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Review

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Format for safe introduction of robotic esophagectomy

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Abstract
The aim of this study is to review the current literature on the learning curve for robotic-assisted minimally invasive esophagectomy (RAMIE) and explore strategies for introducing and implementing RAMIE. A literature search of electronic databases (Pubmed and Science Direct) was conducted using multiple combinations and synonyms of the keywords "esophageal cancer", "robotic esophagectomy", "RAMIE", and "learning curve" up to March 31, 2023. In total, eighteen studies were included. Fourteen studies reported on surgeons with experience in minimally invasive surgery. Seven studies reported on surgeons with prior robotic experience for benign diseases or experience as observant or assistant in robotic surgery or experience on cadaveric robotic training. Four studies reported on a specific training pathway. The learning curve was mostly analyzed using the cumulative sum control chart (CUSUM). The most commonly used measured variables were the total operation time, the thoracic and abdominal console time, the lymph node yield, and vocal cord palsy rates. The learning curve plateaus for the total operative time, the vocal cord palsy rates, and the lymph node yield varied between 20-80, 15-80, and 18-73 cases, respectively. At present, several centers are increasingly adopting RAMIE for esophageal cancer. Education about the learning curve of RAMIE is crucial for the training pathway in order to safely introduce RAMIE in centers without pre-existing robotic esophagectomy experience.

Keywords: Robotic esophagectomy, RAMIE, esophageal cancer, learning curve

INTRODUCTION

Esophageal cancer is the 8th most common cancer worldwide. In 2020, there were more than 600,000 new esophageal cancer cases and about 544,000 deaths globally[1]. The current treatment for locally advanced esophageal cancer is multimodal and grossly consists of perioperative chemotherapy or neoadjuvant chemoradiotherapy followed by esophagectomy[2,3]. A variety of surgical approaches and techniques are currently being used to perform an oncological resection of the esophagus. The type of resection depends on the stage and localization of the tumor, the experience and preference of surgeons, and the comorbidities of patients[2].

The hybrid, totally minimally invasive, and robotic-assisted minimally invasive esophagectomy (RAMIE) are currently the most commonly used technique. In this study, RAMIE is defined as performing a totally robotic esophagectomy or robotic thoracic phase with a laparoscopic abdominal phase and intrathoracic or cervical anastomosis[4-6].

The technical feasibility and safety in terms of oncological outcomes of RAMIE compared to open or conventional minimally invasive esophagectomy have been confirmed in several studies. In 2012, the superiority of RAMIE compared to open esophagectomy was confirmed by the ROBOT trial[7]. Long-term survival and disease-free survival were reported by de Groot *et al.* in 2020. The overall survival and the disease-free survival of RAMIE were similar to open transthoracic esophagectomy, supporting the oncological safety of RAMIE[8]. In 2012, the TIME trial showed a lower incidence of pulmonary infections and better quality of life in the conventional minimally invasive esophagectomy group compared to the open esophagectomy group[9,10]. In 2018, the MIRO trial showed a lower incidence of major complications in the hybrid esophagectomy group compared to the open esophagectomy group[11]. In 2022, Yang *et al.* reported the short-term outcomes of the RAMIE trial. This study compared RAMIE to conventional minimally invasive esophagectomy. It was demonstrated that RAMIE could achieve shorter operative time and better lymph node dissection in patients who received neoadjuvant therapy[12]. Seesing *et al.* compared patients from the national Dutch Upper Gastrointestinal Cancer Audit (DUCA) database who underwent open and minimally invasive transthoracic esophagectomy and observed high anastomotic leakage and reintervention rates during the implementation of conventional minimally invasive esophagectomy. This shows the ethical and clinical risks of implementing a new technique[13].

