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What counts more: the patient, the surgical technique, or the hospital? A multivariable analysis of factors affecting perioperative complications of pulmonary lobectomy by video-assisted thoracoscopic surgery from a large nationwide registry

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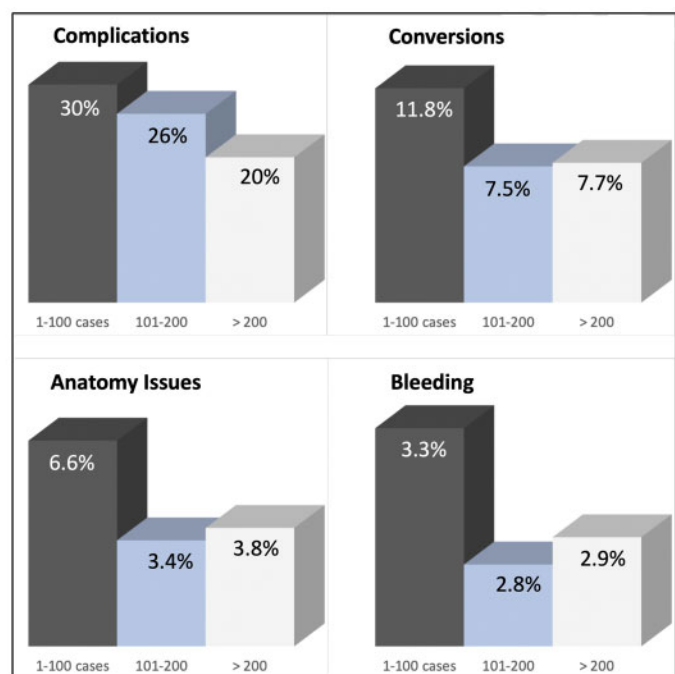
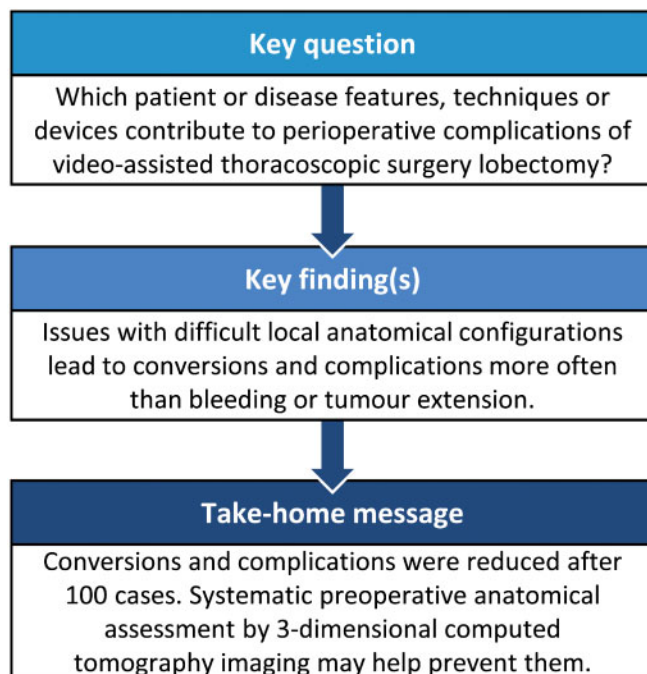
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Abstract

OBJECTIVES: Inherent technical aspects of pulmonary lobectomy by video-assisted thoracoscopic surgery (VATS) may limit surgeons' ability to deal with factors predisposing to complications. We analysed complication rates after VATS lobectomy in a prospectively maintained nationwide registry.

METHODS: The registry was queried for all consecutive VATS lobectomy procedures from 49 Italian Thoracic Units. Baseline condition, tumour features, surgical techniques, devices, postoperative care, complications, conversions and the reasons thereof were detailed. Univariable and multivariable regressions were used to assess factors potentially linked to complications.

