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Original Article

Training in Robotic Surgery Using the da Vinci® Surgical System for Left Pneumonectomy and Lymph Node Dissection in an Animal Model

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Objectives: In Japan, as of March 2010, only 13 hospitals were using the da Vinci system and only for selected cases. Few clinical robotic lung surgery has been done in Japan, and there are no standardized training programs, although some exist in the U.S. and are under consideration by the Japanese society for thoracic surgery. We have used the da Vinci S® Surgical System for pneumonectomy and lymph node dissection in pigs. We report and review future possibilities and problems of robotic surgery, especially concerning education, training, safety management and ethical considerations for pneumonectomy and lymph node dissection in clinical practice.

Methods: The da Vinci® system consists of a surgeon's console connected to a patient-side cart, a manipulator unit with three instrument arms and a central arm to guide the endoscope. The surgeon, sitting at the console, triggers highly sensitive motion sensors that transmit the surgeon's movements to the instrument arm.

Results: We experienced exactly the same sensation as when performing standard open thoracotomy. Visual recognition is 3-D, and the high manipulation potential allows free movement of the various accessory instruments, exceeding the capacity of a surgeon's hands in video-assisted thoracic surgery (VATS) or even standard thoracotomy.

Conclusions: Robotic surgery achieves at least the same level of operation technique for pneumonectomy and lymph node dissection under standard open thoracotomy, and it seemed as safe and easily performed as conventional VATS. The training program using pigs was effective and holds promise as a system to train thoracic surgeons in robotic lung surgery.

Key words: robotic surgery, da Vinci® Surgical System, educational and training systems

Introduction

When introducing a new therapeutic method, particularly one potentially involving the treatment of malignant diseases, it is essential that the method be thoroughly examined to ensure its safety, effectiveness, especially vis-a-vis existing standard approaches, and ethical aspects regarding its indications, and that appropriate training methods of training in the methodology be developed. From those points of view, it is necessary to exert due caution in evaluating and developing training systems for the field of robotic surgery in the thoracic cavity. While there are training programs established for

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da Vinci® Training Program of Intuitive Surgical

Day One

8:00 AM – 8:30 AM	**Arrival/Registration** Program Overview/Objectives
8:30 AM – 9:30 AM	**System Overview** Features, Functions, etc.
9:30 AM – 12:00 PM	**Laboratory Session** **Surgical Skill Drills** *Renal Lab* (Animate Model) *Grip Strengths *Transection *Ligation *Dissection *Manipulation *Intracorporeal suturing
1:00 PM – 4:00 PM	**Surgical Skill Drills (Continued)** *Esophagus & stomach Lab* (Animate Model) *Patient Positioning *Port Placement *Positioning of Surgical Cart *Procedural Steps *Da Vinci applications free session *Lung & mediastinum training* (Animate Model)

Day Two

8:00 AM – 12:00 AM	**Laboratory Session** *Pelvic ~ Abdominal Lab* (Animate Model) *Patient Position *Port placement *Procedural Steps *Robotic Surgical Technique *Tips and Tricks *Troubleshooting System
1:00 PM – 4:00 PM	free session *Lung & mediastinum training* (Animate Model)

Fig. 1 The da Vinci® Surgical System modified Training Program of Intuitive Surgical, Inc.

certification in the use of the da Vinci® Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA) in abdominal procedures, including intra-abdominal esophageal anastomoses, no institution or country has developed a carefully thought-out approach to evaluating the clinical practical aspects of, or practical training programs, in standardized training approaches to intrathoracic approaches to the system, which appears to hold great potential in the treatment of diseases such as lung cancer.

Surgical options until the present have consisted of standard open thoracotomy or video-assisted thoracic surgery (VATS), apart from the small number of cases that can be approached via pulmonary intervention with electrosurgical, cryotherapeutic or photodynamic therapy procedures. However, standard thoracotomy is relatively highly invasive and sometimes involves difficult postoperative management. While VATS is less invasive, there are reports it does not allow as meticulous lymph node dissection as thoracotomy, and there is also the problem of postoperative pain caused by the necessity of leverage on the chest wall during the procedure.