Although the thoraco-laparoscopic esophagectomy and RAMIE are both minimally invasive techniques using the same number of ports, there are some theoretical advantages for RAMIE. Conventional thoracoscopic approaches have some drawbacks, as the rigid instruments and 2D view limit the exposure in the chest. In 2003, the first RAMIE was performed to overcome the technical challenges commonly experienced during the narrow working environment of the thoracic cage[6,14,15]. The magnified 3D view, the improved visualization, and the flexible robotic arms might provide advantages for the upper mediastinal lymphadenectomy, the bilateral dissection of recurrent laryngeal nerves, and the intrathoracic anastomosis[6,16]. The clinical benefit of RAMIE is currently investigated in the ROBOT2 trial, comparing RAMIE to minimally invasive esophagectomy with intrathoracic anastomosis[17].

At present, several centers are increasingly adopting RAMIE for esophageal cancer. Education about the learning curve of RAMIE is crucial for the training pathway in order to safely introduce RAMIE in centers without pre-existing robotic esophagectomy experience. Therefore, the aim of this paper is to review the current literature on the learning curve of RAMIE for esophageal cancer and provide guidance on how to set up a program for RAMIE.

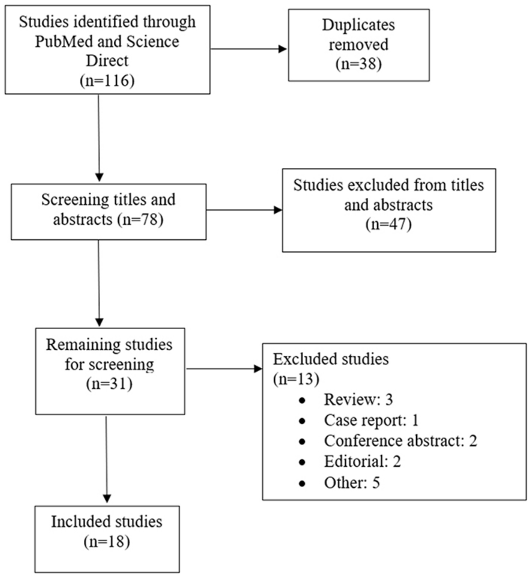

Figure 1. Flow chart of literature review.

METHODS

This is an overview of the most recent literature on the learning curve of RAMIE, and we try to answer the following questions:

(1) What surgical skills are needed before performing RAMIE?
(2) How many cases should the surgeon observe and assist before initiating RAMIE independently?
(3) How many RAMIE procedures are needed to reach the learning curve plateau?
(4) How is the robotic surgeon evaluated?

Search strategy and data collection

Electronic databases Pubmed and Science Direct were searched using multiple combinations and synonyms of the keywords "esophageal cancer", "robotic esophagectomy", "RAMIE", and "learning curve" from incentive up to March 31, 2023. No further search software or extra features were used. This review included studies that reported on the learning curve and outcomes of surgeons introduced to RAMIE. Studies reporting results from surgeons with pre-existing robotic experience for esophageal cancer, reviews, case reports, conference abstracts, and editorials were excluded. Only studies in the English language were included. The author (Maria Erodotou) searched the literature and excluded duplicates. Titles and abstracts were screened to identify citations for inclusion. Data were extracted from the full-text papers: first author's name, year of publication, country, number of patients, robotic technology used, prior surgical experience, part of a procedure performed robotically, number of observational and assisting cases, method of assessing learning curves, and learning curve plateaus. The risk of bias was not analyzed.

RESULTS

The literature search identified 116 studies for the learning curve and outcomes. Seventy-eight studies remained after duplicates were removed. After reviewing the titles and abstracts, 31 articles remained for screening. Finally, 18 studies were included in this review. The study selection flowchart is presented in [Figure 1].