RESULTS: Four thousand one hundred and ninety-one VATS lobectomies in 4156 patients (2480 men, 1676 women) were analysed. The median age-adjusted Charlson index of the patients was 4 (interquartile range 3–6). Grade 1 and 2 and Grade 3–5 complications were observed in 20.1% and in 5.8%, respectively. Ninety-day mortality was 0.55%. The overall conversion rate was 9.2% and significantly higher in low-volume centres (<100 cases, $P < 0.001$), but there was no significant difference between intermediate- and high-volume centres under this aspect. Low-volume centres were significantly more likely to convert due to issues with difficult local anatomy, but not significantly so for bleeding. Conversion, lower case-volume, comorbidity burden, male gender, adhesions, blood loss, operative time, sealants and epidural analgesia were significantly associated with increased postoperative morbidity.

CONCLUSIONS: VATS lobectomy is a safe procedure even in medically compromised patients. An improved classification system for conversions was proposed and prevention strategies were suggested to reduce conversion rates and possibly complications in less-experienced centres.

Keywords: Video-assisted thoracoscopic surgery lobectomy • Morbidity • Conversion • Postoperative complications

INTRODUCTION

Video-assisted thoracoscopic surgery (VATS) has been increasingly adopted for the management of resectable lung cancer in the last 2 decades. Despite a large body of literature indicating that VATS lobectomy may be safer, better tolerated and at least equivalent to open surgery from an oncological standpoint [1–6], some inherent aspects of VATS surgery, e.g. absence of direct tactile sensation, limited room and freedom of movement of instrumentation, loss of 3-dimensional vision, may limit surgeons' ability to deal safely with local factors that predispose to intraoperative accidents, such as hilar calcification and abnormal anatomy, or may lead to inadequate oncological results, such as poorly defined tumour margins and fissure involvement.

In late 2013, the Italian Society of Thoracic Surgery invited thoracic units in Italy to contribute to a nationwide registry (the Italian VATS Group database), on a voluntary basis and without compensation. The registry has since prospectively collected detailed information on clinical characteristics, patterns of surgical care and outcomes of patients receiving VATS lobectomy. To explore which factors may be most important in determining perioperative adverse events in this setting, we analysed complication rates of VATS lobectomy in the Italian VATS Group database in relation to patient characteristics, surgical technique, devices and disease features.

MATERIALS AND METHODS

The VATS Group database (the registry) was queried to extract detailed information on all VATS lobectomy procedures (including those that were eventually converted to an open lobectomy) carried out consecutively in all thoracic units that had contributed to the registry between 1 January 2014 and 30 June 2017, for the purpose of an intention-to-treat analysis.

Patient information in the registry included the following: centre and patient codes, demographic data and baseline performance status, oncological history, and lung function testing, comorbidities and comorbidity burden synthesized by

the age-adjusted Charlson comorbidity index (CCI); details from imaging studies, bronchoscopy, mediastinal staging and preoperative biopsy; detailed information on surgical technique, stapling and energy devices, type of lymph node dissection and number of N1 and N2 nodes harvested, pathology, use of sealants, operative time and blood loss, size and number of chest drains and type of water seal employed.

A conversion was defined as an unplanned thoracotomy for any reason during the VATS operation, whereas the reasons for conversion were recorded in a structured fashion.

Short-term outcome data included days with drainage, length of postoperative stay and daily numeric rating scale pain assessments. Perioperative adverse events were reported according to the Thoracic Morbidity and Mortality (TM&M) System [7]. Follow-up data were required to be entered every 6 months.

For this study, the preoperative stage was obtained by combining all data from chest computed tomography (CT) and 18-fluorodeoxyglucose positron emission tomography (PET) studies, endoscopy and invasive staging T1–2, N0, M0 tumours were defined as early-stage, while T3–4 and/or N1–N2 tumours as locally advanced disease, and postoperative complications were classified as minor to mild (Grade 1 and 2) or major (Grade 3–5).

The number of surgeons performing VATS lobectomies in each centre was obtained from a survey circulated to participating units in mid-2017.

Approval from the ethics committee was obtained, and patient and centre information was anonymized before data extraction and analysis.

