



Learning curve and postoperative outcomes of minimally invasive esophagectomy

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Abstract: Surgical innovation is necessary to increase surgical effectiveness and to decrease postoperative complications, but can be associated with learning curves. The significance of surgical learning curves is increasing and it is important to take surgical learning curves into account when interpreting outcome data that is acquired during an implementation period. This may especially be the case for a technically challenging procedure like minimally invasive esophagectomy (MIE). This review article provides an overview of the published literature that has described a learning curve for MIE, with particular interest in the relationship between the learning curve and postoperative complications. Twenty two studies reported learning curves of different types of MIE. These studies showed that the length of the learning curve of MIE can be significant, but most studies are single center studies of limited methodological quality. In addition, several learning curve analysis methods are used but a clear recommendation regarding the preferred method is lacking. Most studies use intraoperative parameters (e.g., operative time) to define the length of the learning curve. However, significant learning curve effects have been found for clinically more relevant parameters (e.g., anastomotic leak), especially for Ivor Lewis MIE. These studies suggest that patient safety can be substantially compromised during learning curves. To increase patient safety and shorten the learning curve, evidence based and effective safe implementation programs are necessary.

Keywords: Minimally invasive esophagectomy (MIE); learning curve; proficiency gain curve; safe implementation

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Introduction

Innovation is necessary to improve health care. The aim of implementing a surgical innovation is to increase surgical effectiveness and to decrease postoperative complications compared to older procedures. Patients increasingly expect to be operated by the newest techniques, which generally are complex and more difficult to learn. The introduction of surgical innovations, however, is associated with learning curves and learning curves may have a negative impact on patient outcome (1).

It is important to take surgical learning curves

into account when interpreting outcome data that is acquired during an implementation period. In general, the significance of surgical learning curves is increasing, since the complexity of currently implemented surgical procedures is increasing and interventions are implemented at an increasing rate.

In addition to guiding the interpretation of outcome data during the implementation period, learning curve analysis is becoming increasingly important to expose differences in lengths of learning curves and learning associated morbidity (extra morbidity that occurs during the learning phase that could have been avoided if patients were operated by

truly proficient surgical teams). Several studies have shown that learning curves of technically challenging procedures can take years to complete and results can be significantly impaired during this learning phase (2-5). In contemporary surgery, differences in effectiveness between newly implemented, innovative procedures are relatively small in general and therefore, impaired outcome during the learning phase is becoming relatively more significant. This may especially be the case for different types of minimally invasive esophagectomy (MIE). However, different types of MIE have not been compared directly regarding length of the learning curve or learning associated morbidity.

In this article, we aimed to review the results of studies that investigated the learning curve of MIE. Outcome parameters of interest were operative time, intraoperative blood loss and clinically more relevant parameters such as amount of retrieved lymph nodes, anastomotic leakage, overall morbidity, hospital length of stay and postoperative mortality.

Learning curve of MIE

Determining the length of the learning curve is important to inform clinicians about what they can expect after implementation of MIE. However, there is significant heterogeneity in methodology between learning curve studies and important differences exist between studies regarding outcome parameters, learning curve analysis methods and correction for casemix.

Most reports have used intraoperative variables, such as operative time (6-18), but other reports have also used clinically more relevant outcome parameters, such as postoperative complications and anastomotic leakage (13,14,19). Regarding analysis methods, most studies assigned patients to arbitrarily created groups and compared outcomes of patients operated on early after implementation between patients operated on later (9,11,20-27). Other studies used cumulative sum (CUSUM) analysis or variations of CUSUM and therefore omitted splitting a patient population in arbitrarily created groups (6,8,10,11,14,16,18,19). Casemix correction is only performed in few studies that investigated the learning curve of MIE (14).

Because of these differences in study methodology, it is difficult to compare results of different learning curve studies and this is further complicated by the fact that different approaches of MIE exist.

