ESTS DATABASE ANNUAL REPORT 2013

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PRODUCED BY THE ESTS DATABASE COMMITTEE

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Message from the President of ESTS

Dear Members,

Hereby you will find the 2013 annual report on the ESTS database, the fourth in its current form presented as the "Silver Book". I would like to thank Pierre-Emmanuel Falcoz, Director of Database and Alessandro Brunelli, Secretary-General, and all members of the Database Committee who have worked hard to analyse the data and to produce this annual report. I also would like to thank all thoracic units and their data managers for the countless hours they have spent to upload and update their data. I am also happy to see that following France, other national societies have plans to use the ESTS database as their national register so all thoracic surgical data can be uploaded at once for their country. We acknowledge the professional help of Dendrite Clinical System Italy and the financial support by Medela in managing the database.

The ESTS Database was established by Richard Berrisford in 2001 as an initiative for quality improvement and patient safety among European Thoracic Surgeons. Since then, it has grown considerably over the years to include now a total of 56,656 procedures providing clinical information on more than 43,330 lung resections. Data input on other thoracic procedures is also increasing. The ESTS database was recently updated to include more fields on surgical treatment for thymic tumors. Further expansion of data fields to capture outcome after oesophageal resections is to be expected in the coming year based on a proposal by the ESTS Ad Hoc Committee for Oesophageal Surgery. To date, 235 units throughout Europe are sending in data on their patients on a voluntary basis.

Recently, close cooperation was established with the Society of Thoracic Surgeons to create standardizations in nomenclature and variables between both the STS and the ESTS databases so that outcome after thoracic surgery can be compared between the USA and Europe (picture showing Cameron Wright [STS] and Alessandro Brunelli [ESTS] at the 2012 STS meeting in San Francisco).

To assess surgical performance on an international level is one of the main objectives of the database. Under the leadership of Alessandro Brunelli, the ESTS has developed a composite performance score incorporating process and outcome measures available in the database. Those Units that are above the 50th percentile of the composite score are invited to submit their application to the ESTS Institutional Accreditation Program. An audit by an independent professional company (Adamas) is done on site for those Units that apply for Accreditation by ESTS. The hospital, departmental, and professional criteria to be fulfilled, are listed at the end of this report. Since 2011, five units have successfully obtained the ESTS accreditation certificate (University Hospital, Antwerp, Belgium; Ospedali Riuniti, Ancona, Italy; University Hospital, Salamanca, Spain, Hospital Sagrat Cor, Barcelona, Spain; Istanbul University, Turkey). Other Units have recently been audited and their accreditation is pending.

The ESTS database also offers solid grounds for clinical research. To date a dozen of publications has arisen from the ESTS database. Recently, a cohort study on prognostic factors in more than 2000 surgically treated thymoma patients was submitted to Journal of Clinical Oncology. The ESTS database offers a unique scientific platform for other working groups interested to study specific variables on various topics in the field of thoracic surgery to guide our current practice based on recent knowledge.

This ESTS annual database report is another prove that our society is fulfilling its mission statement *to improve quality in all aspects to the benefit of your specialty, your practice, and your patients: from clinical and surgical management of patients to education, training, and credentialing of thoracic surgeons in Europe and worldwide.*

Dirk Van Raemdonck, MD, PhD, FETCS
ESTS President
president@ests.org.uk

Message from the Director of ESTS Database

Dear ESTS members,

This is the fifth annual report of the ESTS Thoracic database, called "Silver Book". This year collection of data ranges from July 2007 to March 2013, in 235 contributing units throughout Europe. It provides the most current appraisal of the thoracic surgical activity in Europe, in the framework of a comprehensive, European-wide, population dataset.
The aim of the report is to provide an "epidemiologic" overview of thoracic surgery activity in Europe. The structure of the current report remains roughly the same as the fourth previous one's. The main focus still remains on lung resections, considered as the most representative procedures of our specialty (and those currently under consideration for the European Accreditation program) but we also added some cumulative trend analysis over time in the entire database. As will be seen from the following pages, the current report is divided in two parts.
The first section (Part 1) focuses on the overall European database cumulative thoracic surgical activity from 2007 (when the internet version has been launched) to 2012. This section is split in three main chapters providing epidemiologic information on: 1°) total surgical activity; 2°) lung resection as a whole; 3°) primary lung cancer surgery. At the end of the first part, we report a comparison of outcomes between 2007-2009 versus 2010-2012 on the total dataset, in terms of 30-day mortality and prolonged air leak.
The second section (Part 2) deals with nation-specific activities and comparative analysis between contributing countries. This section is split in two chapters: the first one shows the distribution of patients (proportion of elderly, measurement of preoperative DLOC, percentage of mediastinal staging, e.g.) in the contributing countries whereas the second chapter focuses more specifically on primary lung cancer surgery per contributing nations. Last but not least, an unadjusted and risk-adjusted outcomes rate of in-hospital mortality is presented.