Statistical analysis

Patient data are presented as number and percentages, mean and standard deviation or median and interquartile range (IQR) as appropriate. For proportion comparisons between groups, the χ^2 test was used, or the Fisher's exact test when necessary, and the conservative Bonferroni adjustment for P -values. Patient-related factors, procedural and technical variables and tumour

data were analysed by scatterplots, and univariable logistic regression models to explore their association with the risk of developing postoperative complications. Independent variables potentially linked to postoperative complications were included in the full generalized linear mixed model with binomial response and centre as a random effect to model the probability of complications following VATS lobectomy. Model-building strategies included checking of convergence and goodness-of-fit test. The Akaike information criterion was used to compare candidate models.

A statistical significance level of 0.05 was adopted for all tests. All statistical analyses were carried out both in the R and SAS software.

RESULTS

This data set consists of 4191 VATS lobectomy procedures carried out by 49 specialized thoracic units on 4156 patients: 2480 men and 1676 women). The median age was 69 (IQR 64–75) years for men and 67 (IQR 59–73) years for women.

Multiple comorbidities were frequent in these patients, and the median age-adjusted CCI was 4 (IQR 3–6) for the whole group. Chronic obstructive pulmonary disease (19.5%) and cardiovascular disorders (26.1%) were the most prevalent Charlson items, whereas all other items had an individual prevalence of <4%.

A preoperative PET scan was available before the procedure in 91% of the cases. Preoperative mediastinal staging by endobronchial ultrasound examination (EBUS) was reported in 3.4% and by mediastinoscopy in 1%.

An anterior 3-portal approach was the most widely employed (69% of the procedures), 2 ports were used in 15% and uniportal VATS lobectomy was performed in 8% of the cases. In the remaining 8% of cases, more than 3 ports were used.

Patient-related, tumour-related and procedural variables significantly linked to perioperative outcomes are summarized in Table 1.

Minor to mild and major complications were observed in 20.1% and in 5.8% of the cases, respectively.

The majority of adverse events consisted in air leaks beyond postoperative day 7 (36.9%), cardiovascular events (31.1%), respiratory complications (22.7%) and postoperative bleeding (12.6%). Major adverse events consisted mostly in pleuropulmonary complications (142 patients, 13.1%) and postoperative bleeding (3.4%). Follow-up data were available for 3485 patients (84%). Thirty-day mortality was 8 out of 3485 (0.23%, 95% CI 0.10–0.45) patients, and 90-day mortality was 19 out of 3485 (0.55%, 95% CI 0.33–0.85) patients.

Conversion rates to unplanned thoracotomy and the reasons for conversion are shown in Table 2.

Low-volume centres were significantly more likely to convert due to issues with difficult anatomy (unrelated to tumour invasion) and slightly more likely to convert for vascular lesions than intermediate- and high-volume centres.

All factors independently related to perioperative complications at multivariable analysis are summarized in Table 3. Among them, lower case-volume and conversion were independently associated with a greater risk of complications of any grade after correcting for confounders.

Factors that were not significant either at univariable analysis or after correcting for confounders are summarized in [Supplementary Material, Tables S1 and S2](#).