Learning curve of McKeown MIE

Twelve studies that conducted a learning curve analysis of only McKeown MIE have been published (*Table 1*). There were no studies that used pooled results of multiple surgeons in multiple hospitals. The number of included patients ranged from 28 to 237. Only 3 studies used CUSUM analysis to determine the length of the learning curve, the other 8 studies compared outcomes between arbitrarily divided groups of patients. The length of the learning curve ranged from 25 (11) to 175 (8) cases based on improved results of operative time (*Table 1*).

Nine studies investigated the length of the learning curve with postoperative complications as outcome parameter, but only three studies reported a decrease in postoperative complications with increased experience. Guo *et al.* (23) reported a decrease in overall complications from 53% in the first 30 patients to 7% in the last 29 patients ($P=0.0005$). Okamura *et al.* (8) found a decrease in pneumonia incidence from 18.9% during the learning curve, the first 175 cases, to 6.5% after the learning curve had been completed ($P=0.024$). Osugi *et al.* (25) also found a decrease in pulmonary infection between the first 34 patients and the last 46 patients ($P=0.0127$). Interestingly, all included studies reported anastomotic leakage rate, but none of the studies found a significant learning curve regarding anastomotic leakage.

Learning curve of Ivor Lewis MIE

There are four studies that conducted a learning curve analysis for Ivor Lewis MIE (*Table 2*). Only one study used pooled results of multiple hospitals (19) and the number of included patients ranged from 80 to 646. Two studies used the CUSUM method and one study used linear regression analysis to determine the length of the learning curve. The other study compared outcomes between two arbitrarily divided groups. Two of these studies (19,21) used anastomotic leak to determine the length of the learning curve, two used operative time.

The length of the learning curve ranged from 40 (8) to 54 (6) based on operative time. Ramage *et al.* (21) who compared the first 50 patients with the subsequent 105 patients had gastric tube necrosis, anastomotic leak, and combined gastric tube necrosis and leak as outcome. They found a decrease from 18% to 7% ($P=0.0457$) and from 22% to 10% ($P=0.0447$) for anastomotic leak and combined gastric tube necrosis and leak rate, respectively.

Table 1 Learning curve of McKeown MIE

Study	No. of patients	Methods	Length of learning curve regarding							
			Total operative time	Blood loss	Total lymph node retrieval	Anastomotic leak	Overall complications	Hospital stay	Mortality rate	
Okamura (8)	237	CUSUM method	175	175	Not performed	Not performed	Not performed	Not performed	Not performed	Not performed
Zhu (11)	82	3 groups of 27, 27 and 28 cases. CUSUM method. 25 [#]	Groups: no plateau reached; CUSUM: reached. 25 [#]	Groups: no learning effect found. CUSUM: not performed	Groups: no plateau reached. CUSUM: not performed	Not performed	Groups: no learning effect found. CUSUM: not performed	Not performed	Groups: no learning effect found. CUSUM: not performed	Not performed
Mu (9)	180	3 groups of 60 cases	60	No learning effect found	No learning effect found	No learning effect found	No learning effect found	No learning effect found	No learning effect found	No learning effect found
Mao (20)	59	2 groups of 30 and 29 cases	Not performed	Not performed	Not performed	Not performed	Not performed	No learning effect found	Not performed	Not performed
Ma (22)	124	4 groups of 31 cases	No learning effect found	No plateau reached	No plateau reached	Not performed	Not performed	Not performed	Not performed	Not performed
Oshikiri (10)	122	CUSUM method and moving average	CUSUM: 44. Moving average: no learning effect found	Not performed	Not performed	Not performed	Not performed	Not performed	Not performed	Not performed
Oshikiri (12)	100	3 groups of 33, 33 and 34 cases	44*	No learning effect found	66	No learning effect found	No learning effect found	Not performed	No learning effect found	No learning effect found
Guo (23)	89	3 groups of 30, 30 and 29 cases	No plateau found	No plateau found	No plateau found	No learning effect found	No learning effect found	No plateau found	No learning effect found	Not performed
Song (24)	28	2 groups of 14 cases	No plateau reached	Not performed	No learning effect found	Not performed	Not performed	Not performed	No learning effect found	Not performed
Osugi (25)	80	2 groups of 34 and 46 cases	No plateau reached	No plateau reached	No plateau reached	No learning effect found	No learning effect found	No learning effect found	Not performed	Not performed
Lin (26)	60	3 groups of 20 cases	No plateau reached	40	40	No learning effect found	No learning effect found	No learning effect found	Not performed	Not performed
Ninomiya (27)	53	3 groups of 12, 9 and 32 cases	No plateau reached	No learning effect found	No learning effect found	No learning effect found	No learning effect found	Not performed	Not performed	Not performed

