Original Article

Robotic- assisted minimally invasive Ivor-Lewis handsewn anastomosis technique and outcomes from a large-volume European centre

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SUMMARY. In minimally invasive transthoracic esophagectomy, intrathoracic anastomoses are usually performed with stapling devices to avoid a technically challenging handsewn technique in the upper mediastinum. Few have published about handsewn anastomotic techniques due to the technically demanding requirements for suturing with rigid instruments in the thoracic cavity. With robot-assisted minimally invasive esophagectomy (RAMIE), the robot provides increased dexterity, enabling construction of a hand-sewn intrathoracic anastomosis. This study aimed to evaluate the outcomes of our technique for hand-sewn intrathoracic anastomosis in RAMIE, following the initial learning phase between 2016 and 2018 in UMC Utrecht. Patients who underwent RAMIE with a robotassisted hand-sewn intrathoracic anastomosis were included in this retrospective study. Data were extracted from a prospectively maintained institutional database. Key technique steps included esophageal stay-sutures, use of barbed sutures for the anastomosis, placement of tension-releasing stitches, and covering of the anastomosis with omentum. The primary outcome was anastomotic leakage; secondary outcomes included anastomotic stricture rate and duration of anastomosis construction. Between 1 November 2019 and 30 May 2023, 89 consecutive patients were included. Anastomotic leakage (defined by the Esophageal Complications Consensus Group) occurred in 11 patients (12.4%), which involved a grade I leak in four patients (4.5%), grade II leak in one patient (1.1%), and grade III leakage in six patients (6.7%). The median duration of anastomosis creation was 33 minutes (range, 23– 55 minutes). Stricture rate was 32.6% (29 patients) at 1 year post-operatively for which dilation was needed for all patients. This study shows that a robot-assisted hand-sewn intrathoracic anastomosis in RAMIE is feasible, safe, and reliable.

KEY WORDS: handsewn anastomosis, intrathoracic anastomosis, robot-assisted minimally invasive esophagectomy (RAMIE), technique.

INTRODUCTION

Esophageal cancer is the eighth most common cancer and is the sixth leading cause of cancer death worldwide. ¹ Treatment of locally advanced esophageal cancer is usually with neoadjuvant chemotherapy (FLOT)² or chemoradiotherapy (CROSS)³ followed by radical esophagectomy. With the advent of minimally invasive surgery, several intrathoracic esophagogastric anastomotic techniques have been described for Ivor–Lewis esophagectomy; such as handsewn, end-to-side circular stapled or side-to-side linear stapled. ⁴ Limited data on handsewn anastomotic

techniques in minimally invasive esophagectomy is reported due to the highly demanding technical requirements for suturing with rigid instruments in the thoracic cavity. Robot-assisted minimally invasive esophagectomy (RAMIE) has been shown to offer advantages over open and minimally invasive esophagectomy with regards to surgery-related post-operative complications (such as pulmonary and cardiac) as well as oncologic safety as seen in the ROBOT⁵ and RAMIE⁶ trials respectively. The presence of 3D, 10 times enlarged stable image combined with robotic articulating instruments improves the dexterity. This allows for intrathoracic handsewn

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anastomosis that would otherwise be very challenging in the conventional thoracoscopic approach.

We describe our centre's intrathoracic (Ivor Lewis) handsewn anastomosis technique for esophagectomy which was introduced in 2016 and subsequently refined to its current technique.

METHODS

Patient selection

Patients were selected from a prospectively maintained database of the University Medical Centre Utrecht, Netherlands. All patients who underwent an Ivor Lewis RAMIE with an intrathoracic handsewn anastomosis between November 2019 and May 2023 were included in this retrospective study. The inclusion period was chosen following the initial learning phase, when the handsewn anastomotic technique was refined and standardized with no further adjustments of technique. The aim of the study was to evaluate the outcomes of this method. The development and refinement of the technique, including its initial challenges and adjustments, have been covered in a previously published paper. We believe this approach ensures that the learning curve presented here is based on the finalized version of the technique, which is most relevant for clinicians seeking to adopt it in its current form.

