(11) Adequate organ functions
(12) No diarrhea or intestinal obstruction
(13) Written informed consent

Exclusion Criteria

(1) Synchronous or metachronous (within 5 years) malignancy, except for carcinoma *in situ* or mucosal tumors curatively treated with local therapy
(2) Active infection requiring systemic therapy
(3) Body temperature $\geq$38°C
(4) Pregnant or lactating women or women of childbearing potential
(5) Severe mental disease
(6) Serious post-operative complications
(7) Patients receiving systemic steroid medication
(8) Poorly controlled diabetes mellitus or receiving the routine administration of insulin
(9) Poorly controlled hypertension
(10) Unstable angina within 3 weeks, or with a history of myocardial infarction within 6 months
(11) Positive serum HBs antigen or HCV antibody
(12) Positive serum HIV antibody
(13) Interstitial pneumonia, pulmonary fibrosis or severe emphysema

Randomization

After confirming the eligibility criteria, registration is made by telephone, fax or a web-based system to the JCOG Data Center. Patients are randomized to either arm A (EP) or arm B (IP) by the minimization method balancing the arms with institution, sex (male versus female), pathological stage (Stage I versus Stage II–IIIA) and pathological type (SCLC versus LCNEC).

Treatment Methods

Patients in the EP arm receive four courses of post-operative EP (etoposide, 100 mg/m^2/day, Day 1–3; cisplatin 80 mg/m^2/day, Day 1) repeated every 3 weeks. Patients in the IP arm receive four courses of post-operative IP (irinotecan, 60 mg/m^2/day, Day 1, 8, 15; cisplatin, 60 mg/m^2/day, Day 1) repeated every 4 weeks. When the leukocyte count is decreased to $<$3000/mm^3 or the platelet count to $<$100 000/mm^3 on the planned first day of both arms, the start of chemotherapy is delayed until the counts recover to 3000/mm^3 or more and 100 000/mm^3 or more, respectively. The administration of irinotecan is skipped on Day 8 and/or 15 when at least one of the following occurs; a leukocyte count $<$2000/mm^3, platelet count $<$100 000/mm^3, diarrhea Grade 1 or higher or a fever of 37.5°C or higher. The dose of etoposide and irinotecan in the subsequent cycles is reduced by 20 mg/m^2 and 10 mg/m^2 from the planned dose, respectively, when the leukocyte count is $<$1000 mg/m^2, platelet count is $<$20 000/mm^3 and/or Grade 3 non-hematologic toxicities (excluding hyponatremia and weight loss) develop. The dose of cisplatin is reduced by 20 mg/m^2 in the EP arm and 10 mg/m^2 in the IP arm when patients have serum creatinine $>$1.5 mg/dl, but not exceeding 2.0 mg/dl, Grade 2–3 peripheral motor or sensory neuropathy, myalgia, arthralgia or other Grade 3 non-hematologic toxicities (excluding hyponatremia and weight loss). The protocol treatment is terminated when serum creatinine exceeds 2.0 mg/dl or patients develop Grade 4 non-hematologic toxicities (other than hyperglycemia, hypernatremia, hyponatremia, hyperkalemia and hypokalemia). After completion of the protocol treatment, patients are observed without anti-cancer treatment until recurrence is detected.

Follow-up

All randomized patients are followed-up for at least 5 years after patient accrual is completed while analysis of the primary endpoint is conducted 3 years after accrual completion.

Chest X-rays are performed every 6 months for the first 5 years and every year afterwards. Tumor markers (CEA, NSE and ProGRP), enhanced computed tomography of the thorax and enhanced computed tomography or ultrasound of the upper abdomen are evaluated every 6 months for the first 3 years and every year from the fourth to the fifth year.

Study Design and Statistical Analysis

This randomized trial is designed to confirm the superiority of IP in terms of overall survival over EP as post-operative adjuvant chemotherapy for pathological Stage I–IIIA completely resected pulmonary HGNEC patients.

We assumed the 3-year survival with post-operative EP to be 70% and expected a 10% increase in the 3-year survival with post-operative IP. According to Schoenfeld and Richter's method (18), the sample size was calculated as 104 patients per arm with a one-sided alpha level of 5%, a power of 70%, an expected accrual period of 6 years and a follow-up period of 3 years. Eighty-eight events in total are expected. The total sample size was set at 220 patients to account for patients lost to follow-up. All statistical analyses will be conducted at the JCOG Data Center.

Interim Analysis and Monitoring

We plan to conduct two interim analyses, taking multiplicity into account using the Lan–DeMets method with the O'Brien and Fleming type alpha spending function (19). The first interim analysis will be conducted after half of the planned number of patients is enrolled and the second interim analysis after the planned patient accrual and their protocol treatment is completed. The Data and Safety Monitoring Committee (DSMC) of the JCOG will review the interim analysis reports independently from the group investigators and group statistician. If the superiority of the IP arm is demonstrated with a one-sided P value of the stratified log-rank test below an adjusted alpha level, the study will be terminated.

In-house monitoring will be performed every 6 months by the JCOG Data Center to evaluate and improve study progress, data integrity and patient safety.

UMIN Registration Number

This trial has been registered at the UMIN Clinical Trials Registry as UMIN000010298 [http://www.umin.ac.jp/ctr/index.htm].

Participating Institutions (from North to South)

Asahikawa Medical Center, National Hospital Organization Hokkaido Cancer Center, KKR Sapporo Medical Center, Miyagi Cancer Center, National Hospital Organization Sendai Medical Center, Tohoku University Hospital, Yamagata Prefectural Central Hospital, Ibaraki Prefectural Central Hospital and Cancer Center, Tochigi Cancer Center, National Nishigunma Hospital, Gunma Prefectural Cancer Center, Saitama Cancer Center, National Cancer Center Hospital East, Chiba University Graduate School of Medicine, National Cancer Center Hospital, Kyorin University Faculty of Medicine, Tokyo Medical University Hospital, Tokyo Metropolitan Cancer and Infectious Diseases Center Komagome Hospital, National Center for Global Health and Medicine, Cancer Institute Hospital of Japanese Foundation for Cancer Research, Juntendo University Hospital, Yokohama City University Medical Center, Kanagawa Cancer Center, Yokohama Municipal Citizen's Hospital, Niigata Cancer Center Hospital, Kanazawa University School of Medicine, Gifu Municipal Hospital, Shizuoka Cancer Center, Nagoya University School of Medicine, Aichi Cancer Center Hospital, National Hospital Organization Nagoya Medical Center, Aichi Cancer Center Aichi Hospital, Kyoto University Hospital, Osaka City University Hospital, Kinki University Faculty of Medicine, Osaka Prefectural Hospital Organization Osaka Medical Center for Cancer and Cardiovascular Diseases, Osaka Prefectural Hospital Organization Osaka Prefectural Medical Center for Respiratory and Allergic Disease, National Hospital Organization Kinki-Chuo Chest Medical Center, Osaka City General Hospital, Kobe City Medical Center General Hospital, Hyogo Cancer Center, Kurashiki Central Hospital, Okayama University Hospital, National Hospital Organization Kure Medical Center Chugoku Cancer Center, Hiroshima University Hospital, National Hospital Organization Yamaguchi-Ube Medical Center, National Hospital Organization Shikoku Cancer Center, National Kyushu Cancer Center, School of Medicine Fukuoka University, Nagasaki University Hospital, Kumamoto University Medical School, Kumamoto Chuo Hospital, Kumamoto Regional Medical Center Hospital and National Hospital Organization Okinawa Hospital

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Conflict of interest statement

None declared.

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High-Speed 3-Dimensional Imaging in Robot-Assisted Thoracic Surgical Procedures

Naohiro Kajiwara, MD, Soichi Akata, MD, Masaru Hagiwara, MD, Koichi Yoshida, MD, Yasufumi Kato, MD, Masatoshi Kakihana, MD, Tatsuo Ohira, MD, Norihiko Kawate, MD, and Norihiko Ikeda, MD

Departments of Surgery and Radiology, Tokyo Medical University, Tokyo, and Department of Health Science and Social Welfare, Waseda University School of Human Sciences, Saitama, Japan

We used a high-speed 3-dimensional (3D) image analysis system (SYNAPSE VINCENT, Fujifilm Corp, Tokyo, Japan) to determine the best positioning of robotic arms and instruments preoperatively. The da Vinci S (Intuitive Surgical Inc, Sunnyvale, CA) was easily set up accurately and rapidly for this operation. Preoperative simulation and intraoperative navigation using the SYNAPSE VINCENT for robot-assisted thoracic operations enabled efficient planning of the operation settings. The SYNAPSE VINCENT can detect the tumor location and depict surrounding tissues quickly, accurately, and safely. This system is also excellent for navigational and educational use.