No learning effect found: a learning curve analysis has been performed. However, there is no statistical significant outcome. No plateau was reached: a learning curve analysis has been performed and a statistical significant outcome has been found. However, the length of the learning curve could not be determined because it was a comparison between two groups, or no plateau between group outcomes has been reached. [#], only for TNM stage I and II, no learning effect was found for stage III and IV; *, only mentioned in text, data not shown. MIE, minimally invasive esophagectomy.

Table 2 Learning curve of Ivor Lewis MIE

Study	No. of patients	Methods	Length of learning curve regarding						
			Total operative time	Blood loss	Total lymph node retrieval	Anastomotic leak	Overall complications	Hospital stay	Mortality rate
van Workum (19)	646	CUSUM method. Between quintiles analysis for 4 different hospitals, H1 t/m H4	CUSUM: not performed. Groups: no plateau reached	Not performed	Not performed	CUSUM: 119. Groups H1, H2: no plateau reached. Groups H3, H4: no learning effect found	Not performed	Not performed	CUSUM: not performed. Groups: no learning effect found
Tapias (6)	80	CUSUM method. 2 groups of 40 cases	CUSUM: 54. Groups: no plateau reached	CUSUM: not performed. Groups: no learning effect found	CUSUM: not performed. Groups: no learning effect found	Not performed	CUSUM: not performed. Groups: no plateau found	CUSUM: 33. Groups: no plateau found	Not performed
Wang (7)	109	Linear regression for learning curve. 3 groups of 26, 62 and 21 cases	Linear regression: 40. Groups: no plateau reached	Linear regression: no learning effect found. no plateau reached	Linear regression: no learning effect found	Linear regression: not performed. Groups: no learning effect found	Linear regression: not performed. Groups: no plateau reached	Linear regression: not performed. Groups: no plateau reached	Linear regression: not performed. Groups: no learning effect found
Ramage (21)	155	2 groups of 50 and 105 cases	Not performed	Not performed	Not performed	No plateau reached	Not performed	Not performed	Not performed

No learning effect found: a learning curve analysis has been performed. However, there is no statistical significant outcome. No plateau was reached: a learning curve analysis has been performed and a statistical significant outcome has been found. However, the length of the learning curve could not be determined because it was a comparison between two groups, or no plateau between group outcomes has been reached. [§], RLN lymph node dissection. MIE, minimally invasive esophagectomy.

In our own learning curve study, that included 646 patients from 4 high volume hospitals, we used CUSUM analysis and found a length of the learning curve of 119 (19) cases based on anastomotic leak. We found a mean incidence of anastomotic leakage of 18.8% during the learning curve and 4.5% after the plateau had been reached after 119 cases. Using area under the curve analysis we concluded 36 patients (10.1% of all patients that were operated during the learning curve) experienced learning associated anastomotic leakage: anastomotic leakage that could have been prevented if the patients were operated by a surgeon who had completed the learning curve.

Learning curve of robot-assisted minimally invasive esophagectomy (RAMIE)

RAMIE is the latest surgical innovation for esophageal resection. Six studies have described a learning curve both for the Ivor Lewis procedure and the McKeown procedure (Table 3). There were no studies that used pooled results of multiple hospitals. The number of patients included in these studies ranged from 52 to 232. Three studies used CUSUM analysis to determine the length of the learning curve and the other three studies compared outcomes between arbitrarily divided groups.