This study was conducted in accordance with the Declaration of Helsinki (as revised in Edinburgh 2000) and approved by the institutional ethical board of the University Medical Centre Utrecht (No. 13–061). The need for informed consent was waived.

Ivor Lewis RAMIE procedure

The procedures were conducted entirely through robotic assistance, encompassing both the abdominal and thoracic phases. A two-field lymphadenectomy was performed (including upper mediastinal nodal dissection (Naruke lymph node stations 4R, 4 L, 5 and 7, 8, 9) followed by construction of a gastric conduit and intrathoracic anastomosis. The technical steps of the thoracic phase and initial experience of this technique have been previously described. All surgeries were performed by two senior surgeons (RvH, JPR), both of whom have been engaged in RAMIE since 2003 and 2011, respectively. They have been performing RAMIE procedures with an intrathoracic handsewn anastomosis since 2016.

Anastomotic technique

Positioning for thoracic phase

Patients were placed in left lateral semi-prone position, 45° tilted towards prone. The camera port (8 mm robotic trocar) was placed in the 6th intercostal space

with three other robotic trocars placed in the 4th, 8th, and 10th intercostal spaces under direct vision. An assistant port (12 mm ENDOPATH XCEL® Bladeless Trocar, Ethicon) was placed in the 5th intercostal space. Robotic arm placement was as follows: Arms 1 and 2 were interchangeable between the Cadiere or Vessel Sealer, 3 for camera and 4 for a monopolar hook or Large Needle Driver. The assistant port was used for suction and introduction of sutures.

Location of intrathoracic anastomosis

Care was taken to place the tube in a straight fashion in the esophageal bed taking the omentum away from the esophageal bed, ensuring the conduit will not be twisted. The anastomosis was created just above the level of the azygous arch. This position is strategic to secure sufficient proximal resection margins and to minimize reflux into the esophagus, as well as to ensure that the anastomosis is positioned outside of any prior radiation field. The location of the gastrostomy on the gastric conduit is determined by administering 7.5 mg of intravenous indocyanine green (ICG). This injection allows for the visualization and assessment of the vascularization of the gastric conduit by fluorescence detection (Fig. 1). This step subsequently determines the optimal anastomotic site at the gastric conduit. If ischaemia is detected at the tip of the conduit, it is excised with a robotic endostapler (Sureform 60 mm) before proceeding with the anastomosis.

A 2 cm vertical gastrostomy was created in the middle of the gastric conduit in a longitudinal fashion parallel to the gastric stapler line with a cautery hook, ensuring at least 1 cm distance from the staple lines to avoid ischemia (Figs. 2 and 3).

Placement of stay sutures in the esophagus

Stay sutures in the wall of the transected esophagus at 4 quadrants were placed with Vicryl 4/0. This is to ensure that the lumen is open and all the layers of the esophageal wall are incorporated during subsequent creation of the anastomosis (Fig. 4).

Suturing of the anastomotic wall

The handsewn anastomosis was performed in an end-to-side fashion with two barbed V-Loc 4/0 running sutures. The first barbed suture was used to close the posterior wall in a single layer continuous suture with bites placed 5 mm apart (Fig. 5). The process was repeated for the anterior wall with the second line of barbed suture. Before closure, the nasogastric tube was then advanced under direct vision into the proximal gastric conduit past the anastomosis (Fig. 6). The sutures were locked by sewing the V-Locs backwards (Fig. 7).



Fig. 1 Showing adequate conduit tip perfusion with ICG. In such cases, no excision of tip is required.

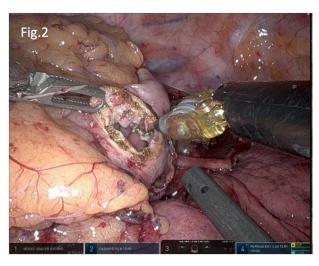


Fig. 2 Creation of 2 cm longitudinal gastrostomy on the conduit parallel to the staple line.

