Four-arm robotic lobectomy for the treatment of early-stage lung cancer

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Objectives: We investigated the feasibility and safety of four-arm robotic lung lobectomy in patients with lung cancer and described the robotic lobectomy technique with mediastinal lymph node dissection.

Methods: Over 21 months, 54 patients underwent robotic lobectomy for early-stage lung cancer at our institute. We used a da Vinci Robotic System (Intuitive Surgical, Inc, Mountain View, Calif) with three ports plus one utility incision to isolate hilum elements and perform vascular and bronchial resection using standard endoscopic staplers. Standard mediastinal lymph node dissection was performed subsequently. Surgical outcomes were compared with those in 54 patients who underwent open surgery over the same period and were matched to the robotic group using propensity scores for a series of preoperative variables.

Results: Conversion to open surgery was necessary in 7 (13%) cases. Postoperative complications (11/54, 20%, in each group) and median number of lymph nodes removed (17.5 robotic vs 17 open) were similar in the 2 groups. Median robotic operating time decreased by 43 minutes ($P = .02$) from first tertile (18 patients) to the second-plus-third tertile (36 patients). Median postoperative hospitalization was significantly shorter after robotic (excluding first tertile) than after open operations (4.5 days vs 6 days; $P = .002$).

Conclusions: Robotic lobectomy with lymph node dissection is practicable, safe, and associated with shorter postoperative hospitalization than open surgery. From the number of lymph nodes removed it also appears oncologically acceptable for early lung cancer. Benefits in terms of postoperative pain, respiratory function, and quality of life still require evaluation. We expect that technologic developments will further simplify the robotic procedure. (J Thorac Cardiovasc Surg 2010;140:19-25)

Lung cancer screening programs in at-risk populations are resulting in increased numbers of early-stage lung cancers potentially best removed by minimally invasive surgical approaches.^{1,2} Thoracoscopic lobectomy has been shown to be safe and effective, with benefits in terms of reduced postoperative pain and better functional and aesthetic results compared with open lobectomy.³⁻¹⁰ Observational studies⁵⁻⁷ and at least one randomized trial³ indicate that oncologic results are equivalent to those of open surgery. However, thoracic surgeons seem reluctant to embrace video-assisted thoracic surgery (VATS) owing to the limited maneuverability and unsatisfactory ergonomic characteristic of the instruments,

the limitations of the 2-dimensional view of the operating field, and persisting controversy regarding oncologic efficacy.^{11,12}

The da Vinci Robotic System (Intuitive Surgical, Inc, Mountain View, Calif) for thoracoscopic surgery overcomes many of the disadvantages of traditional VATS in that it has a superior range of motion and improved ergonomic characteristics, as well as offering 3-dimensional visibility. In addition, surgeons appear to adapt quicker to the surgical robot, and the technology may provide a greater probability of oncologic radicality. At present, very few centers use the da Vinci System to treat lung cancer. Nevertheless, published early experience is encouraging, although the series were small and not compared with open procedures.¹³⁻¹⁵

The aims of the present study are to evaluate the feasibility and safety of the da Vinci System when used to perform pulmonary lobectomy for early-stage lung cancer and to provide indications as to oncologic efficacy by assessing the number of mediastinal lymph nodes removed in comparison with a matched group of patients subjected to open lobectomy for lung cancer. A further aim is to describe our four-arm robotic technique for lobectomy and lymph node removal.

METHODS

From November 2006 through September 2008, 54 patients with suspected or proven clinical stage I or II lung cancer were recruited to undergo

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Abbreviations and Acronyms

CT	= computed tomography
FEV ₁	= forced expiratory volume in 1 second
VATS	= video-assisted thoracic surgery

robotic lobectomy provided they satisfied the following inclusion criteria: lesion less than 5 cm, normal respiratory function (including forced expiratory volume in 1 second [FEV₁] greater than 65% of predicted), no prior thoracic surgery, no neoadjuvant treatment, no need for extended or sleeve resection, and age less than 75 years. All patients underwent complete preoperative staging including positron emission tomography, bronchoscopy with brushing or biopsy, and whole-body computed tomography (CT) (2.5-mm slices). Mediastinoscopy was performed in cases in which visual assessment of positron emission tomographic scans suggested mediastinal adenopathy. Over the study period, 132 other patients underwent conventional lobectomy and 54 a sublobar resection. Only candidates for lobectomy (never those for wedge resection) were potential candidates for robotic lobectomy. We compared the 54 patients having robotic lobectomy with 54 patients having open lobectomy, selected using propensity scores (see Statistical Analysis).