Sarkaria *et al.* (13) included both Ivor Lewis RAMIE and McKeown RAMIE and found a decrease in operative time between 30 to 45 procedures. They also noted a decrease in overall complications from 58% in the first 50 patients to 44% in the last 50 patients ($P=0.046$). Park *et al.* (14) who also included both Ivor Lewis RAMIE and McKeown RAMIE concluded the learning curve was completed after 80 cases based on operative time and 85 cases based on anastomotic leakage. In their study, anastomotic leakage rate decreased from 15% during the learning curve, to 2% after the learning curve had been completed.

Three studies only included McKeown RAMIE. van der Sluis *et al.* (16) concluded McKeown RAMIE could be performed proficiently after 70 procedures based on operative time, intraoperative blood loss and conversion rate. According to Zhang *et al.* (18) the length of the learning curve is only 26 cases based on operative time. This is consistent with Zhang *et al.* (17) who compared outcomes between four groups and found a plateau in operative time, and thus a completion of the learning curve, after 25 cases ($P<0.001$).

Hernandez *et al.* (15) only included Ivor Lewis RAMIE and found a decrease in operative time from 514 to

397 minutes ($P<0.005$) after 20 cases, but they did not find a learning curve regarding anastomotic leak.

Discussion of MIE learning curve study results

The relation between learning curves and postoperative morbidity

Some interesting observations can be made from the studies in this review. First, the included studies have reported a wide range of learning curve length from 20–175 cases regarding operative time, blood loss, harvested lymph nodes, hospital stay and postoperative complications. None of the reviewed studies found a learning curve regarding postoperative mortality. Second, studies that included more patients generally found a longer length of the learning curve for MIE. This is not surprising, since for example small study of 40 patients undergoing MIE can never establish that the learning curve is longer than 40 cases. This finding supports the opinion that the length of a learning curve that is found in a small case series should be interpreted with caution. Third, it is interesting that none of the studies that included patients undergoing McKeown MIE or McKeown RAMIE found a learning curve for anastomotic leakage, but a learning curve of 50–119 cases was found in three studies that included Ivor Lewis (RA)MIE. This can be explained by the fact that a cervical anastomosis is performed by open surgery, and surgeons that were learning McKeown MIE may have already been familiar with this anastomosis. This is in contrast to the minimally invasive creation of an intrathoracic anastomosis, where surgeons that were learning Ivor Lewis MIE also had to learn a new anastomotic technique. All studies that found a learning curve regarding anastomotic leakage after implementation of Ivor Lewis (RA)MIE, found that anastomotic leakage decreased by at least 10% during the learning curve phase. This means that a substantial extra number of patients may be at risk for anastomotic leakage during the learning curve, possibly with devastating sequelae. It may be sensible for surgeons who want to implement a MIE program, to start with a cervical anastomosis (McKeown procedure) and consider implementation of the Ivor Lewis MIE after other important skills have been learned.

Methodological considerations

Drawing general conclusions from the published MIE

Table 3 Learning curve of RAMIE

Study	No. of patients	Methods	Length of learning curve regarding						
			Total operative time	Blood loss	Total lymph node retrieval	Anastomotic leak	Overall complications	Hospital stay	Mortality rate
Mixed McKeown and Ivor Lewis RAMIE									
Sarkaria (13)	100	15-patient cohort groups for defining the plateau. 2 groups of 50 cases	30–45	No plateau found	No learning effect	No learning effect found	No plateau found	No learning effect found	Not performed
Park (14)	140	Observed-expected CUSUM method	80	N/A	28	85	Not performed	85	Not performed
Ivor Lewis RAMIE									
Hernandez (15)	52	10-patient cohort groups	20	Not performed	Not performed	No learning effect found	No learning effect found	Not performed	Not performed
McKeown RAMIE									
van der Sluis (16)	232	CUSUM method	70	70	Not performed	Not performed	Not performed	Not performed	Not performed
Zhang (17)	100	4 groups of 25 cases	25	No learning effect found	50	No learning effect found	Not performed	50	Not performed
Zhang (18)	72	CUSUM method	26	Not performed	32	Not performed	Not performed	Not performed	Not performed