Why should thoracic surgeons be concerned with databases?
All the data and outcome measures presented in this report is of the highest international standard. However, the assessment of outcomes in thoracic surgery is difficult because there are no clear measures of success. For example, 30-day mortality is an imperfect surrogate for the risk of death attributable to surgery. Treatment-related mortality should preferably include all deaths occurring as a consequence of the operation, whatever the time span from surgery to patient's death.
In this report we looked at variations in activity and surgical approach within the ESTS database. It highlights several interesting points (see key points on page 11) but one is of major importance: 30-day mortality has decreased by two along the study period to currently reach the international standard (2.4% for the period 2010-2012). This point provides some encouraging evidence that outcomes measured with feedback programs, benchmark tool and self-assessment capabilities – such as the European database – are effective in improving surgical safety and patient care. In other words, the longer the participation in the ESTS database for a given surgeon (or unit), the better the outcome for a given patient.

Where do we go next in the burgeoning field of data collection in Europe?

The database committee will promote in the coming year the following actions:

1. Continue the expansion of the dataset by including other thoracic procedures (esophageal surgery is to come) but also revising the variables of the dataset to be able to provide a risk assessment for in-hospital mortality based on the Thoracoscore *(J Thorac Cardiovasc Surg 2007)* for each ESTS database patients;
2. Promote the integration of data in the ESTS database. This particular point deserves mention. Following the fruitful example of France, data input is also encouraged via national registries;
3. Promote clinical research within the ESTS database;
4. Favor collaboration between ESTS and the Society of Thoracic Surgeons on the general thoracic database issue (work on process on standardization of nomenclature);
5. Link social ID number to long-term evaluation for the 5-year assessment;
6. Educate database participants and managers. The results of the audit should be incorporated into educational and quality improvement process;
7. Welcome international (outside of European Union) participants;
8. Finally, the ESTS database Committee main goal is to achieve a progressive evolution from morbidity and mortality to total quality management. In other words, within the ESTS database, data should be analyzed over a long-term period with trending, allowing to modulate short-term variation and provide the ability to assess change over time.

We hope that this publication will stimulate debate not only on quantity of procedure but also on safety and quality of surgery!

We need to go forward together! Let's make our dreams come true...

Prof. Pierre-Emmanuel Falcoz
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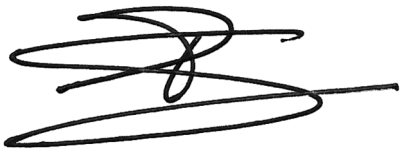


THE EUROPEAN SOCIETY OF THORACIC SURGEONS DATABASE

The European Society of Thoracic Surgeons Database was founded in 2001 by the ESTS Database Committee with the aim to develop risk-adjusted instruments for assessing the performance of thoracic surgery units across Europe. The first version of the Database lead to the publication of the first risk-adjusted multinational risk-score for mortality *(Berrisford R et al. Eur J Cardiothorac Surg 2005; 28:305-311)* which has been already applied to compare the performance of different units *(Brunelli A et al. Eur J Cardiothorac Surg 2008; 33:284-288)*.
The second version of the Database was launched online in July 2007 and has so far accrued approximately 235 general thoracic surgical units. **Data is anonymously reported, independently accessed and encrypted to other users**.
Participation to the Database project is **totally free and voluntary**, but strongly recommended by our Society. You can access the Database from ESTS website or by using the address: https://ests.dendrite.it/csp/ests/intellect/login.csp. To join the Database you need your own personal login account that you can request by downloading and completing an application form from the ESTS homepage (http://www.ests.org).

To the benefit of your patients, your practice and your specialty, your data will contribute to the followings:

- Development of European benchmarks of performance through the analysis of outcomes and processes of care indicators.
- Performance assessment by risk-adjusted outcome and/or process indicators, which will allow you to compare your own institutional performance against European benchmarks.
- Analysis and development of new potential outcomes and processes of care indicators that may complement/substitute current quality of care measures.
- Implement a provider-led quality monitoring and improvement program with the aim to improve your practice.
- Feedback to document quality efforts and areas for improvement in quality of care.
- Data for research projects, which can be used to assess new technologies/pathways of care that can ultimately lead to improved patient care and outcomes.
- Maintain your own data if data is requested or mandated by third parties.
- Use for local hospital administration resource allocation.
- Use for individual negotiations, public relations and expert witness.
- Opportunity to participate in a European quality improvement effort for general thoracic surgery that has a positive impact at the local, national and international levels.

Participants benefits

- Participation to the ESTS Database is a pre-requisite to participate in the European Institutional Quality certification program.
- Participation will be acknowledged and, if requested, local institutional administrations made aware that your unit is enrolled in a European Thoracic Database aimed at implementing quality of care

monitoring and improvement programs endorsed by ESTS and pre-requisite for future clinical Institutional European Accreditation.
- Your own data, collected in a standardized ESTS-endorsed Dataset, can be downloaded at local level and used for your internal quality analyses or institutional research purposes.
- As a future project, participants will receive a periodic confidential feedback on the quality of their data and their performance against International benchmarks.
- Participants can propose their own research projects based on the total data present in the database. Projects should be submitted to the ESTS database Committee for peer review and, if accepted, the requested and anonymized data will be provided to the proponent of the project. ESTS will retain the responsibility for the final analysis and interpretation of results. The proponent of the project will be the first Author of the final manuscript and he/she will be allowed to include, if requested, additional two colleagues, who helped in the elaboration of the manuscript. The members of the Database Committee who contributed to the review process and assisted in the development of the manuscript will be also included in the list of Authors.