Operating time, postoperative hospitalization, perioperative and postoperative complications, and number of mediastinal lymph nodes removed were recorded prospectively in the robotic group and in a group of 54 patients who received open lobectomies at our center over same period. CT-guided biopsy was not performed on a routine basis.

All robotic lobectomies were performed by one surgeon (G.V.) experienced in major lung resection but with no direct experience of VATS lobectomy. The open procedures (lateral muscle-sparing approach) were performed by one of the four senior surgeons (including G.V.) at the Thoracic Surgery Division, Milan. Patients were chosen for the robotic as opposed to the open approach in a nonrandom fashion determined by surgeon choice, da Vinci System availability, (limited to 3 to 4 cases per month over the study period), and position of lung lesion (lesions not suitable for VATS wedge resection with no diagnosis underwent open wedge resection before lobectomy). Operating time was defined as time from first incision to time of closure and also included times for VATS wedge resection and frozen section examination. Patients in the robotic group gave written informed consent to undergo the robotic approach. The patients in the open surgery group also gave written informed consent for their operations. The study was approved by the European Institute of Oncology's Ethical Committee.

Surgical Technique

The patient was placed in the lateral decubitus position and single-lung anesthesia was achieved via a double-lumen endotracheal tube. Patients were prepared and draped with the arm down, but if conversion to open sur-

gery was necessary the arm was moved up and lateral muscle-sparing thoracotomy performed. The robot was positioned at the head of the patient, with the console (the station where the surgeon worked) in the same room (Figure 1).

Port positions and VATS resection. Three port incisions and a 3-cm utility thoracotomy were made at the positions indicated in Figure 2. The ports were standard for all lobectomies except that, on the right side, the camera port through the seventh intercostal space was in the midaxillary line, whereas on the left side this port was moved 2 cm posteriorly (compared with the right) to avoid the heart obscuring vision of hilar structures. The utility thoracotomy was at the fourth intercostal space anteriorly.

Lesions without a preoperative diagnosis were first excised by traditional VATS wedge resection followed by intraoperative frozen section examination. Small or deep undiagnosed lesions were located before the operation (not more than 24 hours before) by injecting technetium 99m-labeled sulfur colloid under CT control. A gamma ray-detecting probe was introduced through a port to precisely locate the "hot" nodule and hence guide the wedge resection.

Hilar dissection. The lobectomy proceeded first by isolation of hilar elements using a hook and two Cadere forceps (Intuitive). The hook was manipulated by the right arm of the robot introduced through the utility thoracotomy for right-side dissections or through the posterior trocar in the eighth intercostal space for left-side lobectomies. One of the Cadere forceps (fourth robotic arm) was used to retract the lung and expose structures. The other Cadere forceps was manipulated by the left arm of the robot and used to grip structures during dissection: it was introduced through the utility thoracotomy for left-side lobectomies or through the posterior trocar in the eighth intercostal space for right-side lobectomies. When a hilar vessel or bronchus was ready to be surrounded with a vessel loop for stapler introduction, a third Cadere forceps was introduced (substituting for the hook). Vessels and the bronchus were sectioned by mechanical staplers introduced through a thoracoscopic port by the assistant surgeon after removal of a robotic arm. The pulmonary vein was usually the first structure to be isolated and divided. If the lesion was in the right upper lobe, vein resection was followed by isolation of the branches of the pulmonary artery and sectioning, followed by isolation of the bronchus and bronchus sectioning. If the lesion was in the right lower lobe or left lung, after pulmonary vein sectioning, the bronchus was usually isolated and stapled before the artery. When middle lobectomy was being performed, the most favorable sequence was vein, bronchus, and artery.