Characteristics of included studies

The 18 selected studies were published between the years 2013 and 2022 from seven regions: China (33.3%, *n* = 6), USA (22.2%, *n* = 4), Netherlands (11.1%, *n* = 2), South Korea (11.1%, *n* = 2), Germany (11.1%, *n* = 2), Italy (5.5%, *n* = 1), and Taiwan (5.5%, *n* = 1). Approximately 72.2% (*n* = 13) of the selected studies were retrospective, and 22.2% (*n* = 4) were prospective. No randomized control trials (RCTs) were included in this review. In total, 2,123 patients underwent RAMIE using the Da Vinci S (11.1%, *n* = 2), Si (33.3%, *n* = 6), or Xi (44.4%, *n* = 8) robotic surgical systems. RAMIE was performed using the McKeown (61.1%, *n* = 11) and Ivor Lewis (44.4%, *n* = 8) approaches. Most of the included studies (55.5%, *n* = 10) performed esophagectomy using the robot on both thoracic and abdominal phases. The characteristics of the included studies are shown in [Table 1].

Surgical skills

A summary for the training pathway steps of implementing RAMIE according to the included studies is shown in [Table 2].

Fourteen studies reported pre-existing minimally invasive experience, and seven studies reported prior robotic experience for benign diseases or experience on observing and assisting robotic procedures or experience on cadaveric robotic training. Sun *et al.* and Hsieh *et al.* reported prior experience on video-assisted thoracoscopic esophagectomy, while Park *et al.* reported no thoracoscopic experience before performing RAMIE. However, after initiating robotic esophagectomy, they started with VATS esophagectomy based on their robotic experience[18-20].

Only four studies reported specific training pathways. In 2020, Kingma *et al.* published the Upper Gastrointestinal International Association (UGIRA) training pathway. They reported prior experience with ten benign robotic cases, and they suggested that pre-existing minimally invasive esophagectomy skills are needed before implementing RAMIE[21]. Sarkaria *et al.* trained surgeons with a single cadaveric operation to plan the technical aspects of RAMIE and identify possible pitfalls. They also highlighted that RAMIE procedures should be performed in high-volume centers by surgeons with experience in challenging esophageal cases, including formal fellowship in minimally invasive esophagectomy and robotic-assisted procedures[22]. Similarly, our group reported that the 18-month upper gastrointestinal fellowship experience of the adopting surgeon, resulted in shorter learning curves[23]. Fuchs *et al.* reported a six modular set-up approach to RAMIE. The newly introduced robotic surgeons first completed simulation and animal model robotic training to become certified as console surgeons. Following, they proceeded to 30 training procedures with increasing difficulty (cholecystectomy, fundoplication). A good proficiency level was achieved, resulting in more favorable learning curve outcomes[24]. One study described a single robotic operation of anterior teratoma resection before performing RAMIE[25].

Observe and assist RAMIE

Only five studies reported information for the preparation of the adopting surgeon before implementing RAMIE. During the proctoring program, our group reported five observational cases and 20 procedures as assisting table surgeons before proceeding to the supervised cases[23]. During the training pathway of 50 RAMIE procedures by Sarkaria *et al.*, the two attending surgeons alternated between the console and assisting roles[22]. In addition, two studies described 50 observational and assisting robotic esophagectomies before operating independently[19,20].

Initiating RAMIE

During the second phase of the UGIRA's pathway, RAMIE was initiated by the new surgeon under the supervision of an experienced proctor surgeon. Depending on the adopting surgeon's robotic level, this phase was extended according to the proctor's judgment. The proficiency of the adopting surgeon was recorded using a proctor checklist and an evaluation form. Following this, the new surgeon proceeded to

