

Learning curves and safe implementation of minimally invasive esophagectomy

Frans van Workum^{1,2}, Frits J. H. van den Wildenberg³, Fatih Polat³, Maroeska M. Rovers⁴, Camiel Rosman¹

¹Department of Surgery, Radboud University Medical Center, Nijmegen, The Netherlands; ²Department of Surgery and Cancer, Imperial College, London, UK; ³Department of Surgery, CWZ Nijmegen, Nijmegen, The Netherlands; ⁴Departments of Health Evidence and Operating Rooms, Radboudumc, Nijmegen, The Netherlands

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Correspondence to: Frans van Workum, MD. Imperial College London (UK)/Radboudumc Nijmegen (NL), P.O. Box 9101, 6500 HB, Nijmegen, The Netherlands. Email: frans.vanworkum@radboudumc.nl.

Abstract: Esophagectomy is the cornerstone of curative treatment for patients with esophageal cancer. Minimally invasive esophagectomy (MIE) has emerged and can reduce postoperative complications, but it is a technically challenging procedure, associated with a long learning curve. During the learning curve, morbidity for patients (“learning associated morbidity”) may be increased as surgeons are gaining proficiency. This viewpoint article addresses the clinical relevance of surgical learning curves in general and of MIE specifically and to provide suggestions on how to implement MIE safely in clinical practice. In the first part of this paper, the challenges of surgical innovation are briefly discussed and the importance of surgical learning curves in general and specifically for MIE is described. Upon implementation of complex interventions, surgeons struggle to acquire and maintain a high level of surgical proficiency for the available procedures. In the second part, possible strategies to ensure efficient surgical learning and safe implementation are explored and discussed against the currently available literature. We conclude with recommendations on how to safely implement complex surgical procedures into practice, based on available literature where possible, and suggest themes for future research.

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

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Introduction

Esophagectomy is the cornerstone of curative treatment for patients with esophageal cancer (1,2). Historically, esophagectomy has been performed as an open procedure, but minimally invasive esophagectomy (MIE) is increasingly used since studies have shown that MIE is beneficial in terms of early postoperative morbidity, without compromising oncological safety (3-5).

MIE is considered to be a complex procedure requiring a higher level of surgical skills than open esophagectomy and

it is associated with long learning curves and an increase in morbidity during the learning curve (6). The occurrence of “learning associated morbidity” [morbidity during a learning curve that could have been avoided if patients were operated by a surgical team that had completed the learning curve (7)] implies that patient safety can be compromised during the learning phase of a new procedure. This is further supported by 2 recent studies, in which favorable results of MIE that were found in randomized controlled trials could not be replicated in national practice (8,9). Since

the learning curve of MIE can take years to complete and there is growing evidence of learning associated morbidity, effective learning methods and safe implementation strategies should be developed, in order to improve patient safety.

The aim of this manuscript is to summarize the clinical relevance of surgical learning curves in general and of MIE specifically and to provide suggestions on how to implement MIE safely in clinical practice. In the first part of this paper, the challenges of surgical innovation are briefly discussed and the importance of surgical learning curves in general and specifically for MIE is described. In the second part, possible strategies to ensure efficient surgical learning and safe implementation are explored and discussed against the currently available literature.

Challenges of surgical innovation and learning curves

Appeal and risk of surgical innovation

Surgical innovation is inseparably connected to progress in surgical science and improvement in patient outcomes. It is not surprising that in public opinion, new innovative procedures are associated with benefits for patients and patient preference is an important motivation for surgeons to adopt new procedures. On the contrary, it is equally true that 30–50% of new interventions have been shown to be ineffective when tested adequately (10). In addition, implementing innovative surgical techniques may in itself pose a risk for patients and an important majority of innovations are associated with an initially increased level of patient harm (11,12).

In surgical science, balancing possible benefits and risks of implementing surgical innovations is often complicated by the limited quality of evidence that supports the added value of surgical innovations over established treatments. This means that surgical innovations are regularly implemented before or without thorough evaluation of effectiveness. Important causes of this may be that regulations for implementation of new surgical procedures were historically less strict than regulations for new medication (13,14) and that performing surgical research can be complicated by differences in the delivery (i.e., varying quality of surgery) of interventions (14–16). Although surgical innovations have been implemented with limited evidence of effectiveness and varying quality of surgery for many years, the increasing relevance of surgical learning curves is making this an important problem.