The recent development of robotic surgery raises the question of whether it can yield comparable results to conventional surgery in terms of safety and curativity for lung cancer.

Because the da Vinci® Surgical System has only been reported for the treatment of lung cancer by a single group,[1] located in Japan, and there are no programs developed for basic animal and clinical training programs, we established a small surgical team to establish such a training system by performing pneumonectomy and lymph node dissection in a pig model. The goal was to determine the feasibility of using the training system for educating thoracic surgeons in robotic surgery for lung cancer.

Methods

Training program

Our experiments in this training program were performed in the laboratory of Intuitive Surgical, Inc., Sunnyvale, CA. During a 2-day modified certifying training program at Intuitive Surgical, participants had to take part in training lectures and surgical skill drills with an animal model (adult pigs were used for this program) (**Fig. 1**). All animals received humane care in accordance with the "Guide for the Care and Use of Agricultural Animals in Research and Teaching" formulated by the Federation of Animal Science Societies, as well as with the "Guide for the Care and Use of Laboratory Animals," prepared by the Institute of Laboratory Animal Resources and published by the National Institute of Health (NIH publication 86–23, revised, 1996).

The animal care protocol in this training program was also approved by the IRB of Intuitive Surgical, Inc. The contents of laboratory sessions consisted of patient positioning, port placement, positioning of the patient-side cart, procedural steps, robotic surgical techniques, and troubleshooting. On the day of the training program, after a lecture on the da Vinci S® Surgical System (the da Vinci S® Surgical System is a newly developed version of the

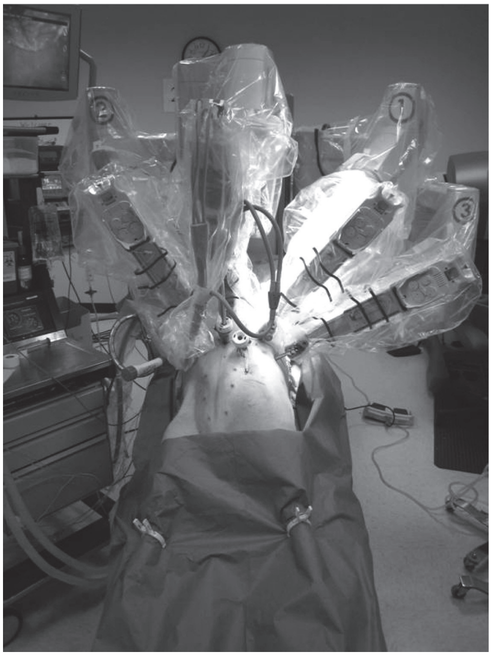


Fig. 2 Instrument arms on an animal model for thoracic surgery.

standard da Vinci® Surgical System), nephrectomy, ablation of the esophagus and suturing of the stomach were performed in pigs under general anesthesia. On the second day, two Tokyo Medical University specialists in thoracic surgery, one at the console and the other surgeon working on the patient-side cart took turns, and the same training schedule as that of the previous day was repeated with the respective roles reversed. After the entire standard training program was completed, our group of 2 expert thoracic surgeons, then went on, on subsequent days to perform training, for the first time in this educational program, to attempt lung resection in pigs. Left pneumonectomies were performed by each surgeon. Normally, the pig pulmonary training is not part of the Intuitive Surgical, Inc. da Vinci® Surgical training program.