Fissure completion and lobe removal. The incomplete fissure was usually prepared with an Endo Gia stapler introduced by the assistant surgeon through one of the ports. The lobe was extracted through the anterior utility thoracotomy using an EndoCatch device (Autosuture; Covidien, Dublin, Ireland).

Mediastinal lymph node dissection. Radical lymph node dissection was performed after lobectomy (in open surgery, suspicious lymph nodes are usually removed before lobectomy), using the same technique as in open surgery.^{16,17} Paratracheal lymph node dissection was performed on

FIGURE 1. Positions of robot and surgeon.

FIGURE 2. Trocar insertion points for robotic right lung lobectomy.

the right side without azygos vein division. The mediastinal pleura between the superior vena cava and the azygos vein was incised. The lymph nodes, together with the fatty soft tissue of the region of Barety, were removed en bloc with the hook and a Cadiere forceps. Sometimes a PK system (Ultracision, Inc, Santa Clara, Calif) was used in patients with large quantities of mediastinal fat.

The nodes of the subcarinal station were removed after resection of the pulmonary ligament and retraction of the lung toward the anterior mediastinum to expose the posterior mediastinum. Bronchial arteries could usually be avoided thanks to the good visibility. If not, they were simply coagulated; usually a clip was not required. Fibrin sealant (Tissucol, Baxter Healthcare Corp, Santa Ana, Calif)¹⁸ was applied to lymphadenectomy sites to reduce lymphorrhea, to the bronchial stump, and to the fissure surface to reduce air leakage. Two 28F (Tyco Healthcare Switzerland, Wollerau, Switzerland) pleural drains were positioned at the end of the operation.

Statistical Analysis

Because of the nonrandomized nature of the study, we used propensity score matching to adjust for differences in demographic and clinical characteristics of patients who underwent open and robotic surgery. A multivariable logistic regression model was fitted to estimate the relative odds of undergoing robotic versus open surgery in relation to the following preoperative characteristics: age, sex, clinical tumor stage, clinical node status, body mass index, smoking status, American Society of Anesthesiologists score, FEV₁ percent predicted, and cardiovascular comorbidity, in the whole study population. The logistic model was used to generate a propensity score for each individual in the data set. The propensity score is the probability of receiving robotic versus open surgery given the covariates of the model. Each of the 54 patients who underwent robotic surgery was then matched to controls (open surgery) on the propensity score using the GREEDMTCH SAS macro (<http://www2.sas.com/proceedings/sugi26/p214-26.pdf>).

We used Fisher's exact test and the Mantel-Haenszel χ^2 test for trend to assess differences in the distribution of characteristics between the 2 treatment groups. Because the small size of the groups and nonnormal distributions of continuous variables (FEV₁, operating time, postoperative hospitalization, number of lymph nodes removed), the nonparametric Wilcoxon test was used to assess differences in median values for these variables. We plotted operating time against date of operation and derived from it a trend line based on a polynomial regression model. We divided patients who underwent robotic surgery into three series (tertiles) of 18 patients each. We used the nonparametric Wilcoxon test to assess

differences in operating time and postoperative hospitalization between the first and second and the second and third robotic series, and also between the second plus third robotic series and patients who received open lobectomy.

All statistical tests were 2-sided. The statistical analyses were performed with the SAS statistical software version 8.2 (SAS Institute, Inc, Cary, NC).

RESULTS

Table 1 shows the characteristics of the 54 patients with lung cancer (including converted cases) who underwent robotic lobectomy and the 54 patients who underwent open surgery and were matched to the robotic group by propensity score. In the robotic group, we performed 16 right upper lobectomies, 4 middle lobectomies, 11 right lower lobectomies, 14 left upper lobectomies, and 9 left lower lobectomies. There were 42 adenocarcinomas, 4 squamous cell carcinomas, 3 carcinoids, 2 small cell carcinomas, and 3 other non-small cell lung cancers. Similar numbers of wedge resections with frozen section examination before lobectomy were performed in the open and robotic groups: 22 (41%) in the open and 30 (55%) in the robotic group. Preoperative localization with radiotracer was used to find the nodule during surgery in 12 cases (4 in the open group and 8 in the robotic group).