(Ann Thorac Surg 2014;97:2182–4)

FEATURE ARTICLES

We previously reported on the importance of appropriate settings in robot-assisted thoracic surgical procedures, because no target is located in the same location within the thoracic cavity [1, 2]. Moreover, once all the da Vinci S (Intuitive Surgical, Inc, Sunnyvale, CA) devices and equipment are positioned, it is difficult to reset the da Vinci S after the operator starts manipulation through the operator console. In this case, a high-speed 3-dimensional (3D) image analysis system, the SYNAPSE VINCENT (Fujifilm Corp, Tokyo, Japan), was used to determine the best positioning of robot arms and instruments preoperatively based on experience with more than 100 video-assisted thoracic operations. Moreover, this system can detect the tumor location and depict surrounding tissues—even 1-mm vessels—quickly, accurately, and safely. An incision for the 3D camera and 2 other incisions are made at the appropriate points according to the SYNAPSE VINCENT analysis. The best angulation of the instrument arms of the da Vinci S are also determined by the same analysis. All computed tomography (CT) must satisfy several conditions necessary to analyze images by the SYNAPSE VINCENT. First, all images are to be taken by multislice CT at more than 64 lines; second, all images are taken at a slice interval thickness of 1.25 mm; third, all image data are saved as digital imaging and communication in medicine (DICOM) image files; and fourth, all images are to be taken using contrast media. The SYNAPSE VINCENT also provides more information concerning tumor size and shape and also whether the tumor invades surrounding tissue and the extent of airway and vessel involvement.

A 38-year-old woman had a posterior mediastinal tumor that appeared spindle-shaped at the upper level of the first to third thoracic vertebrae. The SYNAPSE VINCENT was used to define the tumor together with the surrounding anatomic information and determine the appropriate setting of the da Vinci S and the best positioning of the instrument ports. For the computed tomographic scan, the patient was placed in the same position as projected for the operation. The SYNAPSE VINCENT depicts the tumor and all other anatomic information quickly. Details of thorax, ribs, and virtual imaging of the robot arm directions and placement of the surgical ports are shown in Fig 1. Details of the tumor and surrounding vessels after removal of the image of the rib cage are shown in Fig 2. The direction of the da Vinci S, 3D camera setting, and positioning of arms No. 1 and No. 2 for the clinical operation were determined by

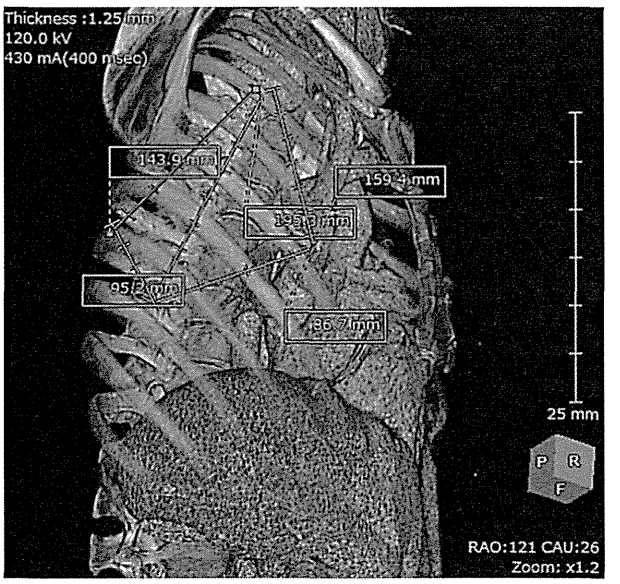

Fig 1. The figures were depicted by the SYNAPSE VINCENT, which showed the tumor (yellow) located in the upper area in the right side of the thorax. Green points on the surface of the patient and lines show the appropriate approaches for the instrument ports and angles of the arms of the da Vinci S and distance of each interval.

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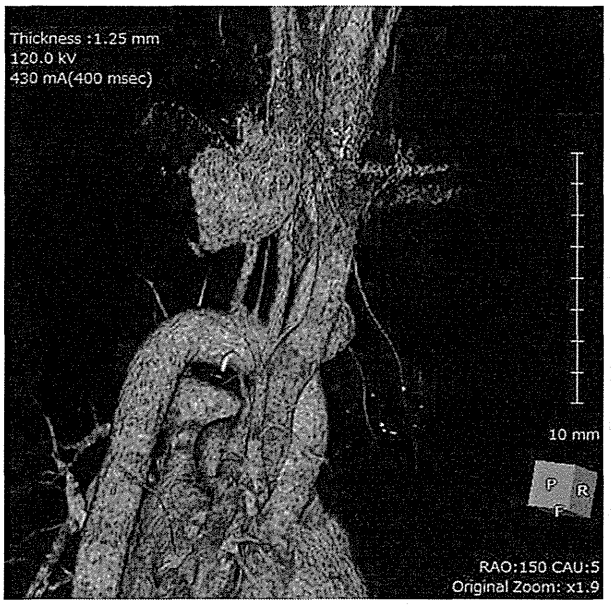

Fig 2. Details of the tumor and surrounding vessels after removal of the image of the rib cage.

preoperative simulation using the SYNAPSE VINCENT (Fig 3). The da Vinci S was rolled in from the 1 o'clock direction, as shown in Fig 3. The patient was placed in a semisupine position. The 3D camera port was placed in the area of the sixth intercostal space at the anterior axillary line. Arms No. 1 and No. 2 and the accessory port were placed in the area of the fifth intercostal space at the anterior axillary line, the sixth intercostal space at the posterior axillary line, and the seventh intercostal space at the anterior axillary line, respectively. Fig 1 shows the 3D anatomic structure of the patient, the suitable points for each instrument port, and the intervals between each point. The distances from the tumor to the point of the instrument port of arms No. 1 and No. 2 and the 3D camera were 143.9 mm, 159.4 mm, and 195.3 mm, respectively. The distances from the 3D camera to the points of the instrument port of arms No. 1 and No. 2 were 95.2 mm and 86.7 mm, respectively.

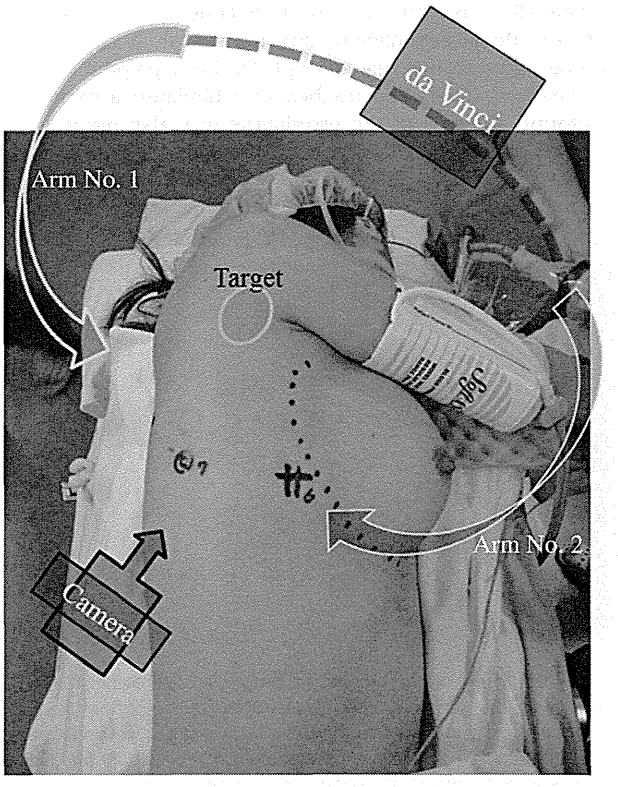

Fig 3. The da Vinci S was rolled in from the 1 o'clock direction, with the patient located between arms No. 1 and No. 2.

The da Vinci S was set up accurately and rapidly for this operation (about 10 minutes until the robot roll-in). The total operation time was 270 minutes, the robot set-up time was 21 minutes, and the console time (the robot working time) was 132 minutes. The amount of bleeding was 167 mL, and the drainage time was 2 days after the operation. The patient had no complications, and slight pain on the visual analogue scale (range 0–10) was a maximum of 1 at the time of discharge from the hospital. The pathologic report revealed a schwannoma (85 × 42 × 20 mm) with no malignancy.

