

• chapter title edit needed - ""Dissection of the structures of the upper mediastinum using LoCoSP device"" **Thank you for your comments. We edited the chapter title**

Please upload a revised high-resolution video here:
https://www.dropbox.com/request/lQsfcOidNVwhhSALvqJJ?oref=e

Reviewers' comments:
Reviewer #1:
The authors described the development of a low-cost single-port device for a transcervical approach in minimally invasive transhiatal esophagectomy. The device is thought to be useful for safely dissecting the structures of the upper mediastinum and produced using cheap and widely available instruments in any operating room.
However, while this device and the method is considered to have clinical value, the authors should revise several points to improve the content.

Manuscript Summary:
Nothing

Major Concerns:
Nothing

Minor Concerns:
1. Text, lines 3:
The title was written as, "Low-Cost Single-Port (LoCoSP) Device for a Transcervical Approach in Minimally Invasive Transhiatal Esophagectomy". This should be written as, "Low-cost Single-port (LoCoSP) Device for a Transcervical Approach in Mediastinoscopic Esophagectomy". -**Thank you for your comments. Esophagectomy is performed through a transhiatal approach. The transcervical approach completes the dissection of the upper medistine and cervical esophagus.**

2. Text, lines 63:
The authors wrote, "Fujiwara et al. described a single-port". Because Tokairin et al. reported this technique prior to Dr. Fujiwara, this should be written as: "Tokairin et al. and Fujiwara et al. described a single-port". The authors should cite the article, "Tokairin Y, Nagai K, Fujiwara H, et al. Mediastinoscopic subaortic and tracheobronchial lymph node dissection with a new cervico-hiatal crossover approach in thiel-embalmed cadavers. Int Surg. 2015;100:580-588" **Thank you for your comments. We cite the article "Tokairin Y, Nagai K, Fujiwara H, et al. Mediastinoscopic subaortic and tracheobronchial lymph node dissection with a new cervico-hiatal crossover approach in thiel-embalmed cadavers. Int Surg. 2015;100:580-588" too**

3. Text, lines 83:
The authors wrote, "The gastroepiploic arcade is examined from the right gastroomental artery to the short gastric vessels". This should be written as, "The gastroepiploic arcade is examined from the right gastroepiploic artery to the short gastric artery". - -**Thank you for your comments. We change the word gastroomental to gastroepiploic**

4. Text, lines 76:
The authors wrote, "Abdominal and Thoracic Time". This should be written as, "Laparoscopic and transhiatal procedure". **Thank you for your comments. We review the text**

5. Text, lines :98:
The authors wrote, "to facilitate dissection and mobilization of the thoracic esophagus of the other mediastinal structures". This should be written as, "to facilitate dissection and mobilization of the thoracic esophagus and the other mediastinal structures". **Thank you for your comments. We review the text**

6. Text, lines 100:
The authors wrote, "adhesions between the aorta and esophagus are released". This should be written as, "the posterior wall of the esophagus is dissected from the descending aorta". **Thank you for your comments. We review the text**

7. Text, lines 103:

The authors wrote, "under vision." This should be written as, "under pneumomediastinum." **Thank you for your comments. We review the text**

8. Text, lines 110:
The authors wrote, "Fabrication of Low-Cost Single-port Device". This should be written as, "Production of a Low-cost Single-port Device". **Thank you for your comments. We review the text**

9. Text, lines 121:
The authors wrote, "Cervical Time. This should be written as, "Transcervical procedure". **Thank you for your comments. We review the text**

10. Text, lines 132:
The authors wrote, "paratracheals". This should be written as, "trachea".- **Thank you for your comments. We review the text**

11. Text, lines 133:
The authors wrote, "we reach the transhiatal dissection". This should be written as, "we reach the region that was dissected using a transhiatal approach". **Thank you for your comments. We review the text**

12. Text, lines 136:
The authors wrote, "Anastomosis of the gastric tube is done with the cervical esophagus." This sentence is difficult to understand. Please consider a more appropriate expression. - **Thank you for your comments. We review the text**

13. Text, lines 147:
The authors wrote, "chordal palsy". This is thought to be "recurrent nerve palsy". Please consider whether this is correct or no **Thank you for your comments. We review the text**

14. Text, lines 147:
The authors wrote, "tracqueal damage". This should be written as, "tracheal damage". **Thank you for your comments. We review the text**

15. Text, lines 149:
The authors wrote, "during operation time". This should be written as, "operation time".- **Thank you for your comments. We review the text**

16. Text, lines150:
The authors wrote, "the transcervical dissection of the cervical esophagus". This should be written as, "the operation time of the transcervical dissection of the cervical esophagus". - **Thank you for your comments. We review the text**

17. Text, lines 163:
The authors wrote, "this technique can improve the dissection of left paratracheal and recurrent lymph nodes and reduce the risk of vascular lesions". This should be written as, "this technique can improve the dissection of the left paratracheal and recurrent lymph nodes". **Thank you for your comments. We review the text**

18. Text, lines 165:
The authors wrote, "Another advantage of this technique is that it is possible to reduce the risk of racheal injury during THE." This should be written as, "Another advantage of this technique is that it is possible to reduce the risk of tracheal and vascular injury during THE".
Thank you for your comments. We review the text

19. Text, lines 167:
The authors wrote, "main bronchi". This should be written as, "the main bronchi" **Thank you for your comments. We review the text**

Reviewer #2:
Manuscript Summary:
Dr. Takeda and colleagues show a low-cost single-port device that helps completing upper mediastinal dissection by a transcervical approach during transhiatal esophagectomy. A total of 12 patients underwent this technique with good postoperative results. I congratulate the authors for this innovative technique and for their high quality and well narrated video. This novel approach should be further evaluated in larger studies, and I believe this video/manuscript will indeed encourage research in this area.

Major Concerns:
NO

Minor Concerns:
NO
Thank you for your comments.

Reviewer #3:
I think the video focuses too much on the standard approaches to minimally invasive esophagectomy which has been well described. The novel aspect of their approach is the use of the low cost single port in the cervical region to facilitate the upper mediastinal dissection of the esophagus and lymph nodes. The video should focus more on the creation of their device, the insertion of their device in the cervical region, the instrumentation utilized and more video should be included for the dissection of the esophagus and upper mediastinal lymph nodes from the cervical route. Less video from the abdominal approach should be utilized.

Thank you for your comments. We review the video and we tried to focus more in production of the low cost single port device and in the mediastinoscopy time.

Thanks for the comments and expertise from the editorial team.

We submitted the revised manuscript: Low-Cost Single-Port (LoCoSP) Device for a Transcervical Approach in Minimally Invasive Transhiatal Esophagectomy.

The change in the video were made and the video was uploaded.

Best Regards,

Flavio Takeda, MD, PhD