Society for Translational Medicine expert consensus on training and certification standards for surgeons and assistants in minimally invasive surgery for lung cancer

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Part I: basic contents of the project

Project name

Training and certification standards for surgeons and assistants in minimally invasive surgery for lung cancer

Purpose and contents

Develop a training program for surgeons and assistants in minimally invasive surgery for lung cancer and establish clear criteria of certification.

Main issues

- (I) Training program for surgical assistants in minimally invasive surgery for lung cancer;
- (II) Training program for surgeons in minimally invasive surgery for lung cancer;
- (III) Certification of surgical assistants in minimally invasive surgery for lung cancer;
- (IV) Certification of surgeons in minimally invasive surgery for lung cancer.

Part II: background and current status

Background information

Lung cancer is one of the most common types of malignant tumor in China and is the leading cause of cancer deaths. Approximately 85% of lung malignancies are non-small cell lung cancer (NSCLC). Lung cancer treatments include surgery, chemotherapy, radiotherapy, and targeted therapy. The principle for advanced or complex cases is to combine non-operative therapies with surgery. Surgical resection is generally preferred for early stage lung cancer, and multimodality therapy is often combined with surgery for more locally advanced tumors with regional nodal involvement.

For decades, an open approach with thoracotomy has been the standard surgical treatment approach for lung cancer. In the early 1990s, Roviaro et al. (1) reported the first case of thoracoscopic lobectomy for lung cancer. Since then, minimally invasive surgery for lung cancer via the thoracoscopic approach has gradually emerged as an important advancement in thoracic surgery. Through the sequential progression from video-assisted thoracic surgery (VATS) via small incisions to multi-portal thoracoscopy, single utility port thoracoscopy, and singleport thoracoscopy, minimally invasive thoracoscopic surgery for lung cancer has matured and is now widely recognized as one of the standard surgical treatments for early stage lung cancers (2-4). Minimally invasive approaches in the surgical treatment of lung cancer have progressively expanded beyond lobectomy. Most procedures that involve parenchyma preservation, such as pulmonary artery sleeve lobectomy and tracheal tumor resection, can be achieved by thoracoscopy (5-7). After 20 years of development, accumulated evidence suggests that the perioperative results and long-term prognoses of patients undergoing thoracoscopic minimally invasive surgery for lung cancer are similar to or better than open thoracotomy (8-11).

For contemporary thoracic surgeons, minimally invasive surgery has therefore become a basic skill that must be mastered. As early as 2007, the National Health and Family Planning Commission in China proposed the implementation of pilot centers of "technical training and certification for endoscopy" which illustrates the importance of standardized training. However, there is still no systematic training system for theoretical study and thoracoscopic skills worldwide, nor are there technical standards of certification. The lack of these standards may lead to potential health risks for patients. Therefore, there is a need to develop standards for the training and certification of surgeons and surgical assistants in minimally invasive surgery for lung cancer.

Current status of the research project

At present, research on the standards of training and certification for surgeons and assistants in minimally invasive surgery for lung cancer mostly involves how surgeons overcome the learning curves of different minimally invasive lung cancer resection (i.e., VATS anatomical segmentectomy and lobectomy) and the application of simulators and animal models in training surgical staff. Some earlier studies reported that, compared with highly qualified and experienced doctors, trained residents were also able to properly complete thoracoscopic resections of early stage lung cancer, however the operation time was prolonged. In addition, there were no significant differences in perioperative complications or sequelae during follow-up. Therefore, under the guidance of experienced doctors, trained residents can complete thoracoscopic lung resections (12,13). Thoracoscopic lung resection must be an important component of all thoracic training programs, which is now a requirement for the American Board Certification.