Comment

Robotic operations using the da Vinci S has been approved in various specialties. However, thoracic tumors can be located at various sites in individual cases. In particular, the crucial factors for successful procedures in robot-assisted thoracic operations are the selection of the appropriate placement and the angle of instrument ports selected individually in relation to the target and patient position, which varies according to the tumor location [1, 2]. The distance separating each instrument port is at least 8 cm to prevent interference from other arms. Furthermore, the distance separating each instrument port from the target is at least 10 to 20 cm to secure a sufficient working space within the thoracic cavity.

The recent development of the SYNAPSE VINCENT raises the issue of whether it can yield comparable results in speed and precision. Mochizuki and colleagues [3] and Ikeda and associates [4] reported the feasibility and safety of the SYNAPSE VINCENT in performing useful preoperative simulation and navigation of surgical procedures [5]. It is safer, more precise, and less invasive for the patient, and it is easy to construct an image, depending on the purpose, in 5 to 10 minutes using the SYNAPSE VINCENT. Moreover, if the lesion is in the parenchyma, it helps to perform simulation with virtual skeletal subtraction to estimate potential lesion movement. It also helps to remember that even in such cases, most vascular structures will not move significantly. Because the angle of the 3D image made by the SYNAPSE VINCENT can be changed freely on a personal computer, an angle image similar to the

operation field in the surgical procedure could easily be obtained as a simulation image. Constructed images are displayed in the operating room on a monitor, which can be used for deciding surgical strategy and for navigation during intraoperative surgical manipulation.

Preoperative simulation using the SYNAPSE VINCENT also reduces the surgeon's stress levels, particularly when highly skilled techniques are needed to operate on lesions in difficult to reach and widely spaced areas of the thoracic cavity. This task, including both preoperative simulation and intraoperative navigation, could lead to greater safety and precision in operative settings and manipulation by creating the appropriate port positioning and direction of the instrument arms. These technologic instruments should be helpful for robot-assisted thoracic operations by thoracic surgeons and are also excellent devices for educational training.

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FEATURE ARTICLES

Treatment of Giant Pharyngoesophageal Diverticulum by Video-Assisted Thoracoscopy

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A 67-year-old woman presented with a giant pharyngoesophageal diverticulum (Zenker's diverticulum) that extended deep into the chest. Surgery, using either an open or endoscopic approach, was difficult. We stapled the common wall between the diverticulum and the esophagus using video-assisted thoracoscopic surgery. The patient exhibited good anatomic and functional results at 6 months' follow-up.

(Ann Thorac Surg 2014;97:2184–6)

Pharyngoesophageal diverticulum (Zenker's diverticulum) is a protrusion of pharyngeal mucosa between fibers of the lower pharyngeal constrictor and cricopharyngeal muscles. Treatment of massive Zenker's diverticulum is a challenge. Open surgical approaches require extensive dissection of the diverticulum, which greatly increases the morbidity and mortality rate. Endoscopic surgery, however, can leave an incomplete common wall transection, leading to persistent dysphagia and vomiting. We report a case of an elderly patient with a giant Zenker's diverticulum successfully treated with video-assisted thoracoscopic surgery.

A 67-year-old woman presented with a sore throat and vomiting for the previous 6 months. She also had progressive dysphagia (for both solid and liquid foods) with weight loss for the previous 6 years. The results of a routine physical examination were unremarkable. A barium swallow test showed significant retention of barium in a massive Zenker's diverticulum reaching the carina (10.0 × 6.0 cm), with minimal conduction of barium into the distal esophageal lumen (Fig 1A). A computed tomographic scan revealed a right-sided large pouch with an air-fluid level. The trachea was deviated anteriorly. Profound stenosis of the esophagus was also noted. An upper gastrointestinal endoscopy revealed a pharyngeal

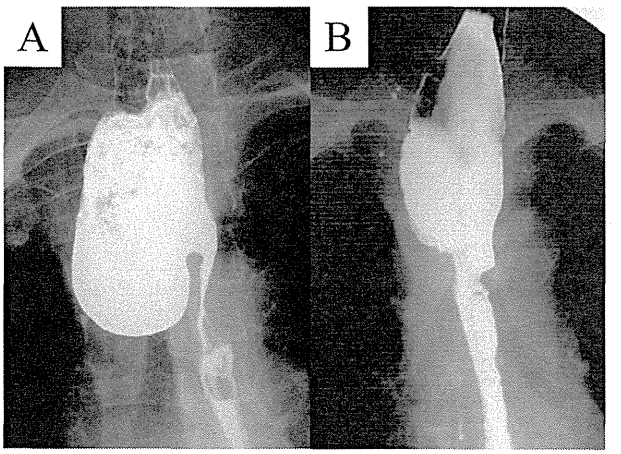

Fig 1. Preoperative and postoperative barium swallow radiographs. (A) Preoperative barium swallow radiograph shows significant retention of barium in a massive Zenker's diverticulum, reaching the carina (10.0 × 6.0 cm), with minimal conduction of barium into the distal esophageal lumen. (B) Postoperative barium swallow radiograph demonstrates free flow of barium into the esophagus and shrinkage of the hypopharyngeal dilatation.

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CASE REPORT

Three-dimensional multidetector computed tomography may aid preoperative planning of the transmanubrial osteomuscular-sparing approach to completely resect superior sulcus tumor

Hisashi Saji · Yasufumi Kato · Yoshihisa Shimada · Yujin Kudo · Masaru Hagiwara · Jun Matsubayashi · Toshitaka Nagao · Norihiko Ikeda

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Abstract The anterior transcervical-thoracic approach clearly exposes the subclavian vessels and brachial plexus. We believe that this approach is optimal when a superior sulcus tumor (SST) invades the anterior part of the thoracic inlet. However, this approach is not yet widely applied because anatomical relationships in this procedure are difficult to visualize. Three-dimensional tomography can considerably improve preoperative planning, enhance the surgeon's skill and simplify the approach to complex surgical procedures. We applied preoperative 3-dimensional multidetector computed tomography to a case where an SST had invaded the anterior part of the thoracic inlet including the clavicle, sternoclavicular joint, first rib, subclavian vessels and brachial plexus. After the patient underwent induction chemotherapy, we performed the transmanubrial osteomuscular-sparing approach and added a third anterolateral thoracotomy with a hemi-clamshell incision and completely resected the tumor.

This study was presented at the 65th Annual Scientific Meeting of the Japanese Association for Thoracic Surgery.

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Keywords 3-Dimensional computed tomography · Anterior transcervical-thoracic approach · Superior sulcus tumor · Surgical techniques · Transmanubrial osteomuscular-sparing approach

Abbreviations

3-D	Three dimensional
CT	Computed tomography
DICOM	Digital imaging and communication in medicine
MD	Multidetector
SST	Superior sulcus tumor
VATS	Video-assisted thoracoscopic surgery

Introduction

The anterior transcervical-thoracic approach applied by Dartevelle and colleagues [1] clearly exposes the subclavian vessels. Furthermore, Grunenwald's [2, 3] improvement preserves the clavicle and sternoclavicular joint. In this procedure, referred to as the "transmanubrial osteomuscular-sparing approach", part of the manubrium and the first costal cartilage are sectioned and moved away with the clavicle. We believe that this approach is optimal when a superior sulcus tumor (SST) has invaded the anterior part of the thoracic inlet. However, this approach is not yet widely applied. One of the reasons may be the difficulty in understanding the concept of this method. Another problem pointed out by several authors is the occasional need for additional thoracotomies for lobectomies with lymph node dissection.

New technologies can considerably improve preoperative planning, enhance the surgeon's skill and simplify the

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approach to complex surgical procedures. Recently, surgical simulation based on preoperative 3-dimensional multidetector computed tomography (3-D MDCT) scans has been developed in the field of thoracic surgery as well as head and neck surgery, neurosurgery, and orthopedic surgery [4, 5]. We applied preoperative 3-D MDCT to a surgical case where an SST had invaded the anterior part of the thoracic inlet, including the clavicle, sternoclavicular joint, first rib, subclavian vessels and brachial plexus. We first applied induction chemoradiotherapy and then completely resected the tumor using the transmanubrial osteomuscular-sparing approach plus a third anterolateral thoracotomy with a hemi-clamshell incision.

Case

A 71-year-old man was referred to our hospital for a detailed examination after he complained of bloody sputum and paralysis of his right upper arm in the medial antebrachial cutaneous nerve area. A chest CT scan revealed a large mass measuring 5 cm in diameter in the apex of the right lung. The CT images indicated that the mass had invaded the first rib, and possibly the subclavian vessels and brachial plexus (Fig. 1a, b). Non-small cell carcinoma was diagnosed on the basis of the results of a transbronchial lung biopsy. After the patient underwent a detailed examination that included a brain MRI and PET-CT scanning, he was treated with preoperative induction chemoradiotherapy, which is the standard treatment for SSTs (clinical T4N0M stage IIIB). The tumor shrank in size following 2 cycles of q3wks, cisplatin (80 mg/m^2) D1 plus vinorelbine (20 mg/m^2) D1, 8 with 40 Gy of irradiation (Fig. 1c). Thereafter, we performed a right upper lobectomy and combined resection the first rib and brachial plexus (C8 and Th1).