Table 1: Variables significantly associated with postoperative complications

Complications	None (%)	Any (%)	G3–G5 (%) ^a	All (%)
All procedures	3108 (74)	1083 (26)	241 (22)	4191 (100)
Male sex	1749 (70)	745 (30)	172 (23)	2494 (60)
CCI 4+	2023 (71)	842 (29)	191 (23)	2865 (68)
Mean age ± SD	67 ± 9.6	69 ± 8.8	69 ± 9.8	67 ± 9.7
Mean %ppoFEV1 ^b ± SD	75 ± 16.9	70 ± 16.6	68 ± 15.0	69 ± 16.7
Centre volume (cases)				
1–100	1116 (70)	471 (30)	96 (20)	1587 (38)
101–200	1010 (74)	363 (26)	93 (26)	1373 (33)
>200	982 (80)	249 (20)	52 (21)	1231 (29)
Procedure (lobe)				
RUL	1008 (72)	400 (28)	102 (26)	1408 (34)
LLL	611 (81)	145 (19)	20 (14)	756 (18)
RML	274 (85)	48 (15)	9 (19)	322 (8)
Wound retractors				
No	1642 (73)	596 (27)	137 (23)	2238 (53)
Yes	1466 (75)	487 (25)	104 (21)	1953 (47)
Pleural adhesions				
No	2572 (77)	783 (23)	150 (19)	3355 (80)
Yes	536 (64)	300 (36)	91 (30)	836 (20)
Use of sealants				
No	2204 (77)	675 (23)	144 (21)	2879 (69)
Yes	904 (69)	408 (31)	97 (24)	1312 (31)
Pain management				
IV only	538 (75)	181 (25)	31 (17)	719 (17)
IV + intercostal block	1864 (76)	577 (24)	138 (24)	2441 (58)
IV + epidural	706 (69)	325 (32)	72 (22)	1031 (25)
Operative time (min), median (IQR) ^c	175 (70)	190 (90)	204 (84)	
Blood loss (mL)				
≤100	1777 (78)	511 (22)	76 (15)	2288 (55)
101–200	1034 (74)	367 (26)	85 (23)	1401 (33)
200+	297 (59)	205 (21)	50 (24)	502 (12)
Conversion				
No	2881 (76)	924 (24)	196 (21)	3805 (91)
Yes	227 (59)	159 (41)	45 (28)	386 (9)
Bronchoscopy				
Negative	1449 (75)	483 (25)	101 (21)	1932 (46)
Positive	302 (67)	151 (33)	41 (27)	453 (11)
Unspecified	1357 (75)	449 (25)	99 (22)	1806 (43)
Pathology				
Adenocarcinoma	2034 (75)	691 (25)	139 (20)	2725 (65)
Squamous	408 (66)	208 (34)	62 (30)	616 (15)
Carcinoid	232 (85)	41 (15)	9 (22)	273 (7)
Other	328 (74)	117 (26)	6 (5)	445 (10)
Non-neoplastic	106 (80)	26 (20)	7 (27)	132 (4)

^aPercentage of G3 or worse complications on total number complications.

^bPercent-predicted postoperative forced expiratory volume in 1 second.

^cPercentages may not add up to 100 because of rounding.

CCI: age-adjusted Charlson comorbidity index; FEV₁: forced expiratory volume in 1 second; IV: intravenous infusion; LLL: left lower lobectomy; RML: right middle lobectomy; RUL: right upper lobectomy.

These include induction chemotherapy, the number of surgical incisions, mediastinal nodal dissection, R1 resection, preoperative pathological diagnosis, pre- and post-treatment tumour stage, number of chest drains, smaller-bore (<24 Fr) chest tubes and the use of energy devices. However, energy devices were associated with a modest, statistically significant reduction in operative time (median 169.5 min, IQR 140–200 vs 180 min, IQR 140–220, $P = 0.0003$).

There was a trend towards an increased complication rate with the number of mediastinal N2 nodes removed, but the association did not reach statistical significance ($P = 0.056$).