There is no generally accepted conclusion about the number of minimally invasive procedures that a surgeon needs to complete in order to achieve a stable performance. By comparing perioperative related indicators for the same surgeon who performed the surgery at different stages of experience, it was found that a majority of surgeons achieved stable technical indicators after completing 30-60 cases of minimally invasive thoracoscopic anatomic lung resection (lobectomy and segmentectomy), indicating that they had overcome the learning curve for minimally invasive surgery for lung cancer (14-18). A surgeon already experienced in thoracic surgery can achieve stability after completing 30-40 cases of single-port thoracoscopic anatomical pulmonary resection even in a direct transition from thoracotomy (19). The length of the learning curve for this newly emerged procedure is also approximately 30-40 surgical cases (20,21). However, the skills of each lobe resection are somewhat different, the distribution of each lobe in the training case series should be appropriately balanced.

To train surgeons and surgical assistants in minimally invasive surgery for lung cancer, commonly employed approaches currently include an endoscopic simulation training box, human anatomy models, simulation software, and live surgery training on animals (such as pigs). The size and shape of pig organs are similar to humans; therefore, pigs have been used for training in minimally invasive surgery for a long time. After one day of systematic training

with animal models, most trainees are gradually capable of performing thoracoscopic surgery in clinical practice (22). The laparoscopic simulation training box is currently the most common and most economical tool for training chest endoscopic skills. It is of great help to train beginners to convert from a three-dimensional (3D) field of view to a two-dimensional (2D) field of view and to master basic thoracoscopic skills. With the continuous development of digital technologies in recent years, simulation software has also been developed for training VATS surgical skills (23). Jensen et al. conducted a randomized controlled study to compare the effects of laparoscopic simulation training box compared with virtual training simulation software. The results showed that the simulation training box was superior to the simulation software (24). However, virtualization software that is more professional for training in thoracoscopic minimally invasive surgery has vet to be developed. Recently, a virtual reality simulator (LapSim[®]) for VATS right upper lobectomy was introduced (25).

Significance of the research/consensus project

- (I) Systemically develop the theory and skills needed for training programs for surgeons and surgical assistants in minimally invasive surgery for lung cancer. These programs will serve as references for personnel training in minimally invasive thoracic surgery;
- (II) Develop certification standards for surgeons and surgical assistants in minimally invasive surgery for lung cancer. These standards will fully guarantee the quality of practitioners, provide assurance of medical safety, and reduce harm to patients.

Part III: main conclusions and recommended program

Open lung cancer surgery as the basis of minimally invasive surgery

Minimally invasive surgery for lung cancer evolved from thoracotomy. Surgeons and assistants performing minimally invasive surgery should have a solid basic knowledge of open thoracic surgery. They must be able to calmly address the common sudden and unexpected circumstances during an open procedure, and if necessary, convert a minimally invasive surgery for lung cancer to an open procedure. A surgeon who has not had experience in minimally invasive thoracic surgery during formal surgical training should

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have independently completed more than 50 open major pulmonary resection cases to have the basic fundamental knowledge of anatomy and surgical techniques to provide the necessary assurance for a safe transition to minimally invasive surgery. However, it should be noted that with the wide adoption of minimally invasive surgery as represented by thoracoscopy, many surgeons and surgical assistants have mostly practiced minimally invasive surgery since starting their studies and have had little opportunity to participate in open chest surgeries. How to optimally integrate training in open thoracic surgery is a necessary component of the study plan for minimally invasive surgery remains controversial.

Recommendation: a surgeon without formal minimally invasive surgical training should have independently completed at least 50 cases of open major pulmonary resections, or demonstrated equivalent experience by virtue of simulation or conversions of minimally invasive cases during the training curriculum (level 5).

Basic theory of thoracoscopy

Minimally invasive surgeries, represented by thoracoscopy, require special imaging systems and particular instruments that are different from open thoracic surgery. Also, strategies for thoracoscopic surgery can be very different from open surgery. Before starting the actual operation, surgeons and surgical assistants who plan to study minimally invasive surgery for lung cancer should be familiar with the lung anatomy from different perspectives, basic principles of endoscopic imaging systems (2D or 3D video system), equipment assembly and control, assembly of endoscopic surgical instruments, operation of commonly used power equipment (including electrosurgical equipment and ultrasonic knife), and the application scopes of the stapler and different staple cartridges.