Emerging challenges of ongoing surgical innovation

Surgical learning curves are becoming more important because surgeons implement more complex interventions with smaller added value compared to alternatives at an increasing rate. To explain this, let us examine two examples of implementation of surgical innovations: the older example of the implementation of tension-free mesh repairs for inguinal hernias and the more recent example of the implementation of laparoscopic surgery for gastrointestinal procedures.

When tension-free mesh repair was introduced for inguinal hernias, this was associated with a substantially lower incidence of hernia recurrence compared to non-mesh techniques (17,18). In addition, the learning curve was relatively short, reflecting the limited complexity of the new technique. Taken together, the short learning curve and the large added value of tension-free mesh repair contributed to making the learning curve insignificant for this procedure and it was easy for surgeons to acknowledge that the new technique yielded better results and should be adopted (*Figure 1A*) (19).

In contrast, innovative procedures that are implemented today are generally associated with a much lower added value compared to standard procedures. For example, randomized controlled trials comparing laparoscopic versus open gastrointestinal procedures have shown more modest improvements in outcome for patients (3,4,20) and the difference in added value is even smaller in trials comparing robotic versus laparoscopic procedures (21). At the same time, the surgical procedures that are currently implemented are of a higher complexity and are associated with longer learning curves and substantial learning associated morbidity (19,22,23). Together, this means that efficient surgical learning and safe implementation of new procedures has become more important (*Figure 1B*) and it has even been suggested that performing a procedure masterfully can be of greater benefit to patients than characteristics of the procedures in itself (24).

The described challenges also apply, to great extent, to the implementation of MIE since implementation of MIE has been associated with long learning curves and significant learning associated morbidity (6). In a particular study from our group, the mean incidence of anastomotic leakage was 10.1% higher during the learning curve compared to after the learning curve, accounting for considerable learning associated morbidity (7). If these extra patients with anastomotic leakage are weighed against the benefit of MIE to open surgery (3,4,25), one might even conclude that the

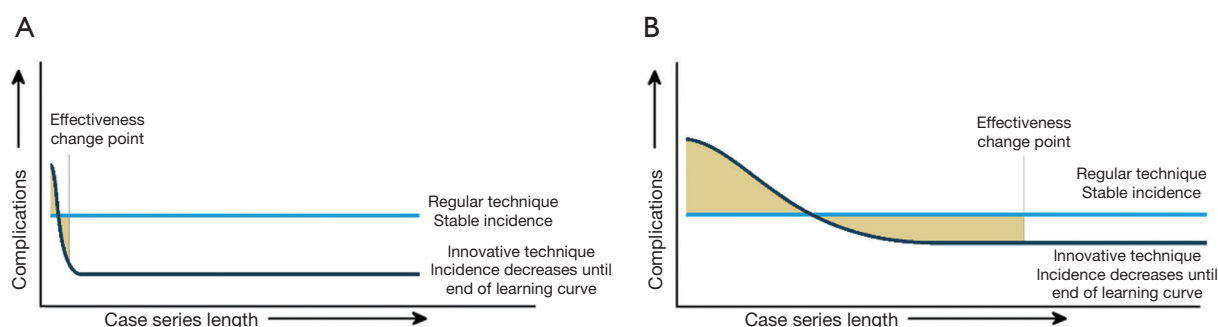


Figure 1 Scenarios in which the differences in the impact that learning curves can have on the effectiveness of an innovative intervention is described. (A) Learning curves can be neglected in case of a short learning curve and large difference in relative effectiveness between the regular technique and an innovative technique. (B) If the learning curve of the innovative technique is significant and the difference in relative effectiveness is small, learning curves can have a large impact on when an innovative technique becomes effective.

benefit of MIE can be superseded by the negative impact on outcome during the learning curve of MIE.