As the ESTS Database approached a more mature stage, and more demanding aspects of data management will be required, it has been decided to make use of professional expertise in running and managing contents, data flow, data merge and so on of our Registry; in Nov 2009 the ESTS Council awarded this task to Dendrite Clinical System Italia srl.

Since 1993 Dendrite has established a highly respected track record in setting up and running a variety of International Registries, with an underlying philosophy of long term partnership with numerous Clinical Associations within and outside Europe.

The main reasons for their widespread activity in this field include:
- Bottom-up approach to data management: the range of products and services starts from database and electronic patient records and serves Clinicians daily needs; it escalates to hospital-wide systems, to regional, national and finally to international registries.
- User-friendly inclusion of all who wish to participate: Import Data Module allows any Contributor to use his chosen type of tool to collect data, and Dendrite will perform the correspondence and data merge required to add their data to the main ESTS Database, if there is conformity with the required dataset.
- Fool-proof suite of clinical statistical analysis integrated in the central data collection installation (server).
- Contributors can retain, download and use own data, from the ESTS site, in MS Excel format, which lends itself to be analyzed by any clinical software product.
- Unblemished track record of data handling integrity: not ever lost, leaked or misplaced third Party data to date.

KEY MESSAGES FROM THIS REPORT

1. The ESTS database is growing: from 45,937 procedures in 2012 to 56,656 in 2013. The database growth is a slow process, because it requires a change in prospective participants practice.

2. The majority of contributions to the ESTS database is direct from willing units and participants; only one nation (France) contributes to the database as a whole.

3. Completeness of the database is almost 100% in the major fields of the database, except for 30-day mortality.

4. The vast majority of ESTS database procedures is dedicated to lung surgery (n=45,446 patients), representing 80% of the procedures.

5. In lung resections, the proportion of VATS dramatically increases from 10.7% to 18.8% between 2007-2009 and 2010-2012. More specifically, VATS lobectomy increases from 2.7% to 11.3% between these two periods.

6. 30-day mortality of the entire ESTS database reaches 2.5% over the period 2010-2012, which corresponds to the international standards of other databases, such as the UK and USA.

7. 30-day mortality of the entire ESTS database decreased by 2 along the study period (2007-2012). This virtuous process implicitly means that "the longer the participation in the ESTS database, the better the outcome".

8. Observed versus predicted mortality rates after major lung resections shows important discrepancies among European countries.

9. Outcomes measured with feedback programs, benchmark and self-assessment capabilities – such as the ESTS database – are effective in improving surgical safety and patient care.

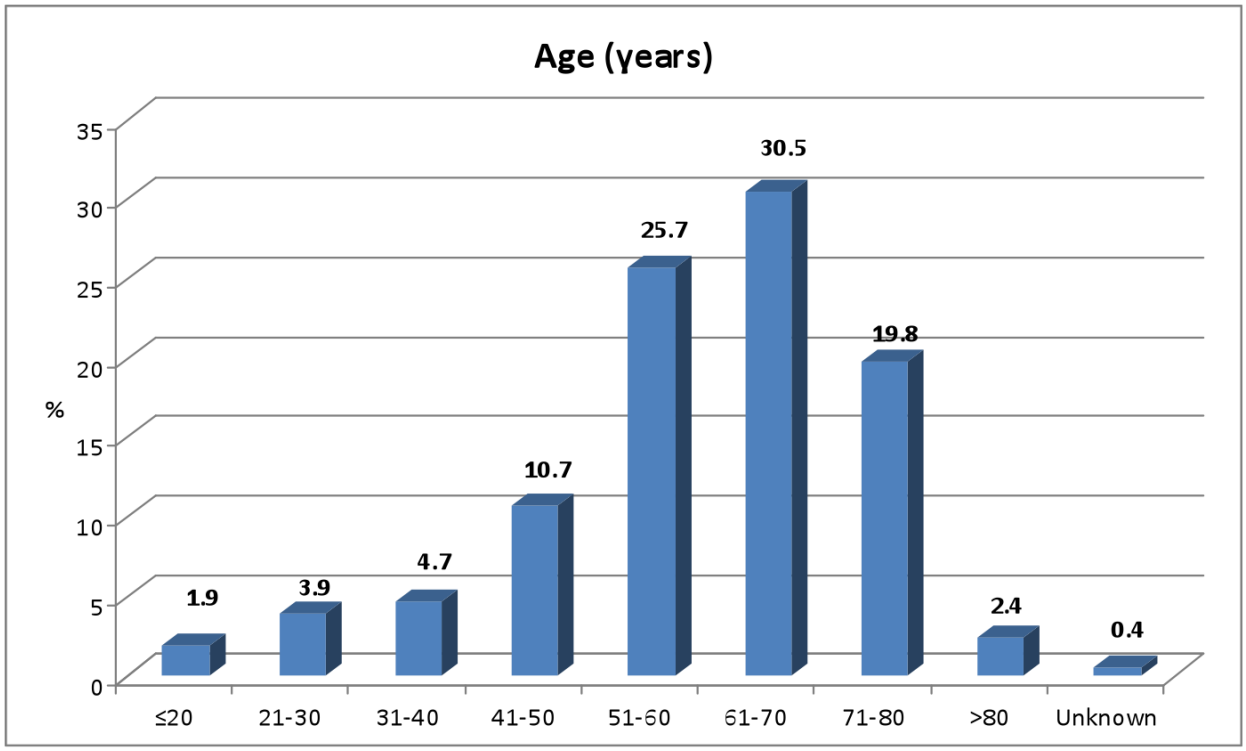
10. The ESTS database is a useful tool for surgeons as a benchmark of the thoracic surgical practice in Europe.