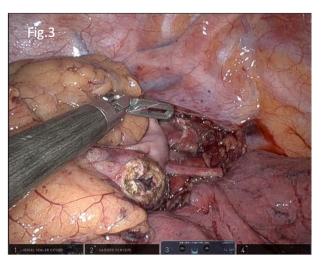


Fig. 3 Creation of 2 cm longitudinal gastrostomy on the conduit parallel to the staple line.

Tension-releasing sutures

Three to four tension-releasing sutures were placed around the anastomosis with Vicryl 3/0 as a second layer to approximate the esophageal wall to the gastric wall using the slipping knot technique (Fig. 8).

Omental coverage

The proximal omentum from the conduit was wrapped over the anastomosis and anchored in placed with the V-Loc sutures from the anastomosis creation (Fig. 9).

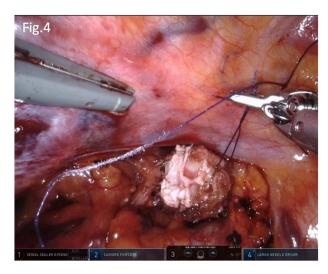


Fig. 4 Placement of oesophageal stay sutures to incorporate all layers of esophageal wall.



Fig. 5 Closure of posterior wall of handsewn anastomosis with V-Loc 4/0 running suture.



Fig. 6 Closure of anterior wall of handsewn anastomosis with V-Loc 4/0 running suture. A nasogastric tube is advanced past the anastomosis prior to full closure of the anterior wall.

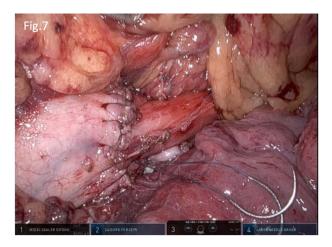


Fig. 7 Completed handsewn anastomosis with locking of V-Loc sutures.

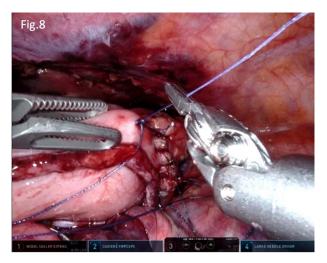


Fig. 8 Placement of tension-releasing sutures around anastomosis with Vicryl 3/0.



Fig. 9 Omental wrap around completed anastomosis with V-Loc sutures.

A cruraplasty using one to three Mersilene 0 sutures was performed routinely following completion of the anastomosis in the thorax to avoid future hiatal hernia (Fig. 10).

Two Jackson Pratt drains were placed bilaterally in the thoracic cavity. A large bore chest tube (eg, 24Fr) was only placed if indicated (eg, pulmonary damage or if extensive lung adhesiolysis performed).



Fig. 10 Cruraplasty performed with Mersilene 0 interrupted suture.

A link to the video on the intrathoracic anastomotic technique is included: (Handsewn Anastomosis Video).

Postoperative management

Our hospital uses an enhanced recovery after esophagectomy protocol for all patients undergoing esophagectomy. All patients received either epidural or paravertebral analgesia and the respective catheters were removed on postoperative day 3. The Jackson-Pratt drains were removed when the volume drained was less than 200ml over 24 hours. A feeding jejunostomy tube was routinely placed intraoperatively for all patients undergoing esophagectomy and enteral nutrition via the tube was commenced the day after surgery. The nasogastric tube was removed if the contrast swallows on postoperative day 4 showed no anastomotic leakage, delayed conduit emptying or vocal cord dysfunction with aspiration; and liquid feeds were started orally and escalated accordingly. All patients were commenced on regular proton pump inhibitor therapy after surgery for about 3 months duration.

Outcomes

All information was extracted from a prospective database maintained by the University Medical Centre, Utrecht. Primary outcomes were rates of anastomotic leakage (as defined by the Esophageal Complications Consensus Group)¹⁰ and anastomotic stricture within 1 year from surgery. Anastomotic stricture was defined as the inability to insert a gastroscope past the anastomosis and need for dilatation of the anastomosis (from 9 to 14 mm). Secondary outcomes were duration of anastomosis. in hospital mortality and length of hospital stay. Total duration of anastomosis was defined as the time taken between the conduit gastrostomy and

completion of the omental wrap. Most operations were recorded and stored on the hospital server, which allowed for assessment and accurate determination of anastomotic duration.