Table 1. Characteristics of included studies

Author	Year	Region	Type of study	Number of patients	Robot	Pre-existing experience	Procedure	Observation cases	Assisting cases	Learning curve analysis method	Learning curve plateau
Chao *et al.*[32]	2020	USA	Retrospective	39	Da Vinci Si/Xi	MIE	McKeown; Robotic thoracic phase	NR	NR	CUSUM	**12** cases for safe lymph node dissection along the left recurrent laryngeal nerve
Duan *et al.*[33]	2020	China	Retrospective	70	Da Vinci Si/Xi	Open/MIE	McKeown; Robotic thoracic and abdominal phase	NR	NR	CUSUM	**43** cases for safe lymph node dissection along the left recurrent laryngeal nerve
Fuchs *et al.*[24]	2019	Germany	Prospective	70	Da Vinci Xi	30 Simple training robotic procedures with increasing difficulty Modular step-up approach	Ivor Lewis; Robotic thoracic phase	NR	NR	Cohort comparison	NR
Grimminger *et al.*[30]	2019	Germany	Prospective	25	Da Vinci Xi	Hybrid and MIE	Ivor Lewis; Robotic thoracic phase	NR	NR	Consecutive 25-patient cohort comparison RAMIE *vs.* MIE *vs.* hybrid	NR
Han *et al.*[16]	2022	USA	Retrospective	124	Da Vinci S	MIE	Ivor Lewis; Robotic thoracic and abdominal phase	NR	NR	CUSUM/ RA-CUSUM	**73** cases for increased lymph node yield **46** cases for decreased total operation time **39** cases for decreased abdominal operation time **55** cases for decreased thoracic operation time **29** cases for stapled anastomoses **15** cases for hand sewing anastomosis **51** cases for decreased major complication rates
Hernandez *et al.*[26]	2013	USA	Prospective	52	Da Vinci	MIE	Ivor Lewis; Robotic thoracic and abdominal phase	NR	NR	Comparison of successive 10-patient cohorts	**20** cases for decreased total operating time
Hsieh *et al.*[19]	2022	Taiwan	Retrospective	179	Da Vinci S/Si/Xi	Open esophagectomies Thoracoscopic lung/mediastinal operations VATE	McKeown; Robotic thoracic phase	NR	50	CUSUM	**41** cases for decreased thoracic operating time from the surgeon with pree-existing > 150 VATE experience (surgeon A) **32** cases for decreased thoracic operating time from

											the surgeon with pre-existing < 5 VATE experience (surgeon B) **24** cases for less postoperative pneumonia for surgeon A **21** cases for les postoperative pneumonia for surgeon B **31-40** cases for decreased vocal cord palsy and increased thoracic lymph node yield for surgeon A **15-49** cases for decreased vocal cord palsy for surgeon B
Kingma *et al.*[21]	2020	Netherlands	Prospective	70	Da Vinci Xi	MIE and ten benign robotic cases UGIRA pathway	Ivor Lewis; Robotic thoracic phase	1	NR	CUSUM	**22** cases for decreased thoracic operating time and intraoperative blood loss
Park *et al.*[27]	2017	South Korea	Retrospective	140	NR	NR	McKeown; Robotic thoracic and abdominal phase	NR	NR	CUSUM	**28** cases for increased lymph node yield **60** cases for decreased vocal cord palsy rates **80** cases for decreased total operation time
Park *et al.*[20]	2017	South Korea	Retrospective	33	Da Vinci Si	No prior thoracoscopic experience	McKeown; Robotic thoracic phase	25	25	CUSUM	**20** cases for decreased vocal cord palsy rates
Rebecchi *et al.*[29]	2022	Italy	Retrospective	40	Da Vinci Xi	MIE	Ivor Lewis; Robotic thoracic phase	NR	NR	CUSUM/RA-CUSUM	**22** cases for decreased operating time **19** cases for proficiency
van der Sluis *et al.*[23]	2018	Netherlands	Retrospective	315	Da Vinci	MIE Proctoring program	McKeown; Robotic thoracic phase	5	20	CUSUM	**24** cases for decreased thoracic and total operating time
Sarkaria *et al.*[22]	2016	USA	NR	100	NR	MIE and single robotic cadaveric operation	Ivor Lewis; Robotic thoracic and abdominal phase	NR	50 Surgeons alternated between console and assisting roles	Comparison of consecutive 15 patient cohorts	**30-45** cases for decreased median operating time
Sun *et al.*[18]	2022	China	Retrospective	45	Da Vinci	VAME	McKeown; Robotic thoracic and abdominal phase	NR	NR	CUSUM	**17** cases for increased left recurrent laryngeal nerve lymph nodes
Yang *et al.*[28]	2021	China	Retrospective	400	Da Vinci Si/Xi	MIE	McKeown; Robotic thoracic and abdominal phase	NR	NR	CUSUM	**40** cases for decreased operating time, estimated blood loss, conversion rates