Recommendation: thoracoscopic surgery training should include fundamental education for surgical anatomy, instruments and devices necessary and available for the planned procedures (level 5).

Simulation training in thoracoscopy

The laparoscopic simulation training box is the most common and most cost-effective thoracoscopy training equipment. It allows beginners to quickly adapt to the transition from a 3D field of view to a 2D field of view, to master the uses and performance of various endoscopic instruments, and to master basic operations under endoscopic view, such as two-handed operation, tissue dissection, suturing, and knot tying. It is usually recommended that thoracoscopy simulation training should include at least 20 credit hours. In recent years, digitized thoracoscopy virtual simulation software has emerged, but it has not been widely adopted. In addition, a randomized controlled study showed that the effectiveness of the laparoscopic stimulation training box is superior to simulation software in operation time (24). Digitization simulation software for training and objective certification system in minimally invasive surgery for lung cancer requires further development and improvement.

Recommendation: learners should have at least 20 credit hours or equivalent of training in simulated thoracoscopic operation. An objective certification is necessary after the training (level 5).

Surgery training with perfused biologic tissue

Building on basic laparoscopic skills, surgeons and surgical assistants should further gain familiarity with surgical instruments and their methods of operation through performing exercises with perfused biologic tissue that can better simulate the actual experience of the human body. From these practical experiences, surgical staff can appreciate how to properly expose and retract tissue, how to dissect and separate tissue planes, and how to stop bleeding under an endoscopic view during an actual operation. Experiences with perfused tissue surgery will further strengthen the learners' sense of space and location under an endoscopic view. Humanely anesthetized animal species have been used classically but such laboratories are becoming less accessible because of cost and ethical concerns. Perfused and non-perfused tissue blocks from abattoirs and cadavers offer alternative options for such training. In the future, it is likely that tissue alternatives may be able to be manufactured by 3D printing.

Recommendation: thoracic surgery training should include perfused tissue experiments as much as practically possible (level 3).

Serving as an assistant in thoracoscopic surgery

The team for a minimally invasive lung cancer resection usually includes a surgeon, a first assistant holding the endoscopic equipment, and a second assistant. The training also needs to follow the following order: second assistant \rightarrow first assistant (holding the endoscopic equipment) \rightarrow

operating surgeon. A beginner can be trained in this order and progressively develop experience in thoracoscopic minimally invasive surgery by following a gradual transition to be the surgeon who completes the operation. First, as the second assistant, through participating in practical operations, a physician further appreciates the practical applications of thoracoscopic surgical instruments and the coordination with the surgeon to complete the operation under endoscopic view. Later, the physician can participate in the operation as the assistant holding the endoscopic equipment. This assistant is equivalent to the eves of the operating surgeon and should be able to fully understand the intent and ideas of the surgeon. As the operation progresses, this assistant adjusts the angle, direction, and distance of the light source. This experience allows for strengthening the sense of space and the ability to position instruments under thoracoscopic view. As first or second assistant, learning how to maintain the proper force of retraction and adjust the orientation of the tissue in concert with the camera view is also very important (26,27). Most of the experts believe that each of these stages requires approximately 30 surgeries. The physician then gradually transitions to the operating surgeon for pulmonary wedge resections and completes a certain number of VATS wedge resections under the guidance of senior physicians. This plan allows beginners to accumulate experience in thoracoscopic surgery through a logical and ordered progression.

Recommendation: a physician should complete 30 surgeries as a second assistant, 30 surgeries as a first assistant holding the endoscopic equipment, and then perform 15 minor cases of minimally invasive thoracic surgical procedures under the guidance of an experienced physician (level 3).