One of the major goals of this operation was to preserve the mobility of the right arm, the patient being an actor. He stated that he did not want the surgery if the mobility of his right arm was affected. With this in mind, we used a 3-D MDCT viewer that runs on QuickTime software to simulate the surgery and to understand the anatomical relationship between the SST and the thoracic inlet, including the clavicle, sternoclavicular joint, first rib, subclavian

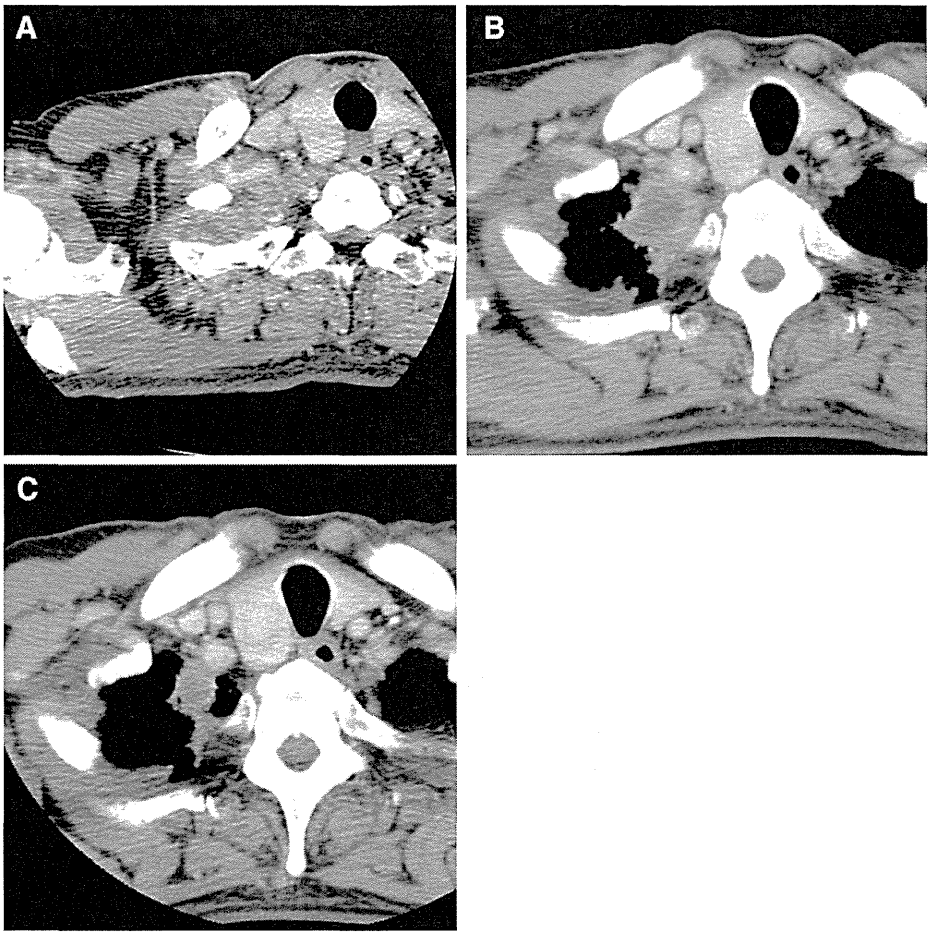

Fig. 1 Chest CT images revealed a superior sulcus tumor invading the anterior part of the thoracic inlet before (**a**, **b**) and after (**c**) chemoradiotherapy. This tumor potentially invaded subclavian vessels and brachial plexus (**a**)

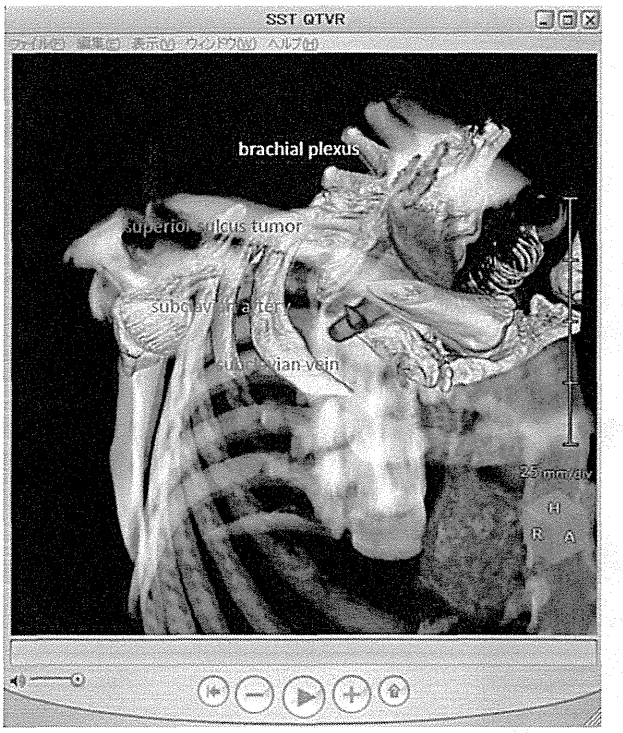

Fig. 2 A preoperative 3-D MDCT reconstruction of the superior sulcus tumor located in the anterior part of the thoracic inlet including the clavicle, sternoclavicular joint, first rib, subclavian vessels and brachial plexus. Made with QuickTime software

vessels and brachial plexus. We planned our surgical approach based on this preoperative simulation (Fig. 2). This 3-D MDCT surgical simulation was performed using a 64-channel multidetector CT (MDCT) (Light Speed VCT, General Electric Company, CT, USA). These digital imaging and communication in medicine (DICOM) data were transferred to a workstation with Synapse Vincent volume-rendering reconstruction software (Fujifilm Corporation, Tokyo, Japan). The DICOM data of MRI were also used to obtain information about the brachial plexus. Both 3D reconstructions of MDCT and MRI were combined and adjusted with costal positions.

On the basis of the results of this surgical simulation, we first applied the transmanubrial osteomuscular-sparing approach to confirm tumor invasion in the upper limit of the C8 segmental branch of the brachial plexus. After confirming that the brachial plexus (C7) was intact intraoperatively (Fig. 3a, b), we carried out a third anterolateral thoracotomy with a hemi-clamshell incision for a right upper lobectomy. Using special 3D viewer that reconstructed both MDCT and MRI, we could understand the anatomical relationship between the SST and the thoracic inlet, including the clavicle, sternoclavicular joint, first rib, subclavian vessels and brachial plexus as a preoperative simulation (Fig. 3c). Finally, we achieved pathological curative resection by performing right upper lobectomy and combined resection of the first rib and brachial plexus (C8 and Th1) with complete mediastinal lymph node dissection. We operated for 7 h with 750 ml of blood loss. His final pathological stage was ypT3N0 (0/18) M0 IIB with Ef. 3: no residual cancer cells.

Discussion

For approximately 40 years, from the 1960s to the 2000s, the treatment strategy for SSTs was induction radiotherapy followed by surgery. This treatment strategy has changed as a result of two Phase II studies that evaluated the use of induction chemoradiotherapy followed by surgery. One was Southwest Oncology Group Trial 9416 (intergroup trial 0160) [6] and the other was Japan Clinical Oncology Group Trial 9806 [7]. The new strategy improved the complete resection rate from about 50 to 70 % and the 5-year survival rate from about 30 to 50 %; as a result, it has become the standard treatment for SST. However, the appropriate surgical technique to completely resect an SST when it invades major anatomical areas is still challenging.

One of the biggest difficulties in achieving complete resection is that when an SST has invaded the thoracic inlet, particularly the anterior transcervical-thoracic area in which the subclavian vessels and brachial plexus are often involved, it is difficult to visualize their anatomical placement. However, the anterior transcervical-thoracic approach developed by Dartevelle and colleagues [1] shows the subclavian vessels clearly. The improvements made by Grunenwald and Spaggiari [2] and Grunenwald et al. [3] to this approach also preserve the clavicle and sternoclavicular joint. During this "transmanubrial osteomuscular-sparing approach", as it is called, part of the manubrium and the first costal cartilage are sectioned and moved away with the clavicle. However, this approach is not still widely used possibly because it is difficult to imagine the anatomical relationships in this procedure or to understand the concept of this approach.