PART 1
EUROPEAN DATABASE CUMULATE ACTIVITY (2007-2012)

Overall age and gender distributions

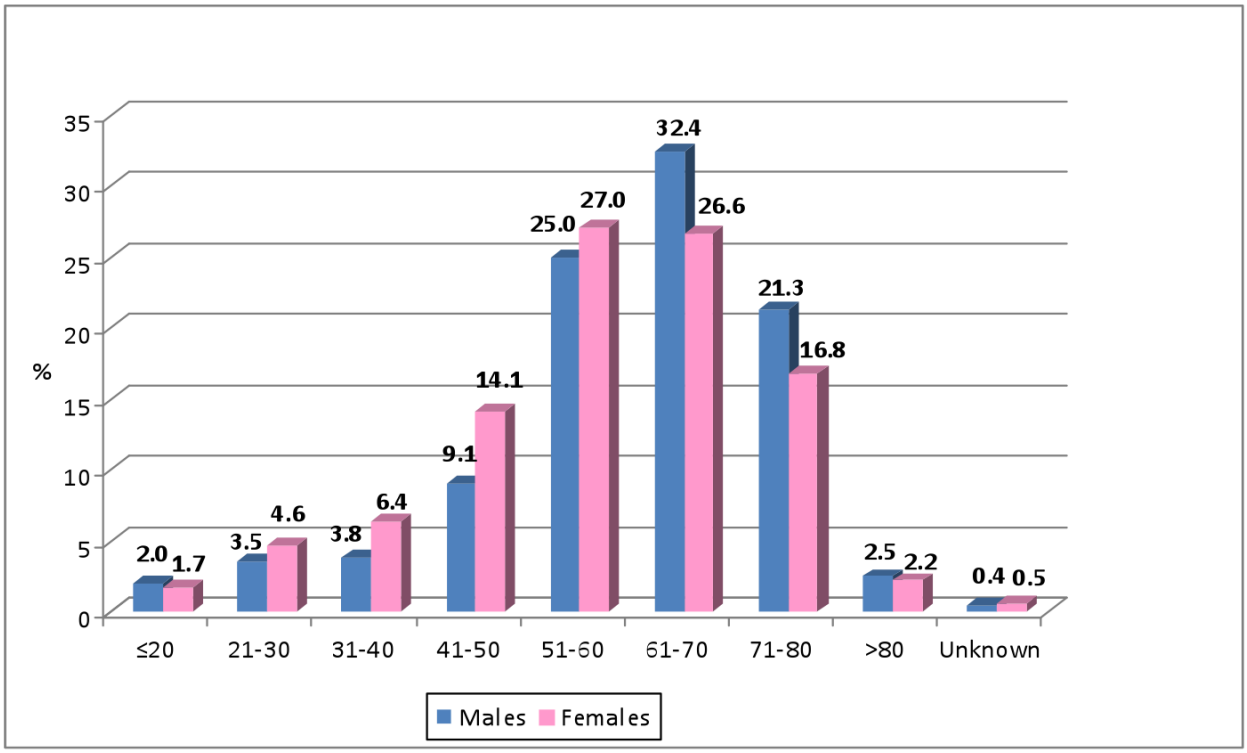
Age (years)

Answer	Occurrences	Percent
≤20	1066	1.9
21-30	2199	3.9
31-40	2651	4.7
41-50	6066	10.7
51-60	14552	25.7
61-70	17294	30.5
71-80	11222	19.8
>80	1359	2.4
Unknown	247	0.4
Total	**56656**	**100.0**



Gender according to age distribution (years)