Animal model

Two adult pigs were placed in a right lateral decubitus position, and we operated on the left lung. Each pig was premedicated with Telazol (5.0 mg/kg IM) and atropine (0.04 mg/kg IM). After the animal is sufficiently anesthetized, an endotracheal tube of the appropriate size for the animal may be intubated immediately. A tourniquet is then applied to the base of the left ear, followed by placement of an 18 or 20 gauge indwelling intravenous catheter in a vein in the left ear. After connecting the anesthesia machine to the animal, the vaporizer was turned on to deliver isoflurane at 3% with an oxygen flow rate of 2 l/min, followed by the ventilator with the tidal volume set to 8–10 ml/kg and the rate to 12–15 resp/min. The pig was also connected to an extension set from a bag of lactated ringer's solution attached to an ear catheter, and the flow rate was set at 10 ml/kg/hr. Finally, the anesthesiologist verified that the animal was in a surgical plane of anesthesia by confirming that vital signs are stable. After general anesthesia with single-lung ventilation, left pneumonectomy and ND2a-lymph node dissection were performed.

The da Vinci® Surgical System

Upper side positioning of the patient-side cart is suitable for thoracic surgery (**Fig. 2**). The vision cart is positioned on the left of the patient-side cart, and the assistant surgeon, who arranges the setting and replacement of arms, stands on the opposite side. Details of the positioning of all units are shown in **Fig. 3**. Port placement is also crucial. The surgical procedure and techniques of robotic surgery closely resemble the standard open thoracotomy procedure, despite the fact that the robotic surgery is performed while guided by a video-assisted system.

To qualify to use the da Vinci® Surgical System, surgeons and nurses have to attend the training course that the Intuitive Surgical Company requires of those wishing to use the system clinically in the U.S.A., while in Japan, surgeons must also participate in an educational component established by Johnson & Johnson Co. Ltd., and they must also acquire a user's license in their own individual name. No surgeon is authorized by the manufacture to perform operations using the da Vinci® Surgical System if they do not have a user's license.

Surgical procedure and operative technique

We found it best to make 4 2-cm incisions (**Fig. 4**) including one for the three-dimensional (3-D) camera (**Fig. 5A**). The camera incision was placed in the 6th intercostal space on the midaxillary line. Another two incisions were placed; one, in the 4th intercostal space anteriorly on the right for scissors, and the other, for a grasper in the 4-5th intercostal space, posteriorly. An additional 1–2 cm incision was made in the anterior axillary line in the 6–7th intercostal space for an endoscopic retractor to maneuver the lung for robotic dissection (**Fig. 4**).

The operative sequence for left pneumonectomy with the da Vinci S® Surgical System was as follows: The robot was used to dissect the pulmonary ligament, the anterior and posterior aspect of the hilum, which including the superior and inferior pulmonary vein, the proximal branches of the pulmonary artery, and the left main

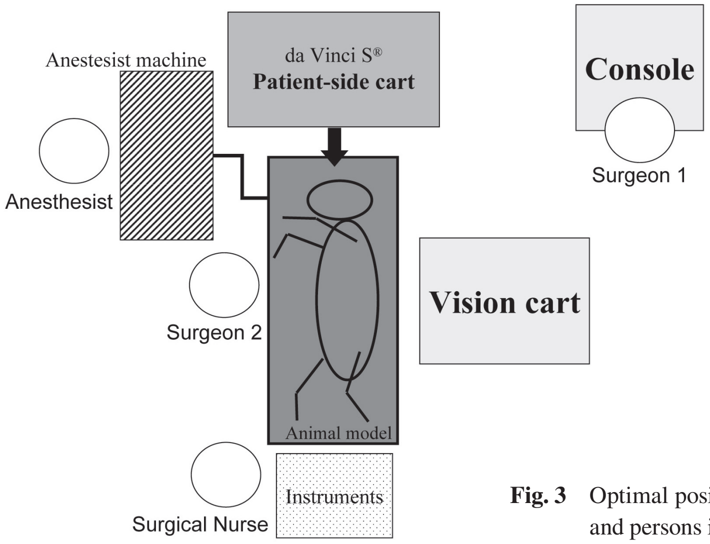


Fig. 3 Optimal positioning of the da Vinci S® Surgical System, other instruments, and persons involved in thoracic surgery.