											40 cases for increased lymph node yield **80** cases for decreased anastomotic leakage rates and vocal cord palsy
Zhang *et al.*[25]	2018	China	Retrospective	72	Da Vinci Si	Open, MIE, and single benign robotic case	McKeown; Robotic thoracic and abdominal phase	NR	NR	CUSUM	**26** cases for decreased total operation time **9** cases for decreased thoracic port set-up and docking time **14** cases for decreased abdominal operation time **16** cases for decreased abdominal port set-up and docking time **32** cases for increased lymph node yield
Zhang *et al.*[34]	2018	China	Retrospective	249	Da Vinci	NR	McKeown; Robotic thoracic and abdominal phase	NR	NR	Comparison between cohorts of 25 procedures for the first 100 cases	**25** cases for decreased thoracic operating time **50** cases for increased lymph node yield and shorter hospital stay
Zhuo *et al.*[35]	2021	China	Retrospective	100	NR	MIE	McKeown or Ivor Lewis; robotic thoracic and abdominal phases	NR	NR	CUSUM	**18** cases for increased thoracic lymph node yield using the McKeown approach

MIE: Minimally invasive esophagectomy; VATE: video-assisted thoracoscopic esophagectomy; VAME: video-assisted McKeown esophagectomy; CUSUM: cumulative sum control chart; RA-CUSUM: risk-adjusted cumulative sum control chart; RAMIE: robotic-assisted minimally invasive esophagectomy; NR: not reported.

phase 3 and performed RAMIE independently[21]. Our study compared the results of the newly introduced surgeon with an experienced proctor (> 150 RAMIE procedures). Initially, the new surgeon performed 15 RAMIE procedures on selected patients with fewer pulmonary and oncologic diseases under firm supervision by the proctor. This resulted in decreased thoracoscopic and total operating times[23].

Learning curve

The definition of the learning curve is the number of operations that must be performed to achieve a steady level of performance, known as the plateau. The cumulative sum control chart (CUSUM) was the most commonly used method for evaluation of the learning curves. CUSUM analysis transforms raw data into the running total of data deviations from the group mean, enabling investigators to visualize the data for trends not discernible with other approaches[23]. The most commonly used measured variables were the total operation time, robot thoracic and abdominal console time, lymph node yield, vocal cord palsy rates, blood loss, anastomotic leakage rates, length of the hospital stay, and conversion rates to an open procedure. A wide variation was noted in the learning

Table 2. Ten - (10) Training pathway steps for implementing RAMIE

Training pathway steps	Implementing RAMIE
Step 1	Experience in open esophagectomy.
Step 2	Basic laparoscopic general surgery skill course.
Step 3	Laparoscopic experience in less technically challenging procedures (e.g. laparoscopic cholecystectomy, Heller myotomy, diaphragmatic hernia repair).
Step 4	Experience in minimally invasive esophagectomy.
Step 5	Upper gastrointestinal robotic surgery hands-on course.
Step 6	Simulation robotic training at expert level.
Step 7	Experience in less complex robotic procedures for benign esophageal cases.
Step 8	Proctoring RAMIE: a. case observation b. assisting c. perform RAMIE under strict supervision
Step 9	Perform RAMIE independently.
Step 10	Evaluation.