No learning effect found: a learning curve analysis has been performed. However, there is no statistical significant outcome. No plateau was reached: a learning curve analysis has been performed and a statistical significant outcome has been found. However, the length of the learning curve could not be determined because it was a comparison between two groups, or no plateau between group outcomes has been reached. RAMIE, robot-assisted minimally invasive esophagectomy.

learning curve studies is challenging because differences in study methodology and the limited quality of most studies that have been performed. Most included studies are small, single center studies. These studies used different learning curve analysis methods. Thirteen studies assigned patients to groups of arbitrary size, which is susceptible to bias because authors can make groups that fit their data. Eight studies performed the CUSUM analysis. CUSUM analysis avoids splitting patients into groups by authors which results in a lower risk of bias. In addition, CUSUM analysis can be used to identify the length of the learning curve per patient instead of analyzing groups of patients, which can result in more precise estimations of the length of the learning curve. Correction for casemix is also important for learning curve analysis, since it is plausible that some surgeons expand indications to more complex cases with increasing experience. However, only 2 of the included studies took casemix into account in the analysis (14,19).

In addition, the experience levels of surgeons that performed the surgeries that were included in the learning curve studies varies widely and it is likely that this contributes to the wide range of learning curve lengths that were found. Most studies have described different levels of experience to some extent, but in order to establish a mean length of a learning curve for a procedure it may be better to analyze pooled data from multicenter datasets.

Safe implementation

With increasing complexity of surgical procedures, it is becoming more and more important to establish effective and safe implementation programs in order to reduce learning associated morbidity. Since some MIE learning curve studies have shown that morbidity can be significantly increased during learning curves (19,21), safe implementation programs could substantially improve outcome during learning curves. Efforts have been made to ensure safe implementation of new surgical techniques and these have for example consisted of (inter)national safe implementation guidelines. However, some of the learning curve studies that were reviewed for this manuscript were performed after safe implementation guidelines had already been established, suggesting that these guidelines have to be improved further to increase effectiveness and enhance patient safety during learning curves.

Various other methods exist that can support safe implementation programs. Video-based platforms can

give feedback regarding performance that can be used for coaching and surgical quality improvement (28). Various training models exist, but there is no consensus on what factors contribute to effective training and there is no consensus regarding what short-term outcomes are most relevant (10,26). Ruurda *et al.* (29) suggested a structured training program for RAMIE that should enable surgeons with basic MIE skills and knowledge to complete the learning curve in 20 cases, but more research is necessary to verify if it is really feasible. Another widely used method for safe implementation is proctorship. Ninomiya *et al.* (27) have shown that an experienced surgeon can instruct surgeons at another institution and possibly shorten the learning curve of the new instructed surgeon. This is consistent with Oshikiri *et al.* (10), who compared the learning curve based on operative time between two surgeons. With surgeon A there was a decrease after the 44th case in operative time. Surgeon B implemented a stable standard procedure developed by surgeon A who also acted as a proctor to surgeon B. With surgeon B there was a decrease in operative time after the 17th case, thus a shorter learning curve.

In general, there is little robust evidence on what factors contribute to more effective learning and safe implementation of innovative and technically challenging surgical techniques.

Conclusions

The significance of surgical learning curves is increasing because recent surgical innovations are complex and therefore the length of the learning curve is longer. Surgical learning curves of MIE can be associated with significant morbidity and this has especially been established for Ivor Lewis MIE. Safe implementation programs are therefore increasingly important to diminish learning associated morbidity. More research is needed to develop evidence based safe implementation programs to ensure patient safety during learning curves.

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Footnote

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