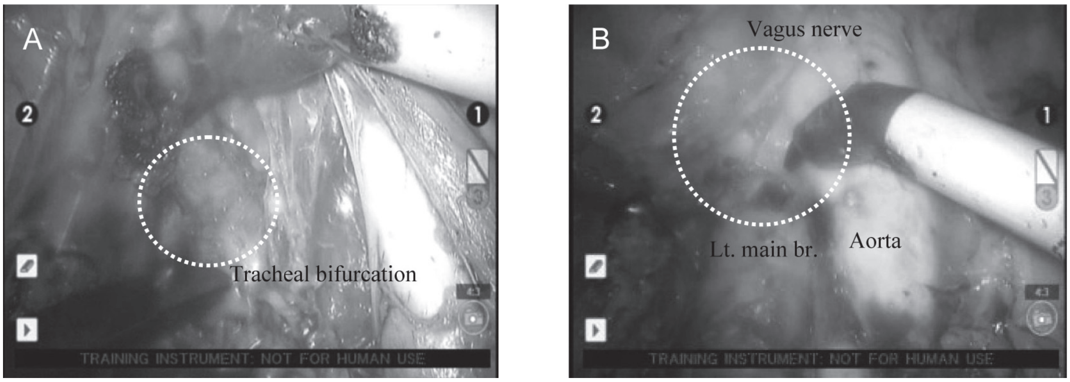


Fig. 4 Panel **A** shows the tracheal bifurcation after the No.7 lymph node dissection. Panel **B** shows the space between left main bronchus and aortic arch after the Nos. 4 + 5 lymph nodes dissection, in which the vagus and recurrent laryngeal nerves were identified.

bronchus. After ligating and cutting the left superior and inferior pulmonary veins, as well as the left main pulmonary artery and the left main bronchus, left pneumonectomy was performed. ND2a-lymph node dissection was also performed using exactly the same procedure as dissection under open standard thoracotomy.

Results

After positioning the da Vinci S® Surgical System, in various ways, the right lateral decubitus position was found to be best for left pneumonectomy, with the patient-side cart placed on the cephalad side of the animal. The table surgeon (assistant) working on the patient-side cart was positioned on the right side of the animal. The console was located apart from the operation table and the operating surgeon manipulated the da Vinci S® Surgical System from there, as shown in **Fig. 3**.

The time for the set-up of the da Vinci S® Surgical System was about 50 minutes, the thoracic surgeons worked using the console for about 90 minutes, and the overall operative time was about 2 hours from the start of the da Vinci S® Surgical System procedure to successful removal of the left lung and lymph nodes (Nos. #4, #5, #6, #7, #8 and #9), **Fig. 4**. The total amount of bleeding during the operation was less than 20 ml.

As a result of various attempts, we determined that the ideal positioning of the instrument arm ports is shown in **Fig. 6**. Various types of surgical arms were also tried for the thoracic surgery procedure, such as ProGrasp forceps (**a**), Maryland bipolar forceps (**b**), a large needle driver (**c**), monopolar curved scissors (**d**), DeBakey forceps (**e**), a permanent cautery spatula (**f**) and a small clip applier (**g**), as shown in **Fig. 5B**. In our experience, almost all

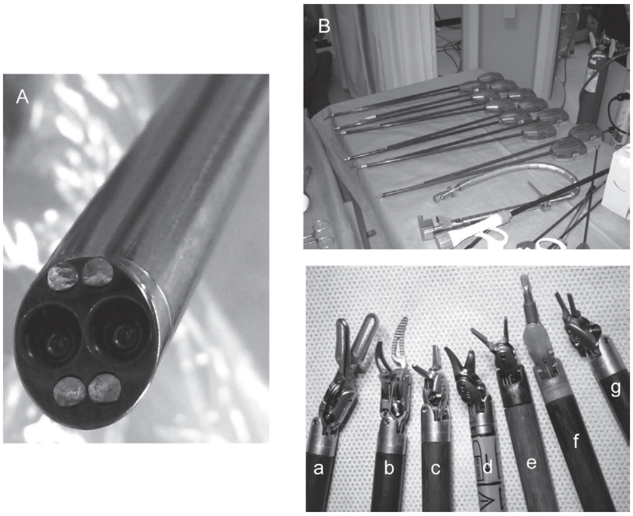


Fig. 5 (**A**) shows the tip of 3-D high-resolution binocular camera. (**B**) shows the various accessory arms (**a**. ProGrasp forceps, **b**. Maryland bipolar forceps, **c**. large needle driver, **d**. monopolar curved scissors, **e**. DeBakey forceps, **f**. permanent cautery spatula, **g**. small clip applier).