Statistical analysis

Continuous variables are shown as a median with range or mean with standard deviation. Categorical data are shown as numbers with percentages. Missing data were considered to be missing at random and handled using imputation with the iterative Markov chain Monte Carlo method (50 iterations). 11 Cumulative Sum (CUSUM) analysis was performed to determine the trends in anastomotic duration and anastomotic leak over the years. 12

Data for each patient in the series were plotted from left to right on the horizontal axis chronologically. This visualization helps identify trends over time in the surgical procedure's efficiency. An upward trend suggests periods with longer than average durations or an above average incidence, possibly indicating challenges or learning opportunities. Conversely, a downward trend suggests improvements in efficiency, with durations becoming shorter than the average. The results were reported according to STROBE guidelines for observational cohort studies. 13 Data was analyzed using SPSS 25.0 (IBM) and R studio 2023.12.0.

RESULTS

Between November 2019 and May 2023, 89 consecutive patients underwent RAMIE with an intrathoracic hand-sewn anastomosis. The patient characteristics are shown in Table 1.

In our center, the majority of patients with squamous cell carcinoma had a tumour that was located predominantly in the upper to mid esophagus, hence the operation of choice for such patients was a 3-stage McKeown procedure with a cervical anastomosis per-



Table 1 Patient characteristics

Patient characteristics	Number (N = 89)
Age, years	65 (Range 15–81)
Gender, male	72 (80.9%)
ASA classification	. ,
I	11 (12.5%)
II	40 (44.9%)
III	36 (40.4%)
IV	2 (2.2%)
Tumour histology	, ,
Adenocarcinoma	78 (87.6%)
Squamous cell carcinoma	11 (12.4%)
Tumour location	, ,
Mid esophagus	6 (6.7%)
Distal esophagus	72 (80.9%)
Gastroesophageal junction	11 (12.4%)
Clinical T staging	, ,
T1	4 (4.5%)
T2	24 (26.9%)
T3	56 (62.9%)
T4	5 (5.6%)
Neoadjuvant therapy	,
Chemotherapy alone (FLOT)	8 (8.9%)
Chemoradiotherapy (CROSS)	74 (83.1%)
None	7 (8%)

Table 2 Patient outcomes following surgery

Patient outcomes	Number $(N = 89)$
Radicality of surgical resection	
R0	86 (96.6%)
R1 (CRM positive)	3 (3.4%)
Lymph node yield	48 (Range 25–87)
Median anastomotic duration (mins)	33 mins (Range 23–55)
90-day mortality	3 (3.4%)
Median length of stay (days)	10 (Range 6–86)
Anastomotic leakage	11 (12.4%)
Grade I	4 (4.5%)
Grade II	1 (1.1%)
Grade III	6 (6.7%)

formed instead. Our centre did not participate in the SANO trial. 14

Patient outcomes following surgery are shown in Table 2. Anastomotic leakage occurred in 11 patients (12.4%), of which 4 (4.5%) were grade I, 1 (1.1%) was grade II, and 6 (6.7%) were grade III leaks. These patients were treated according to the protocol developed in the UMC Utrecht.¹⁵

The four patients with grade I leaks were treated with nil per oral, placement of a nasogastric tube and antibiotics. In one patient with grade II leak (contained leak), treatment with an endosponge subsequently resulted in a bronchial fistula a week later and an esophageal stent was then placed. Of the six patients with grade III leaks, four underwent VATS washout and esophageal stenting at the same sitting, one had a right thoracotomy, washout and esophageal stenting and one underwent VATS washout and placement of endosponge in the defect (which was changed

three times). Three out of 11 patients with anastomotic leaks were detected on contrast swallow on POD 4. The other eight patients with leaks were detected after POD 4 (majority on POD 9–10).

The duration of anastomotic formation was missing for 11 patients and was imputed. The median total anastomotic duration was 33 minutes (range 23–55) and the median length of stay was 10 days (range 6–86). The 90-day mortality was 3.4% (three patients), of which one died from aspiration pneumonia with multiorgan failure, one developed an aortoenteric fistula from mediastinitis due to leak of the conduit staple line just below the anastomosis despite esophageal stenting and one developed a gastro-bronchial fistula which was resected and repaired with a patch and intercostal muscle flap but complicated by patch dehiscence and pneumonia.