RAMIE: Robotic-assisted minimally invasive esophagectomy.

curve plateaus to achieve an acceptable proficiency level. The plateaus for the total operative time, the vocal cord palsy rates, and the lymph node yield varied between 20-80, 15-80, and 18-73 cases, respectively.

According to Kingma *et al.*, 22 cases were needed to achieve the learning curve plateau for both the thoracic operating time and intraoperative blood loss. Shorter operating time, less intraoperative blood loss, and increased lymph node yield were reported in patients who underwent surgery after the plateau[21].

Park *et al.* and Hernandez *et al.* published similar results with at least 20 cases to achieve proficiency in upper mediastinal dissection with less vocal cord palsy rates and a significant reduction in operative time with low complication rates, respectively[20,26]. One study reported reaching the learning curve plateau of total operating time and thoracic console time at case 26. However, the length of the hospital stay, the blood loss, the conversion to open rate, and the number of major comorbidities remained consistent after case 26, confirming the safety of RAMIE during the early stage of experience[25].

In our study, the surgeon reached the maximum of the CUSUM curve after 13 months and 24 cases. However, after case 49, more challenging cases were included, resulting in increased operating times, proving that easier cases may influence the learning curve[23].

Only one study compared the learning curve plateau between two different types of anastomoses. Proficiency in the stapled anastomosis required 29 cases, while mastering the hand-sewing anastomosis required 15[16].

Park *et al.* used risk-adjusted O-E CUSUM curves to assess meticulously the surgeon's robotic skills. After 30 cases, the lymph node yield increased from 25 to 45 lymph nodes, and after 60 cases, the vocal cord palsy rates decreased from 36% to 17%. After 80 cases, the total operation time, the length of the hospital stay, and the anastomotic leakage rates also decreased[27].

Yang *et al.* noticed improvements in operative time, blood loss, and conversion rates after the 40th case. A decrease in the rates of anastomotic leakage and vocal cord palsy was observed after 80 cases. Specifically, the lymph node yield along the recurrent laryngeal nerve reached the plateau after 40 cases[28].

According to the study results by Rebecchi *et al.*, the learning curve plateau for the operating time was observed after 22 cases. They also performed a risk-adjusted cumulative sum (RA-CUSUM) analysis for postoperative complications, which indicated a change point after case 19[29].

Grimminger *et al.* did not assess the learning curves; however, they reported comparable results regarding morbidity and short-term outcomes between minimally invasive esophagectomy, RAMIE, and hybrid esophagectomy[30].

Evaluation

In the study by Sarkaria *et al.*, the junior surgeon received feedback from the proctor surgeon regarding technical imperfections and advice for improvement. In case of postoperative complications, a discussion was held between the study surgeon and the consultant surgeon, together with a video review to identify possible contributing factors[22]. During the UGIRA pathway, the surgeon and proctor kept in contact to solve potential issues. The procedures were recorded and registered for future evaluation and assessment of perioperative outcomes. The proctor re-visited the adopting surgeon after 10-20 independent RAMIE procedures. During this visit, the proctor evaluated the surgeon's proficiency level by completing a scoring form and reviewing the perioperative outcomes[21].

DISCUSSION

Esophagectomy is a highly demanding and complex procedure, and RAMIE should be taken up by surgeons only after a proper training program. Despite the encouraging results of RAMIE, extensive training and proctoring are needed before this procedure can be safely established. According to the included studies, the surgeons should first master open and minimally invasive esophagectomy. Supposing that the surgeons have been trained only in open esophagectomy, they must first complete a basic laparoscopic general surgery skill course on live animal models or cadavers and gain more experience in less technically challenging procedures such as laparoscopic cholecystectomy, Heller myotomy, and diaphragmatic hernia repair. After that, they can proceed to conventional minimally invasive esophagectomies[21]. Sarkaria *et al.* suggested that completing a formal advanced Upper Gastrointestinal fellowship program in a high-volume center is an important step for the training pathway[22].