Recently, surgical simulations based on preoperative 3-D CT scans have been developed in the fields of thoracic surgery as well as head and neck surgery, neurosurgery, orthopedic surgery and general surgery. The efficacy of 3-D CT angiography using MDCT for preoperative assessment for thoracic surgery has been described. Accurately depicting individual anatomies of pulmonary vessels and bronchi, and preoperative simulation using 3-D MDCT could play an important role in facilitating a safe and complete VATS lobectomy procedure, as some previous reports suggested [5]. We also previously reported the benefits of a virtual segmentectomy, a novel surgical simulation system based on high-quality 3-D lung modeling,

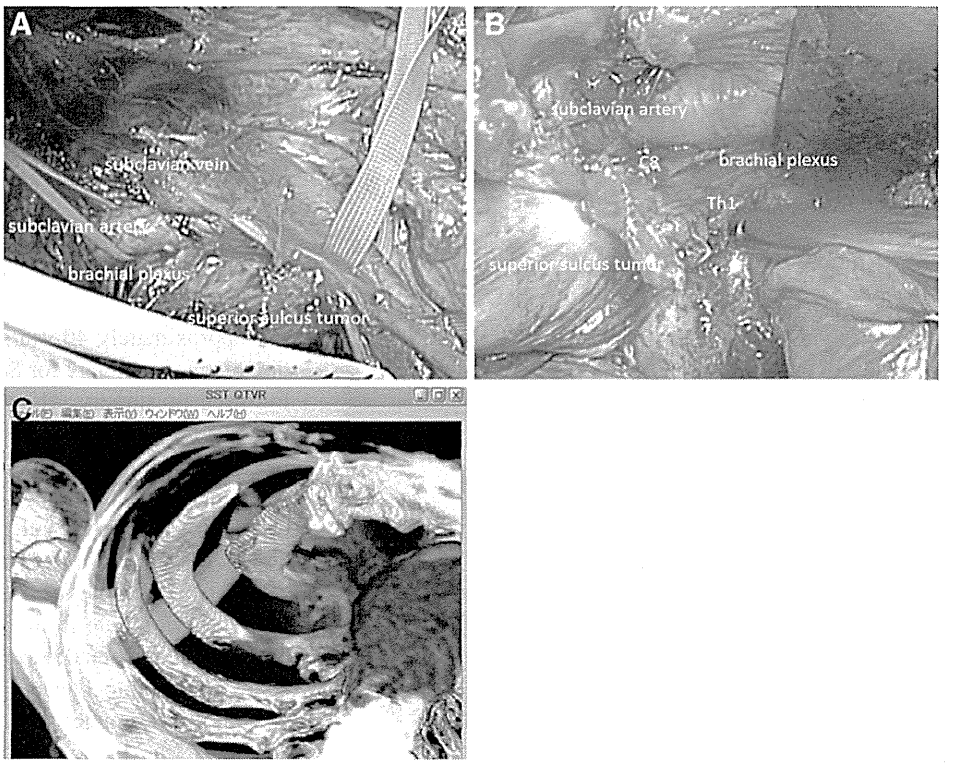

Fig. 3 Operation picture showing the anatomical relationship between the superior sulcus tumor and the subclavian artery, vein and brachial plexus upper limit of C8 of the brachial plexus (**a**, **b**). **c** showed that 3D viewer was able to reconstruct the operation view of **a**, **b**

including vascular and bronchial structures. This new technology can help thoracic surgeons perform appropriate anatomical segmentectomy and curative resection [4].

We performed surgery on our patient with an SST that had invaded the anterior part of the thoracic inlet with the aim of preserving the mobility of his right arm. It was critical to confirm precisely and less invasively whether the tumor had invaded the upper limit of C8 of the brachial plexus. Therefore, we first applied the transmanubrial osteomuscular-sparing approach based on the images we obtained from the 3-D MDCT viewer that showed the anatomical relationship between the SST and the thoracic inlet, including the clavicle, sternoclavicular joint, first rib, and subclavian vessels. Subsequently, we performed a third anterolateral thoracotomy with a hemi-clamshell incision to achieve curative intent resection.

These preoperative simulation and intraoperative navigation using 3-D MDCT appeared to simplify the approach to complex surgical procedures such as the anterior transcervical-thoracic approach including the transmanubrial osteomuscular-sparing approach as well as VATS and segmentectomy. However, as this is apparently the first case report, we have to evaluate further SST cases and other complex surgical procedures. Additionally, we think that there are other examples of new 3-D technology that provide a realistic preoperative simulation and that could help surgeons perform complex operations, such as the thoracic structure model made with a 3-D printer.

Conclusion

We have described the possibility of using 3D-MDCT for preoperative and intraoperative management of complex surgical procedures such as the transmanubrial osteomuscular-sparing approach with an additional third anterolateral thoracotomy with a hemi-clamshell incision to resect an SST following chemoradiotherapy.

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Conflict of interest Two authors (H.S. and N.I.) have given remunerated lectures for Fujifilm. No author received research funding and all had full control of the study design, methods used, outcome parameters, data analysis and production of the written report.

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Original Article

Cost-Benefit Performance of Robotic Surgery Compared with Video-Assisted Thoracoscopic Surgery under the Japanese National Health Insurance System

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Background: Medical economics have significant impact on the entire country. The explosion in surgical techniques has been accompanied by questions regarding actual improvements in outcome and cost-effectiveness, such as the da Vinci® Surgical System (dVS) compared with conventional video-assisted thoracic surgery (VATS).

Objective: To establish a medical fee system for robot-assisted thoracic surgery (RATS), which is a system not yet firmly established in Japan.

Methods: This study examines the cost benefit performance (CBP) based on medical fees compared with VATS and RATS under the Japanese National Health Insurance System (JNHIS) introduced in 2012.

Results: The projected (but as yet undecided) price in the JNHIS would be insufficient if institutions have less than even 200 dVS cases per year. Only institutions which perform more than 300 dVS operations per year would obtain a positive CBP with the projected JNHIS reimbursement.

Conclusion: Thus, under the present conditions, it is necessary to perform at least 300 dVS operations per year in each institution with a dVS system to avoid financial deficit with current robotic surgical management. This may hopefully encourage a downward price revision of the dVS equipment by the manufacture which would result in a decrease in the cost per procedure.

Keywords: robotic surgery, cost-benefit performance, Japanese National Health Insurance System

Introduction

For a long time medical costs have been a remarkably significant large factor determining the national budget. This is significant when a government decides the country's future policies. The current globalization of economic distribution among countries surrounding the Pacific has attracted much international interest. Above all, medical economics has a particularly large implication in Japan which implements a uniform universal health insurance system for the entire country.

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The explosion in surgical technological techniques has been accompanied by questions about actual improvements in outcome and cost-effectiveness. At present, the main procedures for which robotic surgery has been approved are limited to procedures requiring deft and accurate manipulations in limited spaces such as the uterus, and the prostate, since governmental and insurance agencies question the real outcome efficiency and cost benefit performance (CBP) of robot-assisted surgery (RAS) in comparison to video-assisted surgery (VAS) in larger organs.

While RAS has been approved for insurance compensation only in prostate surgery in Japan, robot-assisted thoracic surgery (RATS) has not yet been approved for reimbursement by the Japan National Health Insurance System (JNHIS).

The cost of RAS in Japan is of course greatly affected by the cost of the operator-controlled module, the ancillary equipment and maintenance costs, but not by the surgeon's fee, since in university hospitals in Japan, surgeons are paid a salary determined by the Ministry of Health and Welfare, regardless of the number or types of surgical procedures they perform.

Methods

All patients who underwent RATS in our hospital provided written informed consent after full explanation of the investigational nature of the procedures, and the study was approved by the institutional review board. We performed this institution-funded trial in 20 cases of mediastinal tumors, chest wall tumors and lung cancer, in order to establish the technique of RAS procedures and determine its medicoeconomic aspects in thoracic diseases. All procedures were performed between March 2010 and July 2012 and all costs were borne by the hospital in all cases. All data included in the figures and tables are calculated at ¥80 = $1, which was the average exchange rate as between March 2010 and July 2012.

Instruments

We employed the da Vinci® Surgical System (dVS) (Intuitive Surgical, Inc., Sunnyvale, California, USA), as described in our previous reports.[1–3] The techniques and costs of preoperative workup, anesthesia and postoperative management are essentially the same for RATS and video-assisted thoracic surgery (VATS). The establishment of the four access ports was similar in RATS and VATS. The uniquely different features of RATS are the use of the EndoWrist (the monopolar curved scissors for Arm #1, and Maryland bipolar forceps or Cadiere forceps for Arm #2) and inflation of the typically narrow working thoracic space with high-pressure CO_2 (8–10 mmHg).