Anastomotic strictures that developed within 1 year after surgery occurred in 32.6%, all of which were benign and all subsequently required dilations for dysphagia symptoms and/or the inability to pass an adult gastroscope through the anastomosis (Table 3). Refractory strictures were defined as per Kochman et al, ie, the inability to successfully remediate the anatomic problem to a diameter of 14 mm over 5 sessions at 2-week intervals (refractory) or as a result of an inability to maintain a satisfactory luminal diameter for 4 weeks once the target diameter of 14 mm has been achieved. 16 Dilations were performed with Savary-Gilliard dilators until resolution of symptoms or when an adult gastroscope was able to pass through the anastomosis easily. The median number of dilations needed was 5. In 13 (14.6%) patients the with strictures were refractory. Only 4 out of 29 patients (13.8%) with a stricture had a prior anastomotic leak and a similar number of patients had reflux esophagitis on gastroscopy.

Learning curve

We performed CUSUM analyses to determine the trends in anastomotic leak, anastomotic duration and stricture rates over the years.

The CUSUM graph for anastomotic duration (Fig. 11A) showed that after standardization of our technique the initial learning curve was mounted after 25 cases followed by a gradual stabilization in the duration of anastomosis formation. From case 60 onwards a plateau was reached with less deviation from the average duration of anastomosis formation.

With regard to anastomotic leakage the CUSUM analysis (Fig. 11B) could be divided into three phases: Phase 1 (case 1–25) shows in initial upward trend which indicates a leakage rate above average. Phase 2 (case 26–50) where the first curve is mounted, proficiency is reached and leak rate starts to drop. Phase 3 (case 51–89) represents a more stable phase with a

Table 3 Patient outcomes with regards to anastomotic stricture

Patient outcomes	Number (N = 89)
Intrathoracic anastomotic stricture	29 (32.6%)
Requiring dilation	29
Median number of dilations needed	5 (Range 1–20)
Refractory stricture	13 (14.6%)
Patients with anastomotic strictures who had a leak	4 (13.8%)
Patients with strictures who had reflux esophagitis on OGD	4 (13.8%)
Patients with strictures with cardiovascular comorbidities	14 (48.3%)

leak rate that hovers in close proximity to the overall mean leak rate.

No learning curve for anastomotic stricture rate could be identified based on the CUSUM graph (Fig. 11C). The first part of the CUSUM graph descends, indicating a decline in stricture formation, followed by an upward trend before a plateau was reached.

DISCUSSION

We previously presented our robot-assisted handsewn intrathoracic anastomotic technique as well as the initial outcomes of the first 22 patients. This study aimed to present the updated outcomes with a larger case series showing the ongoing learning curve of this technique of the initial standardization phase. The anastomotic leak rate in the earlier study was 14% compared with 12.4% in this current study. Average time of anastomotic creation also reduced during the study period, and was reduced by 4 mins to the current duration of 33 mins.

Anastomotic leakage

With robotic-assisted minimally invasive esophagectomy on the rise, previous studies have reported anastomotic leak rates of 10%-30% with robotic intrathoracic handsewn anastomosis. 17-19 Of note, the large multicentre study by the Upper Gastrointestinal International Robotic Association (UGIRA) with 856 patients reported the global experience showing an overall anastomotic leak rate of 20% with Ivor Lewis RAMIE (a total of 622 patients).²⁰ In that series the handsewn anastomosis had the highest leak rate of 33%. However, this was attributed to the fact that several centers switched from a cervical or intrathoracic stapled anastomosis to robotic handsewn intrathoracic anastomosis during the study and as such were still undergoing a learning curve and refining their technique. Previous studies have in general described a double-layer anastomotic technique (in combinations of interrupted and/or continuous sutures) which is more time-consuming.¹⁷ Our single-layer anastomotic technique with barbed

4/0 running sutures and tension-releasing sutures is efficient and achieves similar or even better results.