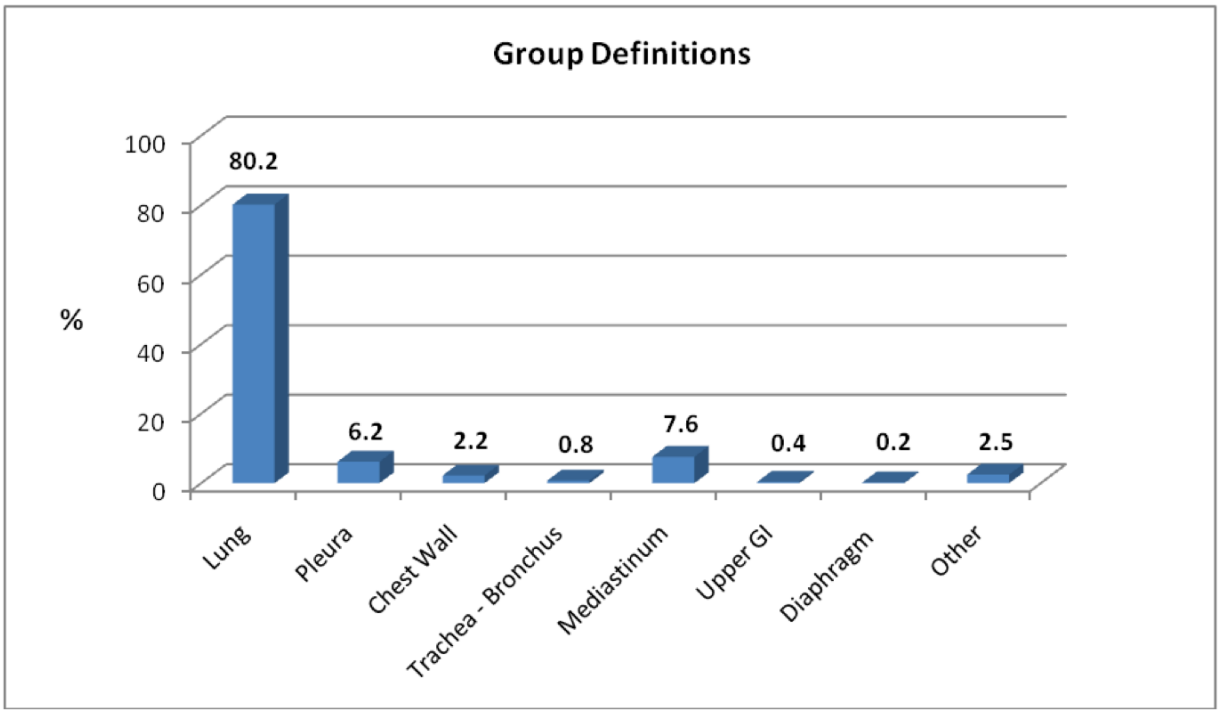
Answer	Males (%)	Females (%)
≤20	2.0	1.7
21-30	3.5	4.6
31-40	3.8	6.4
41-50	9.1	14.1
51-60	25.0	27.0
61-70	32.4	26.6
71-80	21.3	16.8
>80	2.5	2.2
Unknown	0.4	0.5