Role of the funding source

All medical expenses for actual medical examinations and treatment for patients were paid for by Tokyo Medical University Hospital. For research support for studies on robotic surgery, we used a grant from the Cancer Research Institute of Tokyo Medical University.

Results

We compared the costs for RATS and VATS, as decreed by the JNHIS, with RATS for each of the above-mentioned thoracic procedures in the US and Japan (**Tables 1** and **2**). Although the additional costs varied according to the type of procedure, in general the use of RATS increased costs by over $10000 per procedure in Japan (**Table 1A**). However, when we examine the costs according to procedure and according to whether the disease is benign or malignant, we can see that, while, in general, uniform non-RATS procedures cost less in Japan than in the US, perhaps because of the nationally implemented policy of the JNHIS, the use of RATS in Japan almost doubles the cost of open procedure due to the high cost of robotic equipment. Robot-assisted prostatectomy for prostate cancer now receives insurance reimbursement for use of support devices for endoscopic surgery, $6775 under the JNHIS, since April 2012. If the same standard amount were applied to various diseases in the field of general thoracic surgery, the additional cost for RATS, which would also require set-up of the support devices for endoscopic surgery, $6775 which is the same as robotic prostatectomy under the JNHIS, on the basic cost of open thoracotomy approach.

Calculations of costs associated with robotic medical care for institutions which perform dVS-operations 100 times (A), 200 times (B) or 300 times (C) annually, are shown in **Table 1B**. In the JNHIS, reimbursement is based on the insurance point number awarded for a given procedure or the equipment used. The difference of cost for dVS surgery in **Table 3** varies on the assumption of between 100, 200 or 300 robotic cases in a year at one institution with the JNHIS (**Table 3**).

Figure 1 shows the difference between open thoracotomy procedures and RATS procedures, when institutions

Table 1A Costs per robotic surgery case in Japan

Contents	Items	Cost: US $
Surgeon's fee	Surgeons receive only their basic salary	0
dVS equipment fee; based on 100 procedures/year (all specialties)		$5859*
Medical materials	Cadiere forceps (Usable in 10 procedures)	$578
	Monopolar curved scissors (Usable in 10 procedures)	$853
	Maryland bipolar forceps (Usable in 10 procedures)	$780
	Permanent cautery spatula (Usable in 10 procedures)	$578
	Drape, instrument arm (Disposable)	$404
	Drape, camera arm (Disposable)	$114
	Drape, camera (Disposable)	$96
	Cannula seals (Disposable)	$173
	Total for da Vinci instrument items	$3575#
Maintenance cost		$2250**
Total (= Cost/one robotic surgery case)		$11684***

Table 1A shows the cost for the da Vinci® Surgical System (dVS) operation on the assumption of 100 cases in 1 institution per year with the projected Japanese National Health Insurance System (JNHIS) reimbursement system. *repayment cost/operation, **running cost/operation, ***cost/one-robotic case operation, #medical materials cost for the dVS/operation

Table 1B Japanese national guidelines for the calculation of the costs of advanced medical care[10)]

- $3255000 (purchase price of the dVS) × 0.9 = $2929500 (repayment cost)

$2929500/5 years (service life) = $585900/year (repayment cost/year)

At an institution which perform the dVS operation A: 100 times, B: 200 times and C: 300 times in a year

A: ¥ 46872000/100 times (annual use) = $5859* (repayment cost/operation)

B: ¥ 46872000/200 times (annual use) = $2930* (repayment cost/operation)

C: ¥ 46872000/300 times (annual use) = $1953* (repayment cost/operation)

- Amount of maintenance cost/5 years = $1250000

$1250000 × 0.9 = = $1125000 → $1125000/5 year = $225000 (maintenance cost/year)†

A: $225000/100 times = $2250**(running cost/operation)

B: $225000/200 times = $1125**(running cost/operation)

C: $225000/300 times = $750**(running cost/operation)

- Pattern A: $3575# (medical materials cost/operation) + $2250** (running cost/operation) + $5859* (repayment cost/operation) = $11684***/one-robotic case operation
- Pattern B $3575# (medical materials cost/operation) + $1125** (running cost/operation) + $2930* (repayment cost/operation) = $7630***/one-robotic case operation
- Pattern C: $3575# (medical materials cost/operation) + $750** (running cost/operation) + $1953* (repayment cost/operation) = $6278***/one-robotic case operation

Table 1B shows a tentative calculation for the basis of costs associated with robotic medical care for institutions which perform the da Vinci® Surgical System (dVS) procedures 100 times (pattern A), 200 times (pattern B) and 300 times (pattern C) in a year, respectively. *repayment cost/operation, **running cost/operation, ***cost/one-robotic case operation, #medical materials cost for the dVS/operation; †Reduced by Intuitive Surgical to US$90000 (maintenance cost/year) from July 2012.

performed the dVS operation 100, 200 or 300 times per year, and the projected JNHIS additional insurance reimbursement for endoscopic surgery ($6775), for thymectomy for benign disease. The anticipated reimbursement by the JNHIS ($11400) shows the price insufficiency (100 times/year; $ –4900, 200 times/year; $ –85 per procedure) calculated on the basis of the projected reimbursement. Only institutions performing 300 procedures per year would show a positive CBP under the projected reimbursement system.

Figure 2 shows the cost of lobectomy for malignant disease. The differences between open thoracotomy, VATS and RATS procedures are shown in Tables. The projected reimbursement with the JNHIS ($15855) still show a loss (as with benign tumors) if the institution performs only 100 or 200 procedures for year. This pattern also shows that only institutions performing 300 procedures per year would show a profit.

Table 2 Cost for RATS with the Japanese public health insurance system since April 2012

Procedure		Change in cost of procedures performed in USA		Change in cost of procedures performed in Japan $1 = ¥80, average exchange rate Mar.2010–Jul.2012			
		Excluding robot	Including robot	Excluding robot		Including robot (price of "the Excluding robot + $6775)	
				Benign	Malignant	Benign	Malignant
Thymectomy	Thymectomy	$17983[7]	$2400[7]	$4625	Simple resection $4625 Extended resection $7003	$11400	Simple resection $11400 Extended resection $13778
	Extended thymectomy	NA	$3561[8]				
Resection of tumor A. Mediastinal B. Chest wall	Open surgical procedures	NA	NA	A. $2313 B. $1325	A. $4425 B. $2713	A. $9088 B. $8100	A. $11200 B. $9488
	VATS			$7031	NA		
Lobectomy	Open surgical procedures	$8368[9]	$5460[9]	$7294	$9080	$14069	$15855
	VATS	$1479[9]		$7369	$11500		

Table 2 shows the cost for dVS-surgery for 100 robotic cases per year at 1 institution with the projected JNHIS reimbursement system. RATS: robot-assisted thoracic surgery; VATS: video-assisted thoracic surgery; JNHIS: Japanese National Health Insurance System

Table 3 The difference of cost for RATS with the Japanese public health insurance system since April 2012

Procedure		Change in cost in procedures performed in Japan $1 = ¥80, average exchange rate Mar.2010–Jul.2012					
		the dVS operation was performed 100 times in a year		the dVS operation was performed 200 times in a year		The dVS operation was performed 300 times in a year	
		Including robot (price of "Excluding robot + $11675)		Including robot (price of "Excluding robot + $7625)		Including robot (price of "Excluding robot + $6275)	
		Benign	Malignant	Benign	Malignant	Benign	Malignant
Thymectomy	Thymectomy	$16300	Simple resection $16300 Extended resection $18678	$12250	Simple resection $12250 Extended resection $14628	$10900	Simple resection $10900 Extended resection $13278
	Extended thymectomy						
Resection of tumor A. Mediastinal B. Chest wall	Open surgical procedures	A. $13988	A. $16100	A. $9938	A. $12050	A. $8588	A. $10700
	VATS	B. $13000	B. $14388	B. $8950	B. $10338	B. $7600	B. $8988
Lobectomy	Open surgical procedures	$18969	$20755	$14919	$16705	$13569	$15355
	VATS						

Table 3 shows the differences in cost for dVS surgery for 100, 200 or 300 robotic cases per year at 1 institution with the projected JNHIS reimbursement system. RATS: robot-assisted thoracic surgery; dVS: da Vinci® Surgical System; VATS: video-assisted thoracic surgery; JNHIS: Japanese National Health Insurance System