Various adaptations were made during the development of this anastomotic technique in our centre. The addition of tension-releasing sutures was associated with a significant reduction in leak rate. Tensionreleasing Vicryl sutures are used to minimize the risk of anastomotic leakage by reducing tension at the suture line, as tension can lead to gaps and potential ischemia due to the longitudinal stretching of the gastrointestinal tissue. Compared with other gastrointestinal surgeries, the healing of an esophagogastric anastomosis is often more tenuous due to tension on the anastomosis combined with the lack of a serosa layer for the esophagus resulting in the external longitudinal muscle fibers holding sutures poorly. This technique is supported by Tu et al, who demonstrated a lower anastomotic leakage rate with oversewing of the anastomotic circular staple line by placing additional interrupted horizontal mattress sutures to wrap the staple line.²¹ This is similar to our method of placing the tension-releasing sutures and avoids tearing of tissue. Also, in the expert consensus paper by Bartella et al, the expert consensus on anastomotic technique endorsed the use of interrupted sutures placed as a second layer to relieve tension at the anastomotic site.²²

The anastomotic leak rate of 12.4% in our study is even lower than the circular stapling (17%) and linear stapling (15%) anastomotic leak rates reported by UGIRA.²⁰ This reflects that once the learning curve for a handsewn intrathoracic anastomosis is mounted, it achieves outcomes that are comparable to mechanical methods.

Anastomotic duration

Although most authors stress that a handsewn anastomoses prolong the duration of surgery, present challenges in standardization, and requires a longer learning curve compared with other anastomotic techniques, our findings indicate otherwise. This can be potentially attributed to the use of the robotic technique including the barbed suture material instead of standard sutures. A meta-analysis by Wiggins et al. demonstrated that barbed suture

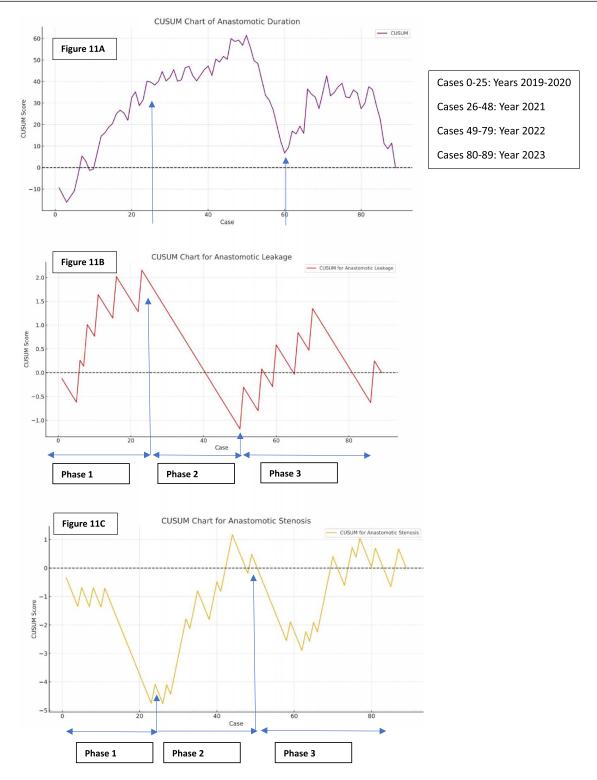


Fig. 11 A to C CUSUM graphs of Anastomotic Duration, Anastomotic Leakage and Anastomotic Duration (respectively).

material was associated with a significant reduction in overall operative time and anastomotic time.²³ When stratified by year, the median duration of handsewn anastomosis in our series showed a progressive reduction which reflects the increased proficiency with time (Fig. 12). Our CUSUM analysis showed that initial learning curve was mounted after 25 cases

with subsequent stability in anastomotic duration. An important time-reducing factor is that the robotic surgeon can perform the entire procedure from the console, independent from the table surgeon. Especially in circular stapled techniques; this part has to be performed non-robotically from the table by a table surgeon.