Table 2 compares variables between tertiles of the robotic series to delineate learning and also presents open lobectomy variables to provide indications of safety and oncologic radicality. In 7 (13%) patients, conversion to open surgery was necessary: for absence of fissure in 5, other anatomic reason in 1, and oncologic reason in another. Major complications were confined to the first two tertiles of the robotic group and consisted of acute respiratory distress syndrome in 2 and transitory neuropathy of the right hand with hypofunction in another. The latter complication was probably related to the patient's position during surgery. Major and minor complications declined across the three robotic tertiles (P trend = .04). The numbers of postoperative complications were similar in the open and robotic groups (P = .77); in particular, similar numbers of patients had postoperative atrial fibrillation (4 vs 3), air leak (5 vs 2), and pulmonary complications (4 vs 7) in the open and robotic group, respectively. No 30-day postoperative mortality occurred. Postoperative blood transfusion was not required by any robotic surgery patient but was required by 3 (6%) open surgery patients (P = .12).

The numbers of lymph nodes removed were similar in the 2 groups (P = .24). However, the median number of mediastinal lymph nodes removed was less in the robotic series (P = .04). Median postoperative hospitalization declined across the robotic series and was significantly shorter (P = .002) in the third plus second tertile than the first one, and was significantly shorter for the robotic group (excluding the first tertile) than the open lobectomy group (4.5 days vs 6 days; P = .002).

TABLE 1. Clinical and pathologic characteristics of patients with 54 lung cancer who underwent robotic lobectomy and 54 matched lung cancer controls who underwent open lobectomy

Characteristic	Robotic lobectomy (n = 54)	Open lobectomy (n = 54)	P value
Sex			
Men	38	34	
Women	16	20	.41
Age (y)			
<55	8	11	
55–59	12	13	
60–64	19	14	
65+	15	16	.54†
FEV ₁ % predicted			
Mean (SD)	95 (19)	95 (20)	.91‡
Median (range)	95 (49–141)	90 (66–169)	.48§
Lobe			
Lower	20	21	
Middle	4	2	
Upper	30	31	.70
Clinical tumor stage			
cT1	45	48	
cT2	9	6	.40
Clinical lymph node status			
cN0	51	51	
cN1	2	2	
cN2*	1	0	
cN3*	0	1	.80†
ASA score			
1	11	10	
2	37	34	
3	6	10	.41†
BMI			
<18.5	1	1	
18.5–25	24	25	
25–30	24	21	
≥30	5	7	.91†
Cardiac comorbidity			
No	48	46	
Yes	6	8	.57
Smoking status			
Never smoked	2	2	
Ex-smoker	18	17	
Current smoker	34	35	.98
Pathologic disease stage			
I	45	42	
II	5	4	
III	4	8	.46
pT1	43	34	
pT2	9	16	
pT3	0	0	
pT4	2	4	.10†
pN0	46	44	
pN1	6	5	
pN2	2	5	.39†

FEV₁, Forced expiratory volume in 1 second; SD, standard deviation; ASA, American Society of Anesthesiologists; BMI, body mass index. *Mediastinoscopy excluded lymph node involvement in these 2 patients with cN2 and cN3 †Mantel-Haenszel χ^2 test for trend ‡t test §nonparametric Wilcoxon test.

Figure 3 shows time trends for the duration of the robotic and open procedures. Operating time was about an hour longer for robotic than for open surgery ($P < .0001$). Median duration of robotic surgery (including conversions) was 43 minutes shorter in the second and third tertile compared with the first ($P = .02$).

DISCUSSION

Modern medicine places greater emphasis than in the past on the wishes, comfort, and quality of life of the patient. Less invasive techniques for oncologic surgery that maintain oncologic radicality and reduce pain, surgical inflammation, and postoperative dysfunction^{3–8}, fit squarely within this philosophy and may bring the added benefit of improved survival.^{18,19} Thoracoscopic procedures can attain these goals in selected patients with lung cancer, but they are uncomfortable and difficult (long learning curves) for the surgeon, with visual information limited to 2 dimensions, and instruments having restricted maneuverability mainly because of the rigid axes that are fixed to the thoracic wall by the entry trocar.^{15,19}

The advanced engineering embodied in the da Vinci System has now made it possible to overcome many of these disadvantages, without compromising oncologic radicality or patient safety. Robotic surgery for thoracic disease is therefore likely to become widespread, provided that the high costs of the early robotic systems can be significantly reduced.