Table 2: Causes of conversion to unplanned thoracotomy

Centre volume	Low (1–100)	Intermediate (101–200)	High (>200)	All	P-value
Number of procedures, N (%)	1587 (38)	1373 (33)	1231 (29)	4191 (100)	
Number of centres, N (%)	35 (71)	10 (20)	4 (9)	49 (100)	
Number of cases per month, median (range)	1.2 (0.2–2.4)	2.9 (2.5–4.4)	7.1 (5.8–9.3)		
Number of surgeons	1–6	2–5	3–5		
Conversion	187 (11.8)	103 (7.5)	95 (7.7)	386 (9.2)	<0.001 ^a
Anatomical issues	105 (6.6)	47 (3.4)	47 (3.8)	199 (4.7)	<0.001 ^b
Adhesions	32 (2.0)	21 (1.5)	12 (1.0)	65 (1.6)	0.085 ^b
Hilar calcification	32 (2.0)	10 (0.7)	21 (1.7)	63 (1.5)	0.013 ^b
Fused fissure	28 (1.8)	6 (0.4)	9 (0.7)	43 (1.0)	<0.001 ^b
Unclear anatomy	13 (0.8)	10 (0.7)	5 (0.4)	28 (0.7)	0.39
Vascular (bleeding)	52 (3.3)	35 (2.5)	35 (2.8)	122 (2.9)	0.49
Technical (learning)	11 (0.7)	2 (0.1)	4 (0.3)	17 (0.4)	0.10 ^c
Time constraints	2 (0.1)	(0.0)	(0.0)	2 (0.0)	
Lesion not found	8 (0.5)	2 (0.1)	4 (0.3)	14 (0.3)	0.24 ^c
Multiple (not bleeding)	1 (0.1)	(0.0)	(0.0)	1 (0.0)	
Tumour extension	13 (0.8)	15 (1.1)	8 (0.6)	36 (0.9)	0.46 ^b
Close to hilum	7 (0.4)	10 (0.7)	5 (0.4)	22 (0.5)	0.44 ^c
Invading fissure	6 (0.4)	5 (0.4)	3 (0.2)	14 (0.3)	0.53 ^c
Unspecified cause	6 (0.4)	4 (0.3)	1 (0.1)	11 (0.3)	0.35 ^c

Percentages refer to the number of procedures in each subgroup. Fused fissure: low-volume centres differ from intermediate- (adjusted $P = 0.002$) and high-volume centres (adjusted $P = 0.0506$); Hilar calcification: low-volume centres differ from intermediate-volume (adjusted $P = 0.009$) and high-volume centres (adjusted $P = 0.003$); anatomy: low-volume centres differ from intermediate- (adjusted $P < 0.001$) and high-volume centres (adjusted $P = 0.003$).

^aLow-volume centres differ from intermediate- (adjusted $P < 0.001$) and high-volume centres (adjusted $P \leq 0.001$).

^bThe χ^2 test.

^cThe Fisher's exact test.

DISCUSSION

This analysis of a large series from a network of specialized Italian thoracic units with variable levels of expertise showed the overall morbidity rate after VATS lobectomy to be ~26%, with major complications occurring after 5.8% of the procedures.

The overall conversion rate was 9.2%. Low-volume centres had an increased rate of conversion and complications compared with the intermediate-volume centre and the high-volume centre (Table 2). As a surgeon may convert electively to avoid getting into trouble, conversion was not considered as a complication in itself, in this analysis.

For a more in-depth investigation into the reasons for conversion to thoracotomy, we used a modified classification, similar to the already proposed VALT system [8] that discriminates between tumour extension and fibrous adhesions. Issues with difficult local anatomy, such as a fused fissure, adhesions, calcified hilar nodes or unclear anatomy, led most commonly to conversion across all levels of expertise, but more so in centres that had performed <100 VATS lobectomies, without clear differences between centres that had performed 101–200 or over 200 cases.

Conversions due to vascular lesions, unclear anatomy and technical issues related to the learning curve effect were also more frequent in high-volume centres; however, numbers were too small to reach statistical significance.

Other authors have also previously reported similar factors as predictors of unplanned thoracotomy [9–12], and that conversion rates were lower in highly experienced centres. Nonetheless, serious intraoperative complications may occur at any level of expertise, possibly due to a greater propensity of experienced surgeons to tackle more difficult cases by VATS [13].

However, in our series and in contrast with previous reports [14], unplanned thoracotomy was also independently associated with an increased risk of postoperative complications.

This observation is in agreement with Puri *et al.* [9] who observed overall complication and 30-day mortality rates of 23% and 0%, respectively in 517 successful VATS lobectomies, compared to 46% and 1.1% in 87 procedures converted to thoracotomy and 42% and 0.8% in 623 planned open lobectomies carried out in the same period of time in their institution.

The median age-adjusted CCI in our population was 4 (IQR 3–6) indicating a substantial comorbidity burden, which in turn carries a higher risk of complications of any grade (Table 1). However, despite one-third of the cases having been operated upon in centres with previous experience of <100 cases, postoperative morbidity and mortality in the VATS Group database compare well with the most recent VATS lobectomy series where morbidity rates vary around 25–35% and 30-day mortality is typically around 1% [1–6].