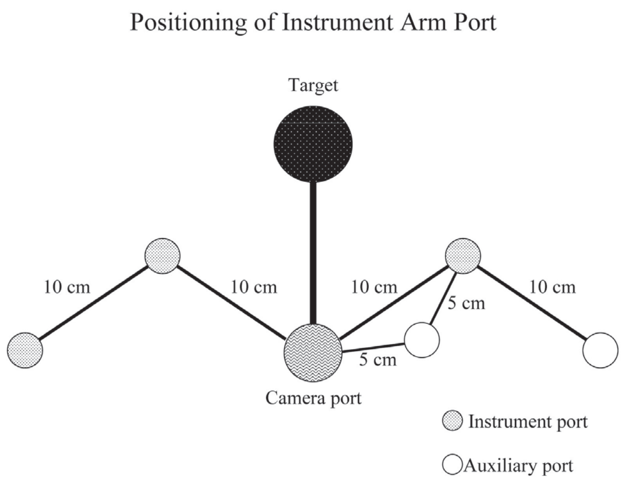
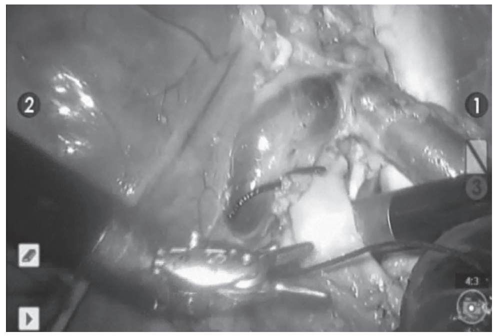


Fig. 6 Typical positioning of the Instrument Arm Port. The camera port was placed approximately 20 cm from the target through the disposable 12-mm trocar. Instrument arm ports were placed minimally 10 cm away from the camera port or the other Intuitive instrument arm ports. Assistant port (s) consisting of disposable 5–12 mm trocars were placed at least 5 cm (3 finger-breadths) away from any camera or Intuitive instrument arm ports.

manipulations were performed with the DeBakey forceps for the left arm, monopolar curved scissors for the right arm and ProGrasp forceps for the retractor trocar.

In cases of human pneumonectomy, the pulmonary artery branches, pulmonary vein and the pulmonary bronchus are usually divided using a stapler. However,

Video 1 Left Pneumonectomy using de Vinci Surgical System; Left pulmonary vein ligation and cutting (Video is available online.)



Video 2 Lt. pulmonary aratery ligation and cut (Video is available online.)

staplers of the vessels and bronchi for the da Vinci® Surgical System are now under development. In this training program, vascular ligation (left superior and inferior vein, left main artery shown in **Video 1** and **2**) and suturing for the left main bronchus were performed.

Discussion

We set out to determine the best possible training system for surgeons learning the field of robotic surgery, particularly in thoracic surgery. The introduction of a radically new approach to surgery in any field requires much forethought regarding ethicality, safety management, determination of indications and training of specialists in the new field. Robotic surgery, as exemplified at present by the da Vinci® system is one such radically new approach.

With the increased precision, range of accessories and, anticipated decrease in cost, it appears likely that robotic surgery will be increasingly and widely performed. However, apart from a certification program for applications of the system in intra- abdominal procedures held by Intuitive Surgery in the U.S.A. and a supportive educational system available from Johnson & Johnson Co. Ltd. in Japan, there are no other extant educational programs for robotic lung surgery apart from that described by Suda et al.,[1] and there are only 3 accredited programs for intrathoracic surgery recently initiated, in the USA. Recognized by Intuitive Surgical. We believe it is, therefore, essential that a systematic approach to the technical, ethical and safety considerations of the system should be developed, which is why we undertook the study described here.