Total surgical activity within the entire dataset

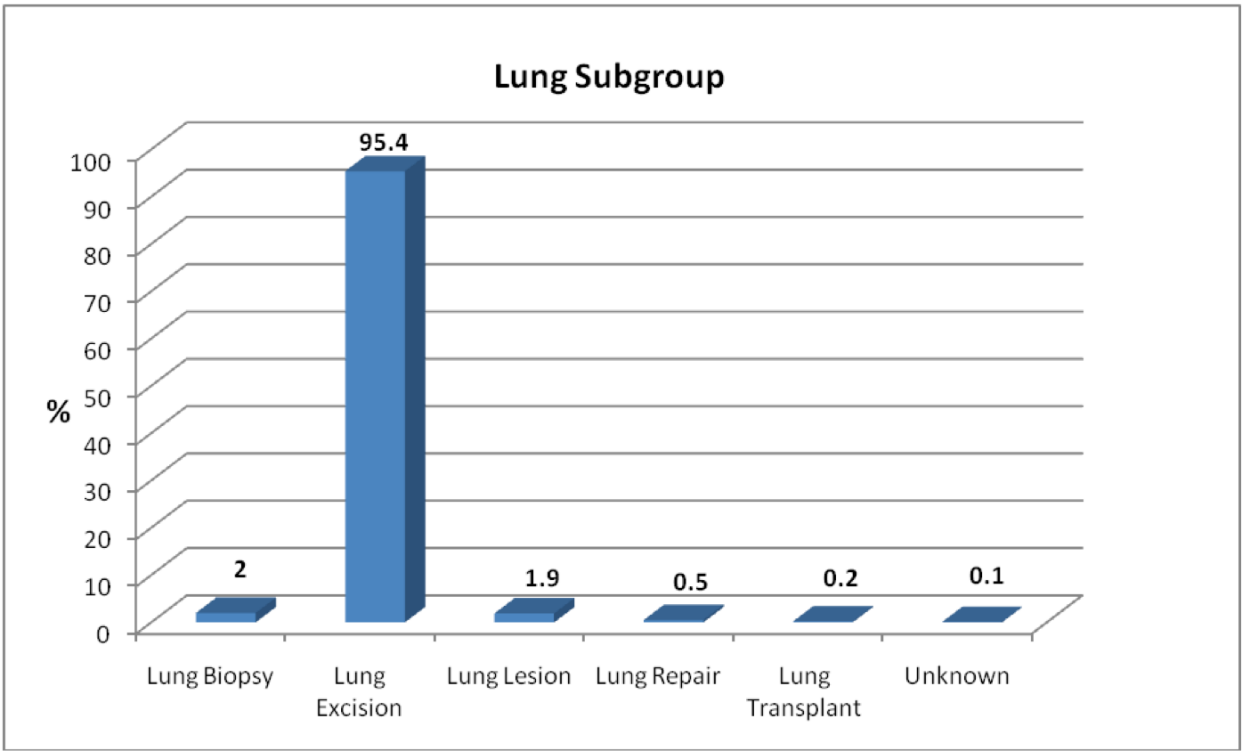
Group Definitions

	Occurrences	Percent
Lung	45446	80.2
Pleura	3509	6.2
Chest Wall	1219	2.2
Trachea - Bronchus	427	0.8
Mediastinum	4301	7.6
Upper GI	207	0.4
Diaphragm	115	0.2
Other	1432	2.5
Total	**56656**	**100.0**



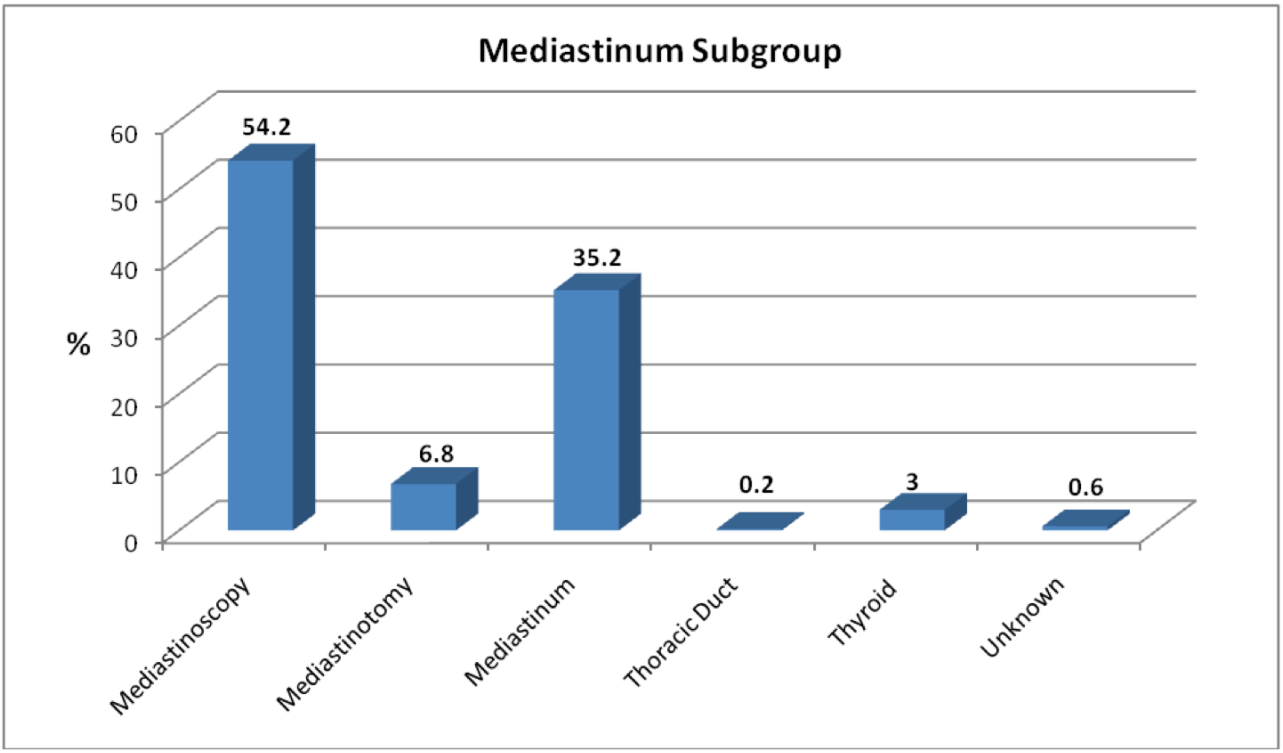
Lung Subgroup

	Occurrences	Percent
Lung Biopsy	909	2
Lung Excision	43333	95.4
Lung Lesion	870	1.9
Lung Repair	216	0.5
Lung Transplant	69	0.2
Unknown	49	0.1
Total	**45446**	**100.0**