We hypothesize that participation in a nationwide registry encourages all centres to adopt internal protocols that may contribute to improving perioperative outcomes. The impact of male gender on the risk of postoperative complications has been consistently reported [3, 4, 12], and may possibly be related to higher smoking exposure (not captured in the database) or to gender-related biological differences yet to be elucidated.

The low percentage of invasive mediastinal staging is most likely due to case selection, as not many centres routinely perform EBUS preoperatively and rely on PET scan for mediastinal assessment.

In addition, a positive mediastinal biopsy would likely prompt the administration of induction chemotherapy, and not many surgeons performed VATS lobectomy after induction, as shown by the relatively small number of patients receiving neoadjuvant treatment in this series.

As the registry collects detailed information on all technical aspects of VATS lobectomy, a great number of variables could be tested in the statistical model (Table 3 and Supplementary Material Tables S1 and S2).

Table 3: Multivariate analysis

	Postoperative complications							
	Any grade				G3–G5			
	Univariable		Multivariable		Univariable		Multivariable	
	P-value	OR	95% CI	P-value	P-value	OR	95% CI	P-value
Gender								
Female		1						
Male	<0.001	1.404	1.201–1.641	<0.001	<0.001			
CCI								
0–3		1				1		
4	0.004	1.296	1.051–1.599	0.015	0.38			
5–6	<0.001	1.728	1.428–2.091	<0.001	<0.001	1.622	1.123–2.341	0.011
7+	<0.001	2.467	1.943–3.131	<0.001	<0.001	2.074	1.352–3.181	0.001
%ppoFEV ₁	0.001				0.001	0.992	0.987–0.998	0.006
Blood loss (ml)								
<100		1				1		
101–200	0.002				0.036			
>200	<0.001	1.561	1.237–1.969	<0.001	<0.001			
Centre volume								
50–100		1						
101–200	0.051				0.42			
>200	<0.001	0.693	0.554–0.868	<0.001	0.033			
Procedure (lobe)								
RUL		1				1		
LLL	<0.001	0.608	0.486–0.761	<0.001	<0.001	0.348	0.212–0.572	<0.001
RML	<0.001	0.532	0.379–0.748	<0.001	0.006	0.438	0.213–0.900	0.029
Operative time (minutes)								
≤140		1				1		
140–180	0.38				0.38	1.034		
180–220	0.001				0.002	1.548	1.001–2.393	0.049
220–540	<0.001	1.343	1.069–1.687	0.011	<0.001	1.781	1.171–2.707	0.007
Conversion								
No		1				1		
Yes	<0.001	1.429	1.118–1.826	0.004	<0.001	1.676	1.153–2.436	0.007
Wound retractors								
No		1				1		
Yes	0.21	0.772	0.658–0.906	0.002	0.27	0.723	0.545–0.958	0.024
Pleural adhesions								
No		1				1		
Yes	<0.001	1.422	1.192–1.696	<0.001	<0.001	1.959	1.46–2.616	<0.001
Sealants								
No		1				1		
Yes	<0.001	1.199	1.020–1.408	0.027	0.002			
Pain control								
I.V. only		1				1		
Intercostal block	0.38				0.14			
Epidural	0.003	1.384	1.103–1.736	0.005	0.002	1.875	1.191–2.953	0.007
Bronchoscopy								
Negative		1				1		
Positive	<0.001	1.394	1.095–1.775	0.007	0.002	1.722	1.155–2.567	0.008
Pathology								
Adenocarcinoma		1				1		
Squamous	<0.001				<0.001	1.732	1.244–2.412	0.001
Carcinoid	<0.001				0.23			
Benign	0.19				0.79			
Other	0.64				0.52			

CCI: age-adjusted Charlson comorbidity index; CI: confidence interval; I.V.: intravenous infusion; LLL: left lower lobectomy; OR: odds ratio; ppoFEV₁: percent-predicted postoperative forced expiratory volume in 1 second; RML: right middle lobectomy; RUL: right upper lobectomy.