The transition from a laparoscopic surgeon to a robotic surgeon must be done slowly and in a similar manner. The minimally invasive surgeon should ideally complete an upper gastrointestinal robotic surgery hands-on cadaver course and succeed in the simulation robotic training at an expert level. Following that, the surgeon can start performing less complex robotic procedures for benign esophageal cases before proceeding to proctor RAMIE[21,23]. RAMIE is a time-consuming surgical procedure, with the gastric interposition and esophagogastric anastomosis being the most complex part. Without a doubt, pre-existing minimally invasive esophagectomy experience and robotic training on less complex procedures are mandatory before implementing RAMIE.

Case observation and assisting with robotic procedures are essential. Additional committed staff, including anesthesiologists, operating room (RAMIE-trained) scrub nurses, and circulating staff, are also important to achieve shorter learning curves[21]. According to the UGIRA structured training pathway for RAMIE, the surgical team, together with the dedicated esophagogastric anesthetic team, should observe at least one full RAMIE case in an expert center[21]. The competence of the bedside assistant surgeon performing docking, undocking, and exchanging instruments is crucial for a successful RAMIE. Hence, the assistant surgeon should be trained and familiar with all steps of RAMIE[25].

Following the observation and assisting phase, the adopting surgeon can start performing RAMIE under strict supervision by the proctor[22]. Succeeding that in a proficiency level, the surgeon can initiate performing RAMIE independently. At the start of this undertaking, the surgeon may face longer operating time, higher intraoperative blood loss, lower lymph node yield, more complications, and higher conversion rates. Therefore, a certain number of cases is required during the proctoring before reaching a steady level of performance. In this review, the learning curve plateaus for the total operative time, the vocal cord palsy rates, and the lymph node yield varied between 20-80, 15-80, and 18-73 cases, respectively. Some surgeons prefer to avoid challenging cases at the start of their training pathway to limit technical difficulty and decrease the risk of adverse events[23]. In addition, a sufficient caseload, more than 20 RAMIEs per year, and access to a robotic system are of great importance. If 20 operations are not achievable by a surgeon within one hospital, then collaborations or centralization should be considered strongly[23]. Without a doubt, RAMIE should be performed only in large volume centers.

This study has some limitations, mainly due to the differences in the included studies, and thus, strong conclusions are unfeasible. A large degree of heterogeneity was observed between the selected studies. This observation can be explained by the different case volumes in each study, the methods used for learning curve analysis, and the presence of prior robotic experience. In a recent study from de Groot *et al.*, 70 patients underwent RAMIE with intrathoracic anastomosis for esophageal cancer in a high-volume center with 15 years of experience in transthoracic robotic esophagectomy. Prior experience with robotic platforms resulted in a shorter plateau (case 22) for the robotic abdominal operation time compared to the thoracic operation time plateau (case 24), which was analyzed by the same study group in the past[31]. To our knowledge, the number of cases and the time needed to reach the learning curve plateau depend on several factors, such as the pre-existing minimally invasive and robotic experience of the surgeon, the presence of a dedicated anesthesiologist and scrub nurse team, the adopting center, the characteristics of the selected cases, and the type of esophagectomy and anastomosis.

CONCLUSION

Nowadays, several centers are increasingly adopting RAMIE as their preferred approach to esophagectomy for cancer. Education about the learning curve of RAMIE is crucial for the training pathway in order to safely introduce RAMIE in centers without pre-existing robotic esophagectomy experience. More structured training programs and consensus in learning curve analysis will help guide future robotic surgeons to implement RAMIE.

DECLARATIONS

Authors' contributions

Made substantial contributions to the conception and design of the study and performed data analysis and interpretation: Erodotou M

Revised the work critically for important intellectual content and provided final approval of the version to be published: Lagarde SM, Wijnhoven BPL, van der Sluis PC

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Ethical approval and consent to participate
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Consent for publication
Not applicable.

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