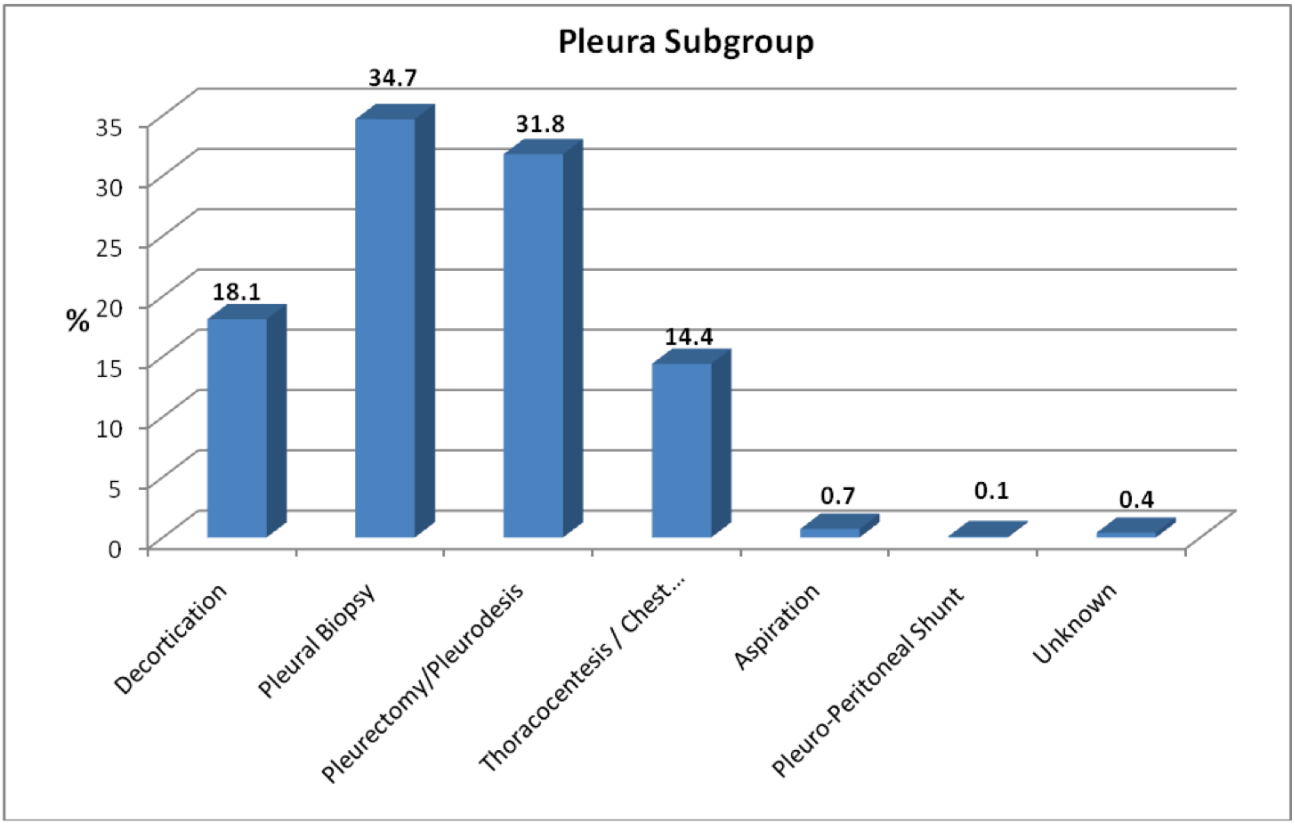
Mediastinum Subgroup

	Occurrences	Percent
Mediastinoscopy	2332	54.2
Mediastinotomy	294	6.8
Mediastinum	1514	35.2
Thoracic Duct	9	0.2
Thyroid	128	3
Unknown	24	0.6
Total	**4301**	**100.0**