No significant difference in postoperative morbidity rates was observed in relation to the number of surgical ports, suggesting that uniportal or biportal approaches are comparable to the classic 3-portal anterior approach with respect to postoperative morbidity.

Systematic lymphadenectomy and the number of N1 and N2 lymph nodes harvested were similarly not linked with higher

morbidity rates, a finding that supports the notion that hilar nodal dissection can be performed adequately and safely by VATS [15–17].

Additionally, we could not find any significant difference in complication rates with the use of 1 vs 2 chest drains, or with a large bore (28–32 Fr.) versus smaller bore chest tubes.

On the contrary, soft-tissue retractors were associated with a reduced risk of complications. We hypothesize that their use might reduce the need for repeated camera cleansing causing less fatigue and stress within the surgical team.

Energy devices were not associated with an increased or reduced risk of complications, but their use saves some time and effort, therefore, surgeons can elect to make use of them or not, depending on time constraints and financial considerations [18].

The use of sealants was instead associated with a higher probability of complications in this series, which may be due to a 'selection by indication' bias, i.e. their preferential use in patients who are intraoperatively perceived to be at higher risk, such as after a difficult dissection, or those with emphysematous lungs (data not captured in the registry).

Epidural analgesia was also associated with an increased postoperative complication rate in this analysis. Once again, a selection bias may be present. Nonetheless, it is also possible that procedural morbidity of epidural analgesia (albeit generally mild) may surpass its expected benefits after a relatively less painful, minimally invasive procedure [19, 20]. Further investigation is warranted on this important aspect of postoperative care after VATS lobectomy.

Limitations

The main limitations of this study lie in its retrospective nature and absence of a control arm; exclusion of open lobectomies from the registry precludes any comparison with traditional surgery. Moreover, the database does not capture information on case-volume per single surgeon. As caseload may be unevenly distributed within a unit, these data may not accurately reflect the effect of case-volume. However, low-volume surgeons in an intermediate- or high-volume unit may benefit from obtaining support from experienced staff. Additionally, Birkmeyer *et al.* [21] showed that surgeon volume is a relatively less powerful determinant of perioperative mortality after pulmonary lobectomy compared with other surgical cancer procedures. By extrapolation, centre case-volume may be more relevant than individual caseload in relation to perioperative outcomes, due to a system effect.

The plus points of this study are that a large amount of data was available from a large series of cases on virtually all aspects of VATS lobectomy. Information on the baseline status was carefully collected in a prospective fashion and used to construct the age-adjusted CCI, a reproducible and validated measure independently linked to short and long-term outcomes in lung cancer patients [22]. And postoperative morbidity data were collected and classified according to the comprehensive and reproducible thoracic morbidity and mortality system, based on the entity of the countermeasures taken to restore the patient's clinical course towards normal [7, 23].

Comparisons of early postoperative outcomes among surgical patient cohorts are, in fact, hampered by a lack of standards in reporting on baseline status and postoperative morbidity, with several classifications adopted in the literature [4, 24].

Such variability can have consequences in the interpretation of data: in 2 recent studies [25, 26], 45–62% of major cardiopulmonary complications according to the ESTS classification were reclassified as minor ones by the TM&M system, and in such cases the postoperative course and length of stay were significantly shorter than in those that remained 'severe' by

both systems. The TM&M classification may, therefore, allow a better estimate of the financial impact of postoperative complications [27].

CONCLUSIONS

In conclusion, this analysis supports the notion that VATS lobectomy can be considered a relatively safe procedure even in compromised patients.

Conversion to unplanned thoracotomy leads to an increased risk of postoperative complications and a case-volume of 100 procedures at least, carried out in a centre during the observation period was associated with lower conversion rates and reduced postoperative complications.

An improved classification system for conversions is proposed, based on which it is suggested that a systematic preoperative assessment of the local anatomy based on 3-dimensional-CT reconstructions [28] or even 3-dimensional-printed models [29] should be investigated as a strategy to reduce operating time, conversions and possibly complication rates after VATS lobectomy.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *EJCTS* online.

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