Overcoming the challenges of surgical innovation and learning curves

Establishing effectiveness of innovations

In general, revealing and aligning the views of all stakeholders involved in a surgical innovation is a prerequisite for surgeons who want to implement any surgical innovation (26,27). The first challenge is deciding whether it can reasonably be assumed that an innovation will be beneficial to patients. These decisions can be informed by obtaining patient preferences, appraisal of clinical data and experience with similar innovations, but there are often many uncertainties. Early health technology assessment modeling can be used to substantiate the probability of effectiveness of innovations, without disregarding uncertainties in the available data (28).

In order to help innovators systematically generate data regarding the effectiveness of new interventions, the IDEAL framework has been created (26). This framework provides recommendations on the appropriate evaluations during different stages of innovation, from the conceptualization (Idea stage) to broad implementation and long term follow-up (Long term follow-up stage). If followed, these recommendations help informing surgeons by providing more data on both the benefits and risks of new surgical procedures. It has been reported that making these safety decisions in a dedicated team on a hospital level can both increase innovation acceptance speed and increase

patient safety (27).

For MIE, effectiveness has now been established over open esophagectomy in high quality randomized controlled trials for hybrid MIE (4), total MIE (3) and robot-assisted MIE (25). Although these trials provide quality evidence of the superior effectiveness of these different types of MIE over open esophagectomy, the 3 surgical approaches have not been compared directly. These uncertainties have to be taken into consideration when moving from hybrid MIE to total MIE or robot-assisted MIE or when moving from total MIE to robot-assisted MIE. The possible benefits of adopting the innovative technique should be weighed against reported learning curve effects in order to make a considerate decision on whether or not to implement a new procedure.

After it has been established that an innovation may be beneficial to patients and should be implemented, it is of prime importance to ensure that implementation is as safe as possible. Strong efforts should be made to reduce learning associated morbidity since learning at the expense of patient safety should be prevented. Patients undergoing new interventions should be informed about this and understand the possible risks and intended benefits of the new procedure. No universal guidelines for safe implementation of surgical procedures exist, but local or national guidelines may be available and should be followed (29,30).

After reviewing relevant literature, the following aspects that may influence safe implementation can be identified and these can be subdivided into 4 domains (31-34):

(I) Environment: a surgical unit that has requisite

criteria to enable safe implementation of a complex surgical intervention. These factors can for example be the experience of the surgical team, presence of an ICU that is equipped to care for patients with severe sepsis and a minimum number of surgical procedures performed annually.

- (II) Procedure: a procedure can have properties that make it more difficult to implement safely (e.g., complexity). In addition, a procedure that is in an earlier stage of innovation may be more difficult to implement safely: pioneering is likely to be different from implementing a fully developed and standardized surgical innovation.
- (III) Training: a structured training program, in which the surgical team can learn the essential steps and pitfalls of the procedure and practice their skills to a sufficient level. Proctors, who can be a mentor in the operating theatre may also play a role in training surgeons.
- (IV) Feedback: a structured assessment tool for surgical skills that can provide focused feedback to the surgical team so that the team knows if and where there is room for improvement. In addition, a prospective outcome database can help inform regular internal evaluations of the intervention and can substantiate decisions on whether or not to continue or adjust innovations.

An example of implementation of MIE

To convey how the domains of safe implementation can give insight into changeable factors that may contribute to patient safety we will provide a clinical example, in which we assess to what extent domains of safe implementation were satisfied at the time of implementation of Ivor Lewis total MIE.

The CWZ Nijmegen was the first hospital in the Netherlands to implement Ivor Lewis total MIE as the standard procedure for patients with resectable esophageal cancer in 2010. At that time, there were no applicable guidelines that specifically concerned implementation of new surgical procedures, although these have become available later (29,30). Circumstances of implementation of Ivor Lewis total MIE in the CWZ Nijmegen have been discussed in more detail previously (35,36).

At the time of implementation, the environment of the center was suitable for implementation of the procedure

according to an international consensus statement that was published by a group of MIE experts in 2017 (environment domain) (33). However, a detailed description of a standardized and reproducible procedure (procedure domain) was lacking and there was no structured training program or proctor available (training domain). There was no feedback tool available at the time, but there was a prospective outcome database and regular evaluation meetings with the whole treatment team were held (feedback domain).

In this example, safe implementation was hampered by finding the optimal exact surgical technique, the absence of structured training and a lack of structured feedback. This resulted in “learning by doing”, or “pioneering”. Other Dutch centers consequently adopted Ivor Lewis total MIE as their standard procedure in the following years and had similar circumstances regarding the described domains of safe implementation. We later showed this resulted in substantial learning associated morbidity (7).