Discussion

In Japan, prostectomy for prostate cancer using the dVS is the only application recognized for reimbursement by the JNHIS of the Ministry of Health, Labour and Welfare, and this has been only since April 2012. We are still waiting for recognition by the Ministry of Health, Labour and Welfare for reimbursement of dVS operations in other clinical fields, such as gastrectomy, uterectomy, pulmonary lobectomy and thymectomy. Nevertheless, dVS

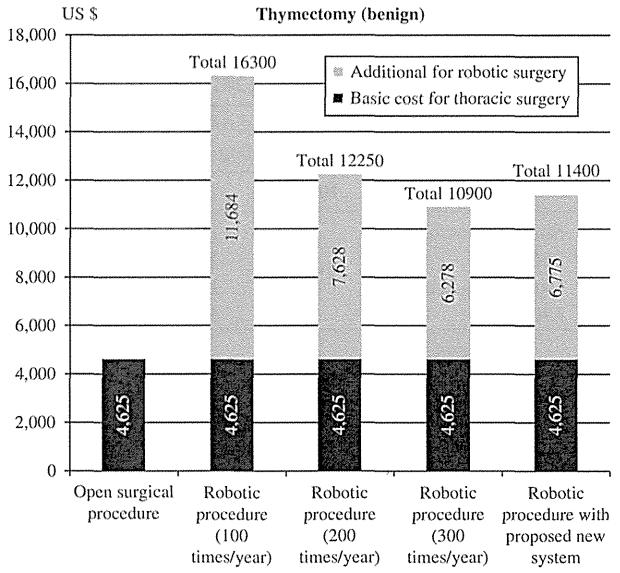

Fig. 1 Differences between open surgical procedure and robot-assisted thoracic surgery (RATS) procedure for thymectomy. The financial differences are shown among institutions performing RATS procedures, in which institutions performed the da Vinci® Surgical System (dVS) operation 100, 200 or 300 times per year. Figures are based on data contained in Tables 1A, 1B, 2 and 3. Since the purchase price and 5-year service life cost are set by the government, the cost per RATS procedure in the institution obviously decreases with the number of procedures performed annually.

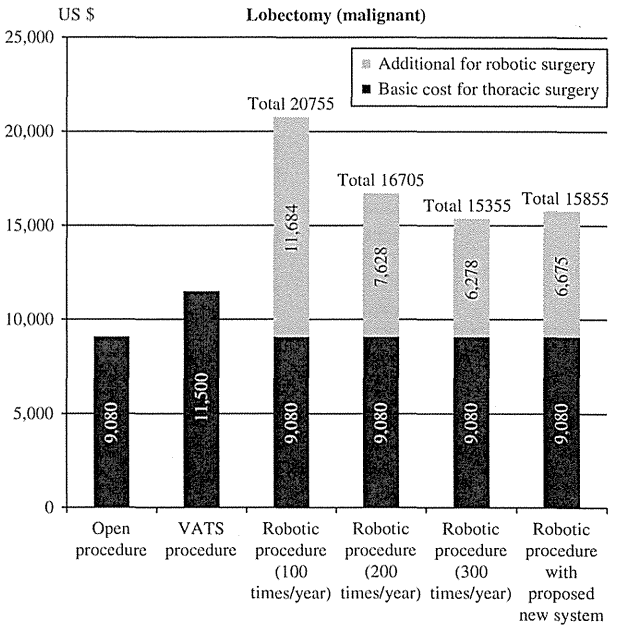

Fig. 2 Cost of pulmonary lobectomy for malignant disease among open thoracotomy, video-assisted thoracic surgery (VATS) and robot-assisted thoracic surgery (RATS) procedures, in institutions which performed the da Vinci® Surgical System (dVS) operation 100, 200 or 300 times in a year. Figures are based on data contained in Tables 1A , 1B, 2 and 3.

operations are now increasing rapidly in Japan. The total number of dVS operations in Japan was 209 in 2009, 498 in 2010, and 971 in 2011. Rapid decisions concerning JNHIS applications for dVS operations are necessary for many other procedures.

Good long-term outcomes from robotic surgery for thymectomy with nonthymomatous myasthenia gravis and lobectomy for non-small cell lung cancer have recently been reported.[4–6] These reports also show satisfactory outcomes for RATS. In the near future, these reports will encourage many thoracic surgeons to attempt to widen the indications of robotic surgery in Japan.

As for the clinical hypothesis in Japan, it appears that no final conclusion can be reached unless the number of cases of RATS increases. Past reports[4,5] are retrospective investigations in the field of thoracic surgery. However, such clinical evidence is not yet shown even in other fields, particularly in urology, and evidence showing a significant difference is only available for thymectomy by RATS for myasthenia gravis. We consider that RATS, if fairly priced, would be worth performing for thoracic disease in Japan. It appears that randomize prospective studies in RATS are necessary in the future. Such studies are essential because the medical cost is high, which is the first practical issue that needs to be addressed to solve this clinical problem. As a result, accumulation of sufficient number of cases evaluated by randomized prospective studies is expected to bring about medico-economic improvement. These series of studies enable cost-benefit analysis leading to the reduction of the medical cost which can finally pave the way for the extension of the benefits of robotic surgery to many patients.

The clinical use of a dVS in Japan began in 2006, and even today only a few hospitals and institutions possess it. As of April 2012, 45 dVS systems were being used for clinical or educational purposes in Japan. Because only a few hospitals can afford it, even for government-sanctioned procedures such as prostatectomy, only those relatively few hospitals will accumulate many more patients, at the expense of other hospitals and perhaps to the detriment of some patients.

The JNHIS has covered the whole nation of Japan since 1961. Now the medical copayment the patients have to pay is 30%, with all their other medical expenses being paid by the government. Regardless of the lower per capita medical costs for Japan in comparison with other countries, because all prices are fixed by the government, the tendency of medical costs to increase annually continues to be a point of much political disagreement. The background is complicated and includes Japan's rapidly aging society, advanced medical developments and the increasing cost of drugs. To limit the national health care financial burden as much as possible, the Japanese Government must always consider improving and controlling the medical insurance system which means that the costs of robotic surgery are problematic.

The Japanese medical reimbursement assignment revision by the Ministry of Health, Labour and Welfare in April 2012 did not accept the dVS robotic system as a basic medical instrument. Instead, dVS robot-assisted surgery was approved, under several detailed conditions, for example, the experience of the users, as additional technical support in the insurance system, that is, it was considered medical technology supporting a surgical procedure.

However, despite the enormous potential for the spread and development of robotic surgery in various fields, including the field of telemedicine, the single greatest negative feature preventing this, at least in Asia, is the hugely greater cost of the equipment in Japan, Korea and Taiwan.

The cost of a dVS system in Japan is US$3255000 (November 2012 exchange rate), despite the fact that Japan only applies a 7% sales tax, but no import tax. The cost in Korea is similar. Thus, as of September 2011 the cost in Japan was 2.17 times that in the US (US$1500000), 1.46 times that in the UK and 1.59 times that in Germany and France. Despite repeated requests for an explanation for this from the manufacturer, no satisfactory answer has been forthcoming.

One possible related factor is that Intuitive Surgical Inc. is the sole manufacturer of the dVS device and there are as yet no other comparable competitive systems on the market.[7] Despite our ignorance of the intricacies of patent law that are related to the present situation, we are sanguine that, as competition for such devices spreads, the attendant lower prices might stimulate increases in the applications of and education in RAS.

In establishing its policy regarding remuneration for RAS techniques, the Japanese government decided, for whatever reason, that RAS is not a basic medical technique, but rather an "add-on" technological support system. In defense of this policy, it can only be said that with a population of 127570000, of whom 30740000 are over 65 and 16650000 are under 16, the Japanese government is constantly caught in a conundrum whereby they must seek to provide best possible care but yet not pay exorbitant amounts.

The fact remains that, under the present system, any given institution in Japan would have to be able to perform 300 or more procedures annually to break even financially, and few institutions are willing to take on that responsibility.

There are several limitations to this study. The first two concern financial matters: i.e., the pricing policy of the dVS manufacturer is absolutely opaque, while the second is that the remuneration policy of the Japanese government is equally murky. Thirdly, unless it is made possible for clinicians to explore possible wider indications of the equipment, as well as the true value of RAS and RATS for patients, institutions and health systems, it may take a long time for these procedures to be understood and implemented.

We believe that it is essential for these primarily financial concerns to be clearly addressed in order for the benefits of RAS to reach the public.