Robotic surgery in humans was first described by Cadiere and associates²⁰ in 1997. Today the commonest indication for robotic thoracic oncology is resection of mediastinal masses,²¹ with relatively few publications on robotic lobectomy for lung cancer.^{13–15} The experience reported in the present study suggests that robotic lobectomy for lung cancer is feasible and safe. We had no major complications or bleeding that required urgent conversion to open surgery, and postoperative complications were similar to those in our series of patients with open surgery operated on over the same period for closely similar disease (Table 1). The notable difference was that postoperative hospital stay was shorter in the robotic series than the open series, although we may have tended to discharge robotically treated patients sooner than open cases.

We consider that the learning phase for the technique lasted for the first 18 patients (Table 2) and this appears shorter than the average of 30 to 35 operations reported for VATS lobectomies.²²

One of the most important differences in the robotic technique compared with VATS is that it requires the surgeon to abandon the operating table and sit at a control console, so that all tactile feedback is lost, and a new set of manual and eye-hand coordination skills must be acquired.¹⁵

Thirteen percent of our cases were converted to open surgery. This is in the middle of the range reported for VATS

TABLE 2. Comparison of learning variables between the three tertiles of robotic surgery patients and the open surgery group

	First tertile, series 1	Robotic lobectomy		Open lobectomy	P value*	
		Second tertile, series 2	Third tertile, series 3		First vs second + third robotic series	Second + third robotic series vs open
No. of operations	18	18	18	54		
No. of conversions	3 (17%)	1 (6%)	3 (17%)	N/A	.67	—
No of complications	6 (33%)	4 (22%)	1 (6%)†	10 (19%)	.15	.77
Major/minor	4/2	3/1	1/0	9/1		
Blood transfusions	0	0	0	3	—	—
Median operating time, min (range)	260 (152–513)	213 (165–351)	235 (146–304)	154 (74–224)	.02	<.001
Median postop hospitalization, d (range)	6 (4–24)	5 (3–23)	4 (4–7)	6 (3–19)	.002	.002
Median No. of lymph nodes removed (range)	15 (4–37)	17 (4–28)	17 (9–30)	18 (4–27)	.24	.72
Median No. of lymph nodes removed at first level (range)	9 (3–20)	10 (0–19)	12 (3–23)	10 (2–21)	.46	.55
Median No. of lymph nodes removed at second level (range)	4 (0–18)	6 (1–21)	4 (2–25)	7 (0–17)	.34	.04

*Nonparametric Wilcoxon test for continuous variables; Fisher's exact test for categorical variables (number of conversion, number of complication) †trend across robotic series P = .04.

lobectomies by expert surgeons: 2.5% by McKenna, Houck, and Fuller,⁹ 19% by Yim and colleagues,¹⁸ and 23% by Roviario and associates.⁸ Regarding robotic series, Park, Flores, and Rusch¹⁴ reported a conversion rate of 12%, Gharagozloo, Margolis, and Tempesta,¹⁵ who described a hybrid robotic-VATS technique carried out on 61 patients, reported a remarkable 0% conversion rate, while Kernstine, Casandra, and Falabella²³ reported a 3% conversion rate in their experience with three-arm robotic lobectomies.

Robotic surgery required about an hour more to complete than open surgery, even at the end of the learning curve. Median duration of robotic surgery was 217 minutes for the last two tertiles of our series; this is similar to the 218 minutes reported by Park, Flores, and Rusch¹⁴ in 34 published cases and the 240 minutes reported by Gharagozloo, Margolis, and Tempesta.¹⁵

Our data on number of lymph nodes removed provide some indication of the likely oncologic radicality of the robotic operation.^{16,17} Although the number of lymph nodes removed tended to increase with experience, there was no significant difference between the robotic and open procedures in terms of lymph nodes removed. Increasing use of high-resolution CT reduces the risk of leaving occult lung lesions in residual lobes—a phenomenon described in relation to lack of palpation associated with VATS¹¹—thereby supporting the use of minimally invasive surgery.