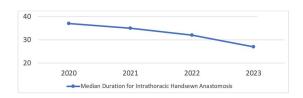


Fig. 12 Graph showing a reduction in median duration for creation of intrathoracic handsewn anastomosis.

Anastomotic stricture

Anastomotic stricture following esophagectomy is one of the most common complications. Although less life-threatening than anastomotic leakage, it is still a complication that impairs the initial functional outcome as it impacts swallowing, nutrition, and post-operative quality of life (given the potential need for frequent endoscopic treatment). Reported rates of anastomotic stricture that occur following esophagectomy range from 14%-24.5%. 24-26,28 In an observational study of 737 patients by Na et al., 30% of patients underwent handsewn anastomosis with a stricture rate of 22.2% compared with circular stapling (14.5%) and linear stapling $(16.1\%)^{27}$

In our series, we report a stricture rate of 32.6% which is higher than rates reported in the current literature. One might expect increase in stricture rates with increase in anastomotic leakage as leakage is a known risk factor for developing anastomotic strictures but it was not seen in our series. This may be due to the size of the gastrostomy created (2 cm) on the conduit which is smaller than the anastomosis sizes of the circular stapler (25 or 28 mm) or linear stapler. The size of the gastrostomy is usually created to match the diameter of the remnant esophagus and is limited by that. In the study by de Groot et al. which reviewed the technical details of both handsewn and circular stapled intrathoracic anastomoses in 2 high-volume European centers, for the handsewn anastomosis it was found that the median gastrostomy incision length was 14 mm (range 10-18) and median esophageal diameter was 17 mm (range 12-22). However, their study did not report on anastomotic stricture rates and our current study is the first to report this outcome from our high-volume centre. One possible way to increase diameter size of the remnant esophagus would be to perform a tangential transection. We hypothesize that this will allow for a wider esophageal aperture diameter, which may in turn reduce risk of stricture. However at present, we lack experience or outcome data to support this hypothesis.

Another potential reason for the higher stricture rate may be the use of barbed suture for the anastomosis. Although it helps with avoiding gaps between the stitches and improving the speed of anastomosis, excessive tightening of the suture may narrow the lumen and may cause microischaemia at the anastomosis which leads to stricture formation. Two published meta-analyses which compared barbed sutures to conventional suture materials found that there was no significant difference in complications including anastomotic leak, bleeding or stricture.^{23,28} Of note, these studies were focused on laparoscopic gastrointestinal anastomoses which allow the surgeon tactile feedback when suturing and can prevent excessive tightening of the barbed suture.

In addition, our CUSUM analysis revealed no learning curve for stricture rate. Despite thorough investigation a definitive explanation for this pattern remains elusive. This observation underscores the complexity of stricture formation and the need for further research and technical modifications to unravel the underlying mechanisms of driving this phenomenon. As noted on our CUSUM graphs, there may be a fine balance between having tight sutures (with resultant decreased risk of anastomotic leakage) and possible microischaemia with excessively tight sutures (with resultant increased risk of anastomotic stricture).

We propose that this handsewn technique reduces the need for a trained bedside assistant compared with other mechanical forms of anastomosis as it relies mainly on the operative surgeon to position the bowel and perform the anastomosis singlehandedly. This technique can be a viable option for surgeons who are proficient in robotic surgery and are looking to maximize the benefits of operating with a robotic platform. We do acknowledge the relatively higher stricture rates reported in this study and we are working to identify and make adjustments to our handsewn anastomotic technique accordingly.

CONCLUSION

Few minimally invasive handsewn intrathoracic techniques have been adopted by surgeons despite the increasing shift to minimally invasive esophagectomy because it is technically demanding with the lack of articulating instruments. With the robotic platform, we have demonstrated in our series that the handsewn intrathoracic anastomosis in the upper mediastinum is feasible, safe, and reliable. This technique also reduces the need for a trained bedside assistant to help introduce and manipulate the staplers required for mechanical anastomoses, giving the robotic surgeon greater control. The magnified 3D view as well as the dexterity and movement provided by the robotic arms in a rigid thorax allows the surgeon to execute this otherwise technically difficult handsewn anastomosis in a simplified and controlled manner with acceptable outcomes.



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