Conclusion

Because of the high cost of the system in Japan, it is necessary to perform dVS surgery at least 300 times in a year at one institution to prevent a deficit in income. We hope that marked competition will eventually reduce the cost of robot-related devices. Without a large decrease in cost of the system, it is difficult to envision rapid spread and development of RAS even in countries with highly developed national insurance systems.

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ORIGINAL ARTICLE

High-quality 3-dimensional image simulation for pulmonary lobectomy and segmentectomy: results of preoperative assessment of pulmonary vessels and short-term surgical outcomes in consecutive patients undergoing video-assisted thoracic surgery†

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Abstract

OBJECTIVES: The aim of this study was to evaluate the effectiveness of 3-dimensional computed tomography (3D-CT) software in short-term surgical outcomes and the assessment of variations of pulmonary vessel branching patterns on performing video-assisted thoracic surgery (VATS).

METHODS: The study included 179 consecutive patients who had undergone VATS anatomical lung resection, of which 172 were lobectomies (96%) and 7 were segmentectomies (4%), from May 2011 through January 2013. There were 124 patients (69%) in whom 3D-CT was performed and 55 patients (31%) who had not undergone 3D-CT. Observed actual pulmonary vessel branching patterns by intraoperative findings or footage were compared with the 3D image findings. Various surgical outcomes, including the occurrence of postoperative complications, in this study defined as those of Grade 2 or above under the Clavien–Dindo classification system, and total operative time, were retrieved from available clinical records.

RESULTS: Among the 124 patients with preoperative 3D imaging, there were 5 (4%) conversions from VATS to thoracotomy. The incidence rate of patients with postoperative complications was 8% ($n = 10$), and there were no 30-day or 90-day mortalities. Pulmonary artery (PA) branches were precisely identified for 97.8% (309 of 316) of branches on 3D images, and the sizes of the seven undetected branches (five in the right upper lobe, two in the left upper lobe) ranged from 1 to 2 mm. The 3D images accurately revealed 15 cases (12%) of anomalous or unusual PA branches and 5 cases (4%) of variant pulmonary veins. Multivariate logistic regression analysis of the association with postoperative complications and operative time in 165 lung cancer patients demonstrated that male gender was the only statistically significant independent predictor of complications (risk ratio: 5.432, $P = 0.013$), and patients without 3D imaging tended to have operative complications (risk ratio: 2.852, $P = 0.074$), whereas conducting the 3D-CT (risk ratio: 2.282, $P = 0.021$) as well as intraoperative bleeding amount (risk ratio: 1.005, $P = 0.005$) had significant association with operative time.

CONCLUSIONS: High-quality 3D-CT images clearly revealed the anatomies of pulmonary vessels, which could play important roles in safe and efficient VATS anatomical resection.

Keywords: 3-Dimensional computed tomography • Simulation • Video-assisted thoracic surgery • Lobectomy • Pulmonary vessels

INTRODUCTION

Video-assisted thoracic surgery (VATS) lobectomy and segmentectomy have been established as standard surgical techniques for the treatment of lung cancer, metastatic lung tumours and benign lung tumours. A number of reports have documented the safety and effectiveness of a thoracoscopic approach, which has less morbidity, better postoperative respiratory function and equivalent oncological outcomes to conventional thoracotomy [1–4]. Anatomical variants of pulmonary vessels can cause serious problems such as unexpected bleeding in patients undergoing VATS [5, 6]. Detailed preoperative understanding and simulations of the surgical anatomy using image modalities would greatly contribute to safely performing VATS.

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Multidetector computed tomography (MDCT) allows surgeons to construct 3-dimensional (3D) images of lung structures. We have used 3D lung modelling based on CT images taken using the Fujifilm Synapse Vincent system (Fujifilm Corporation, Tokyo, Japan) to obtain 3D images of the pulmonary vessels and the tracheobronchial tree for surgical simulations [7, 8]. Several reports have addressed the usefulness of pre- or intraoperative use of 3D evaluations in the field of thoracic surgery [7–12]. However, the influence of 3D simulation on perioperative surgical outcomes in VATS has not been well described. The aim of this study was to evaluate the effectiveness of 3D software in short-term surgical outcomes and the preoperative assessment of variations of pulmonary vessel branching patterns for safely performing VATS.

PATIENTS AND METHODS

Patients

From May 2011 to January 2013, 561 patients underwent pulmonary resection at our department. Among them, 179 (31.9%) consecutive patients who had undergone VATS anatomical lung resections were included in this retrospective study. Our original indications of VATS anatomical resection for malignancies were for peripheral tumours less than 5 cm in diameter without nodal involvement. However, we have applied the VATS procedure in patients with multiple comorbidities who would otherwise not be suitable candidates for the conventional thoracotomy approach. We have preoperatively constructed 3D lung modelling based on CT images of lung structures taken using the Synapse Vincent system for the majority of patients scheduled for VATS lobectomy or segmentectomy. Data collection and analyses were approved and the need to obtain written informed consent from each patient was waived by the Institutional Review Board of Tokyo Medical University.

Preoperative 3D image construction and simulation

Patients underwent CT imaging with a 64-channel MDCT (Light Speed VCT, GE Medical Systems, Milwaukee, WI, USA) set at the following parameters: gantry rotation speed of 0.4 s per rotation, collimation of 0.625 mm, table incrementation speed of 39.37 mm/s with a helical pitch of 0.984, tube voltage of 120 kV, and the tube current was used with an automatic exposure control system. Axial sections (1.25 mm in thickness) were reconstructed at intervals of 1.0 mm. A total of 100 ml of iohexol (Omnipaque, 300 mg of iodine per ml; Daiichi-Sankyo Pharmaceutical, Tokyo, Japan) was injected by a mechanical injector (Dual Shot GX7; Nemoto Kyorindo, Tokyo, Japan) at a rate of 1.5–2.0 ml/s without an injection of saline solution afterwards. Each CT image was acquired within 1 breath hold of about 5 s, after a delay of 70 s during which the contrast media injection took effect. The presented CT scan protocol has been used for not only the 3D image construction but also standard staging for lung cancer patients to be suitable for contrast radiography. These digital imaging and communication in medicine data were transferred to a workstation with the volume-rendering reconstruction software. After this step, a surgeon can construct 3D images completed within approximately 5 min for surgical simulations. We have performed VATS with double monitor guidance: one was a thoracoscopy television monitor, and the other was the 3D imaging system. The simulation system was implemented as a plug-in in the processing workstation (Dell Precision T5500, Windows 7 Professional, 64-bit, 12 GB, DDR3 RDIMM).

Operative procedure

Operations were performed with the patient in the lateral decubitus position under general anaesthesia with one-lung ventilation. Three or four incisions were used in each patient. A 10-mm camera port was placed in the sixth intercostal space (ICS) at the midaxillary line, through which a 30-degree thoracoscope was positioned. An access incision of 3 cm was placed in the fourth ICS and centred at the anterior axillary line, and a 10-mm accessory port was placed in the sixth ICS at the anterior axillary line. A 15-mm assist port was placed at the tip of the scapula. Rib resection or rib spreading was not performed.

Analysing evaluation data

To determine the ability of 3D images to enable the assessment of pulmonary artery (PA) branching patterns involved in operation, vascular size, the route of the pulmonary vein (PV) and the results of all examinations were interpreted by two surgeons (at least one of whom was a board-certified thoracic surgeon) and one chest radiologist (Soichi Akata) in consensus. The intraoperative footage was postoperatively evaluated by two surgeons, who were blinded to patient identification. When pulmonary vessels identified by the footage could not be visualized in the 3D images, they were considered 'undetected' vessel branches. Short-term outcomes, such as operating time, approximate blood loss, mortality rate and postoperative complications, were retrieved from available clinical records. The development of postoperative complications in this study was defined as Grade 2 or above for severe complications under the Clavien–Dindo classification system.

Statistical analysis

The χ^2 test and Fisher's exact or Student's *t*-test were used to compare proportions and continuous variables in analysing the frequency of occurrence of postoperative complications and operative time. Multivariate analyses were performed using the multiple logistic regression analysis, and we checked the validity of the model using the Hosmer–Lemeshow χ^2 test (a larger *P* value signifies greater reliability) on an external validation data set. All tests were two-sided, and *P*-values less than 0.05 were considered to indicate a statistically significant difference between the two groups. All statistical calculations were performed using the SPSS statistical software package (version 21.0; DDR3 RDIMM, SPSS, Inc., Chicago, IL, USA).

RESULTS

The characteristics of the patients who underwent VATS anatomical lung resection during this study period are summarized in Table 1. The study cohort of 179 patients included 88 men and 91 women, of whom 165 (92%) had primary lung cancer and 172