Over the past 2 years we have standardized to a four-arm technique not described previously. Use of a fourth arm brings major advantages compared with the three-arm technique in use so far¹³⁻¹⁵; it limits the requirement to change instruments by the assistant, avoiding possible conflicts between thoracoscopic and robotic instruments; it permits maneuver/retraction of the lung directly by the surgeon at the console; it allows exposure and tensioning of the operating field exactly as the surgeon prefers so that it is more stable; and it also allows the assistant at the table to use the utility incision to insert ancillary instruments such as aspirator or sponge, as required. The availability and at least one robotic Cadiere forceps into the chest also allows the surgeon to deal with potentially severe problems like major hemorrhage. We

FIGURE 3. Comparison of operating time trends in 54 lung cancer patients subjected to robotic lobectomy and 54 matched lung cancer patient controls who underwent open surgery.

have found that port placement can be standard in most patients and for all types of lobectomy, while for most VATS or robotic techniques, the position of the trocars varies according to the type of lobectomy.

Other authors have developed different techniques. Gharagozloo, Margolis, and Temp¹⁵ perform a VATS lobectomy, adding the robot to do the lymphadenectomy. Kernstine, Cassandra, and Falabella²³ do a completely robotic lobectomy with three arms, but enlarge the axillary port to a (variable) size sufficient to extract the lobe and mass. Park, Flores, and Rusch¹⁴ use a three-arm technique but, like us, employ a utility incision to extract the lobe.

We have limited indications for the robotic approach so far to patients with early-stage lung cancer who are candidates for standard lobectomy with no major respiratory impairment. Indications may expand in the near future to patients with cardiologic comorbidities, those who have been pretreated, and those requiring a typical segmentectomy. However, patients with functional impairment seem at increased risk of postoperative acute respiratory distress syndrome,²⁴ probably in relation to the long duration of the operation during which operated lung is excluded from ventilation. The 2 patients in whom adult respiratory distress syndrome developed were treated at the beginning of our experience when selection criteria did not take full account of functional variables. Although FEV₁ percent predicted was over 65% of predicted in both cases, preoperative arterial oxygen tension (50%–60%) and arterial oxygen saturation (91%–92%) were not optimal. The operations lasted 285 and 225 minutes but did not require transfusion or conversion. As a result of experience with these 2 cases, we added blood-gas analysis to the preoperative work-up.

We expect that the postoperative hospitalization period can be further reduced by liberal use of sealant and fibrin glue to limit fluid and air leakage, and hence reduce the time that drains need to be in place. It may also be possible to further reduce operating time when a robotic mechanical stapler, at present not available, is introduced.

With regard to costs, we calculated that each robotic procedure was associated with an overcost of about 2000 euro compared with open surgery or VATS, but this would reduce if the robotic system were used more extensively (the break-even point was calculated at 254 procedures per year all disciplines). Robotic systems will be extensively developed and improved in the near future, resulting in further simplification of the technique and encouraging wider acceptance.

An important limitation of the present study are that it is observational and that our comparison group of open surgery patients—operated on the same time period in the same institution—were selected retrospectively. However, we applied the same inclusion and exclusion criteria to the both groups to reduce selection bias and residual confounding, and we approached the study as if it were a randomized

trial using propensity score matching to create 2 groups well balanced for all measured baseline characteristics (Table 1).²⁵ Clearly, randomized controlled trials are necessary to establish the real advantages of the technique.

A second limitation is that comparative data on early and late postoperative pain and quality of life, postoperative respiratory function, and immune system activation are not available. It will be important to obtain this information to further validate the robotic procedure. Finally, comparison with VATS lobectomy will be important to assess the real benefits of the robotic approach. This comparison was not possible at our institute, as our standard approach to lung lobectomy is muscle-sparing thoracotomy.

To conclude, the present study indicates that our method of robotic lobectomy with lymph node dissection is feasible and safe for the treatment of early-stage lung cancer and appears to provide an oncologically adequate resection, justifying further assessment of the robotic system in lung lobectomy.

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