The VATS technique which is now employed in cases of early-stage lung cancer and mediastinal tumors, has the advantages of minimally invasive surgery (MIN) with little tissue trauma, short hospitalization, relative little pain and good cosmetic results in comparison with standard thoracotomy.[2] According to a 2007 national survey of 1914 institutions by the Japanese Association for Thoracic Surgery,[3] 60.4%, 33696 of all thoracic surgery cases involved by VATS, out of a total of 55832 of all general thoracic surgery cases. However, much of the spread of VATS techniques was through mentoring, workshops, and scientific reports, rather than by standardized educational systems, which has understandably not resulted in a uniform technical approach.

Indeed, there do remain some questions as to whether complete lymph node dissection by conventional VATS lobectomy for lung cancer, especially for resection of Nos. #4, #5 and #7 lymph nodes from a left side approach, is technically possible for every thoracic surgeon, yielding the same curativity rate as standard thoracotomy. This problem, caused by the anatomical structures of the lung and mediastinum, which limit the movements of presently available surgical instruments in such narrow spaces, may eventually be overcome to some degree by the development of more dedicated instruments.

In an effort to improve standard MIN techniques, telerobotic surgery has gradually evolved in the U.S.A., and, at present, the da Vinci® Surgical System has been approved by the US Food and Drug Administration (FDA). Over 1,300 da Vinci® Surgical Systems are now used in various fields (968 in the U.S.A., 229 in the EU and 60 in Asia), such as cardiovascular thoracic surgery, urology, gynecology and gastrointestinal surgery as of the end of September 2009. However, in Japan, only 13 hospitals possess this system now, to the best of the authors' knowledge; therefore, we speculate that there will be a large increase in such systems, which makes the necessity of standardized training methods all the more important.

Fig. 7 Overall view of the da Vinci S® Surgical System in the animal laboratory room. The surgeon sits at the console and manipulates the surgical arms on the cart to control remote controlled arms with a 3-D high vision monitor view.

The da Vinci S® Surgical System consists of a patient-side cart (robotic 4-arm cart with a central arm to guide the endoscope), a surgeon's console and a vision monitoring cart (Insite vision system) (**Fig. 7**). We are now beyond the basic research stage of robotic surgery worldwide, and this system is now beginning to be used more frequently in clinical practice. Nevertheless, operations using the da Vinci® Surgical System are performed with fewer robot arms via the surgical ports than the same procedure with conventional VATS. The insite vision system of the da Vinci® Surgical System has an endoscope providing a 3-D high-resolution binocular view of the surgical field, which is capable of a 12-fold enlarged view field. This enhances the safety of operations compared with conventional VATS.

Other issues regarding conventional VATS are that the reliability of pulmonary hilar and mediastinal lymph node dissection is inferior to standard thoracotomy. Many institutions, therefore, still perform the conventional VATS lobectomy in early-stage lung cancer due to the limitations of the movement of conventional VATS instruments.

The operation arm of the da Vinci® Surgical System, the EndoWrist® instrument system, which has the ability of 7° of freedom and with 2° of axial rotation, replicates human wrist-like movements and, therefore, can accomplish the operational objective. Lymph node dissection with the system enables accurate and simple safe surgery, because the range of motion of the robot arms within small spaces such as the thorax is extremely extensive. Bronchial and vascular anastomoses with the robot arms closely resemble the standard thoracotomy procedure. The EndoWrist® technology has other functions, which include 3-step motion scaling (no scale 2:2, fine 3:1, ultra fine 5:1) and the elimination of physiological surgeon vibrations. These technologies allow minimally invasive anastomoses.