Overcoming the learning curve of minimally invasive surgery for lung cancer

Like any other surgery, to achieve a proficient level to perform minimally invasive surgery for lung cancer, a physician needs to conduct repeated study and practice. Cases of minimally invasive resection of lung cancer performed by the same surgeon at different stages may have remarkable differences in surgery-related technical indicators. Several famous surgeons in China and abroad have reported their experience in thoracoscopic lung resection. At early stages, the operative time, blood loss, rate of conversion to open surgery, postoperative complications, and other indicators can be higher than surgeons at a relatively mature stage. Most researchers reported that by completing 30–60 thoracoscopic lung cancer operations within six months to a year, their surgeryrelated technical indicators reached a relatively stable state (14-18). This number is similar for single-port surgery and port-assisted thoracoscopic surgery. At the initial stages of independent thoracoscopic lung resection, a physician still needs a senior physician's assistance and guidance. In addition, less common operations like unusual segmental resections or post-induction cases require more experience but the optimal numbers are not known.

Recommendation: at the initial stage of independently performing thoracoscopic lung resection, a surgeon still needs a more experienced physician's assistance and guidance. After completing 50 cases of minimally invasive surgeries for lung cancer, the physician in training can substantially overcome the learning curve and achieve a relatively stable performance (level 2A).

Minimum annual amount of surgery to maintain surgical technique

Even after overcoming the learning curve of thoracic surgery, to maintain stable performance and continue to improve their technical skills, surgeons and assistants for minimally invasive lung cancer surgery should maintain a certain number of surgeries every year through which they should constantly summarize, discover, and solve problems during the operations.

Recommendation: every year, a junior surgeon should perform at least one case of thoracoscopic anatomic lung resection every week while a senior surgeon should perform at least one case every other week to maintain surgical technique. The junior surgeons should record and review their own surgeries for self-teaching and mentor review (level 3).

PART IV: major problems under dispute

Existing controversial issues

- (I) Whether open thoracic surgery is a necessary part of the training program for minimally invasive surgery or not;
- (II) The effects of digital simulation software for training surgeons and assistants in minimally invasive lung cancer surgery need to be further clarified;

- (III) Once receiving systematic training and overcoming the learning curve, whether the surgeon needs to perform a certain amount of operations every year to maintain an appropriate skill level;
- (IV) Which one is better video system for training between 2D and 3D?

Causes, reasons, and shortcomings of the controversial issues

- (I) As the technology for minimally invasive surgery matures, the proportion of procedures performed using a minimally invasive approach increases, and the proportion of thoracotomy decreases. This trend is particularly evident in large medical centers. As such, many beginners directly start practice by learning minimally invasive surgery and have little opportunity to participate in open chest surgeries. Currently there is a lack of sufficient evidence to support a fundamental role of thoracotomy in training programs for minimally invasive surgery;
- (II) Digital simulation software for training in minimally invasive surgery for the chest is still relatively limited; its effect on developing and enhancing surgical skills has yet to be further investigated;
- (III) Currently, there is a lack of appropriate evidence to support whether to assess the ability of a surgeon to complete a sufficient number of minimally invasive lung cancer surgeries each year to maintain stable performance once the surgeon has successfully completed a substantial number of minimally invasive surgical procedures and has overcome the learning curve.

Part V: the main program of research in the future

Lack of evidence-based medicine for this project

There is not enough high-quality evidence-based medicine research to support the issues addressed in this project. Existing conclusions are mostly based on observational studies or expert opinion.

A draft of a multi-center research design in China

(I) Compare the performance of physicians with a good background in thoracic surgery and physicians who start learning minimally invasive surgery directly in terms of their learning curves for minimally invasive surgery, perioperative indicators, and long-term outcomes;

- (II) Develop digital simulation training systems for minimally invasive surgery. Conduct multi-center randomized controlled studies to compare the effects of such systems and of the endoscopic simulation training box. The strategy is to search for more effective measures of staff training;
- (III) Conduct multi-center observational studies to observe the relationship between the number of thoracoscopic procedures, operation time, and progression of skills in trainees who participate as assistants. Conduct regular assessments to determine a reasonable point at which they can start the next stage of training as the operating surgeon;
- (IV) Study differences in the perioperative outcomes and prognosis of lung cancer patients operated on by surgeons who complete different numbers of surgeries annually. This assessment will determine the minimum annual number of independent surgeries required to maintain skills growth as surgeons in minimally invasive thoracic surgery.

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Footnote

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