Implementation of Ivor Lewis total MIE in current practice

It has become clear that if patients are to benefit from broad implementation of Ivor Lewis total MIE, it is of paramount importance that surgical teams implementing Ivor Lewis total MIE can progress safely through the learning curve. In recent years, there has been an increasing awareness of the importance of safe implementation of complex surgical innovations. In the Netherlands, the federation of medical specialists (FMS) has published guidelines on safe implementations of new interventions, although the uptake of these into practice has been slow (30).

In addition to increased general awareness and guidance, characteristics of several domains of safe implementation have changed for MIE. Proctors for Ivor Lewis total MIE are now abundantly available in Europe. There is an annual course in Utrecht where basic steps of standardized total MIE can be learned and where surgeons can acquire surgical skills on human cadavers. A standardized training program has not yet been established, but consensus has been achieved on what features a training program should have (33). A generally accepted standardized description of Ivor Lewis total MIE and appurtenant feedback tools are still lacking, although our group is aiming to publishing these in the nearby future. Since standardized training and proctorships have been effective for learning other procedures (37-39), we expect that a tailored training

program for Ivor Lewis total MIE will contribute to safer implementation of MIE. This should, however, be confirmed in future studies.

Evidence for factors that are associated with effective learning

Although it may seem obvious that factors in the environment, procedure, training and feedback domains can contribute to safe implementation and efficient surgical learning, it is important to investigate the clinical relevance of these. Only two studies investigated associations of factors with efficient learning in the clinical setting of patients undergoing esophagectomy (40,41). In these studies, high surgical volume was associated with more efficient learning or safe implementation. The findings of these studies present an argument for further centralization, in addition to the argument that high case volumes are associated with improved outcomes (42,43). Alternatively, these findings could imply that it may be more effective to send a surgeon, who is planning to implement a complex innovative technique in a lower volume center, to a high volume expert center in order to acquire the necessary skills there. This strategy might even be cost-effective given the high costs of increased postoperative complication rates during learning curves, but may be difficult to arrange in busy surgical practices and proctorship is often sought instead. However, it is currently unclear to what extent proctorship can guarantee safe implementation of complex surgical innovations and what characterizes effective proctorship.

Recommendations for implementing surgical innovations

The paucity of studies that use clinically relevant outcome parameters to study factors that are associated with efficient surgical learning and safe implementation demonstrates a clear knowledge gap and a need for future research. The following recommendations are based on the limited available evidence and our experience.

In our view, surgeons should consider to what extent their outcome can be improved by moving to a new, innovative surgical technique. They should appreciate how long the reported learning curve is and assess whether there are reports of learning associated morbidity. Substantial learning curve effects should prompt caution, especially if the reported added benefit of the new technique is

limited (i.e., there is not much effectiveness to gain by implementing the new procedure) or in situations where there is no evidence of added effectiveness at all. This implies that in some scenarios, it is better for surgeons to keep performing a procedure that they have mastered fully, rather than moving to a new procedure with a limited added benefit and a long learning curve with high learning associated morbidity. A decision whether or not to implement a new technique is preferably made within a specialized team on hospital level (27).

Consequently, clinicians should make strong efforts to ensure implementation is as safe as possible. A prerequisite is following national and local guidelines for safe implementation and based on these, surgeons should formulate an implementation strategy. The domains of safe implementation can help identify changeable factors that may hamper safe implementation. Learning a new procedure in a high volume environment can facilitate higher patient safety and proctor supervision may also be sought. However, proctor supervision has not been proven to be effective (yet) from clinical studies and it cannot be regarded as a guarantee for patient safety during learning curves and different characteristics of a proctoring program (e.g., intensity and number of proctoring sessions) should be given careful consideration.

Conclusions

Substantial learning curves and learning associated morbidity have been described for MIE and this should prompt surgeons to implement MIE procedure with care. When implementing MIE is considered, expected benefits of MIE should be weighed against initial learning curve effects. Changeable factors that may contribute to increased patient safety during implementation should be appreciated and optimized if possible.

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Footnote

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