If the da Vinci® Surgical System could be applied to lung and mediastinal surgery, the field of thoracic surgery would benefit from the advantages of both standard thoracotomy and VATS.[4–16] However, very few institutions perform robot-assisted thoracic surgery routinely. In particular, there is only one report of robotically operated lung cancer. Several factors seem to be related to this, at least in Japan. Firstly, the da Vinci® Surgical System is not yet approved for insurance reimbursement by the Japanese Ministry of Health, although it was officially recognized as a treatment method in November 2009. Labor and Welfare, and secondly it is expensive. Robotic surgery is useful for human operations. It seems that there are no social or ethical issues and no operational violations of human dignity if it is used for surgery. Operations using robotic systems, such as the da Vinci® Surgical System seem destined to spread worldwide in various clinical areas.

We set out to determine the feasibility and safety of the da Vinci S® Surgical System in performing pneumonectomy and lymph node dissection in an animal model. The left pneumonectomy procedure using the da Vinci S® Surgical System was even smoother and easier than the authors expected. Although this experience was only one session for each thoracic surgery specialist, the operator's tactile sense was remarkably similar to direct manipulation by hand.

The operation time was similar to conventional VATS for lung resection. We also felt less technically challenged than in conventional VATS lobectomy. The VATS system employs 3-D movement of a small number of linear instruments. Considerable experience in thoracic surgery and a delicate tactile sense, which surgeons can learn only with direct manipulation of instruments, is essential for conventional VATS lobectomy. This first experience for Japanese thoracic surgeons with lung resection in an animal model demonstrated the safety and reliability of the da Vinci® Surgical System. Robotic surgery training has been established worldwide, and the techniques to use the da Vinci® Surgical System can be taught in a short time. The learning curve for manipulation is short, especially for those experienced in conventional VATS for thoracic surgery. This point is the greatest difference from conventional VATS, in which the surgery cannot be accomplished safely if the surgeon cannot skillfully operate using long, rigid instruments. This is one reason why robotic surgery is regarded as the continuation of the evolution of standard thoracotomy. However, differences between robotic surgery and standard thoracotomy include the advantages of the 12-fold enlarged operation field of robotic surgery, and the ability to access difficult-to-reach areas like the mediastinum.

The da Vinci® Surgical System has a wide range of accessory arms which can be employed in many surgical fields other than thoracic surgery, including urology, gynecology and cardiovascular surgery. We selected accessory arms suitable for lung resection, and especially the monopolar curved scissors, large needle driver, DeBakey forceps, ProGrasp forceps, permanent cautery spatula and clip applier are very useful for lung resection, allowing free movement, and the 3-D high vision camera contributes to ND2a-lymph node dissection with a tactile sensation similar to open standard thoracotomy. The robotic surgery system is particularly useful in suturing vessels and bronchi with minimal physiological vibrations, which is advantageous over conventional VATS.

However, the da Vinci® Surgical System still has some issues to be resolved. The main limitation for robotic surgery is the lack of sufficient dedicated instruments, such as a robotic surgery stapler. At present, surgeons can use current staplers, which are used for lung resection as substitutes. Further development of instrumentation is only a matter of time. In our experience, it was sometimes difficult to judge the amount of strength to apply when tying sutures. This issue needs to be solved in the near future. Another issue is the system of medical insurance coverage in Japan. This system is not yet recognized by the Ministry of Health, Labor and Welfare, but we hope that status of robotic surgery within the national insurance system will soon be established.

The data contained in this report were obtained through the understanding and cooperation of Intuitive Surgery in providing pigs for experimental thoracic surgery training (which is not included in their regular training program) for two of the authors (N.I., N.K). We believe these data will be of exceptional value as references for the development of future standards for technical approaches, safety and ethical considerations in the field of robotic surgery.

Conclusions

Robotic surgery using the da Vinci® Surgical System in pigs yielded results compatible with those of standard thoracotomy and yet appears safer, and the instrumentation is easier to use than conventional VATS procedure for pulmonary operations including lymph node dissection. This system is a promising method for training thoracic surgeons, but much work is needed on standardizing techniques and establishing educational systems for robotic surgery in Japan, as an example for other domestic and international societies.

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Disclosure Statement

The authors declare no conflicts of interest.

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