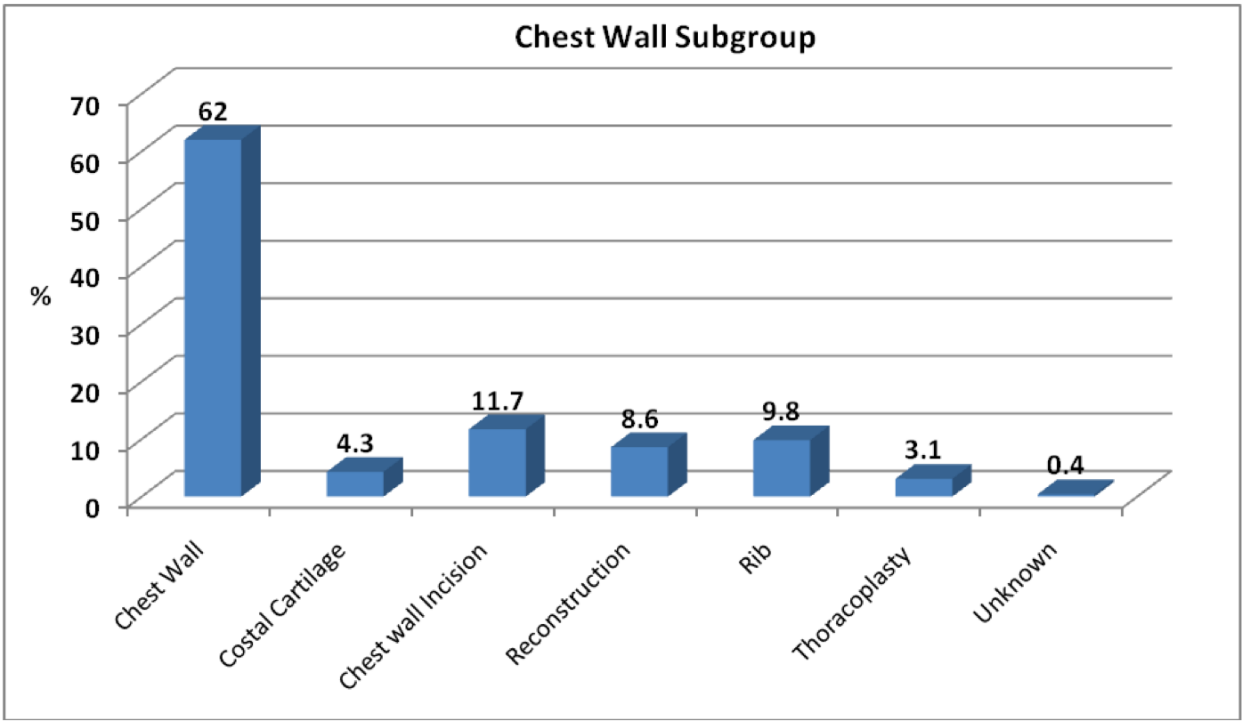
Pleura Subgroup

	Occurrences	Percent
Decortication	634	18.1
Pleural Biopsy	1216	34.7
Pleurectomy/Pleurodesis	1115	31.8
Thoracocentesis / Chest Tube	504	14.4
Aspiration	23	0.7
Pleuro-Peritoneal Shunt	2	0.1
Unknown	15	0.4
Total	**3509**	**100.0**



Chest Wall Subgroup

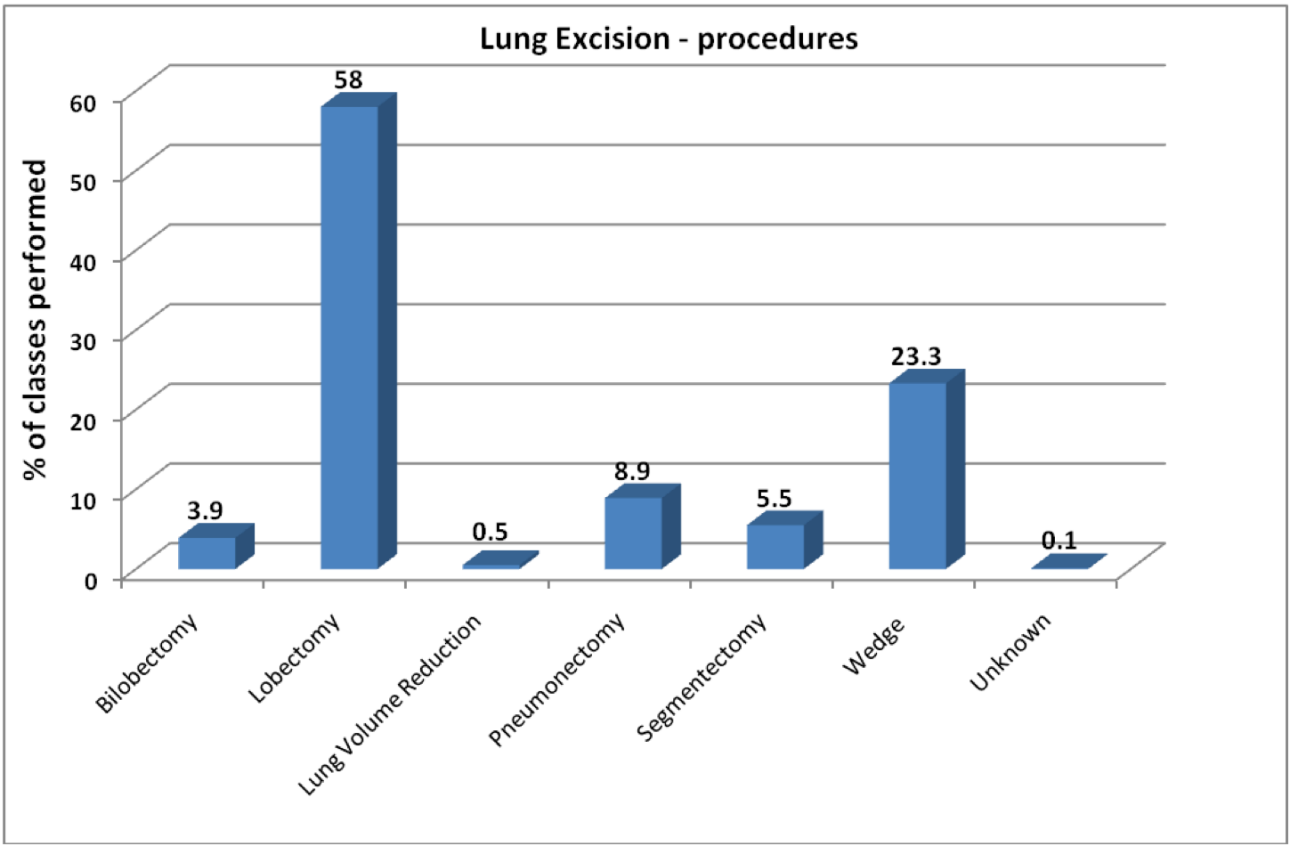
	Occurrences	Percent
Chest Wall	756	62
Costal Cartilage	53	4.3
Chest wall Incision	143	11.7
Reconstruction	105	8.6
Rib	119	9.8
Thoracoplasty	38	3.1
Unknown	5	0.4
Total	**1219**	**100.0**



Lung resections

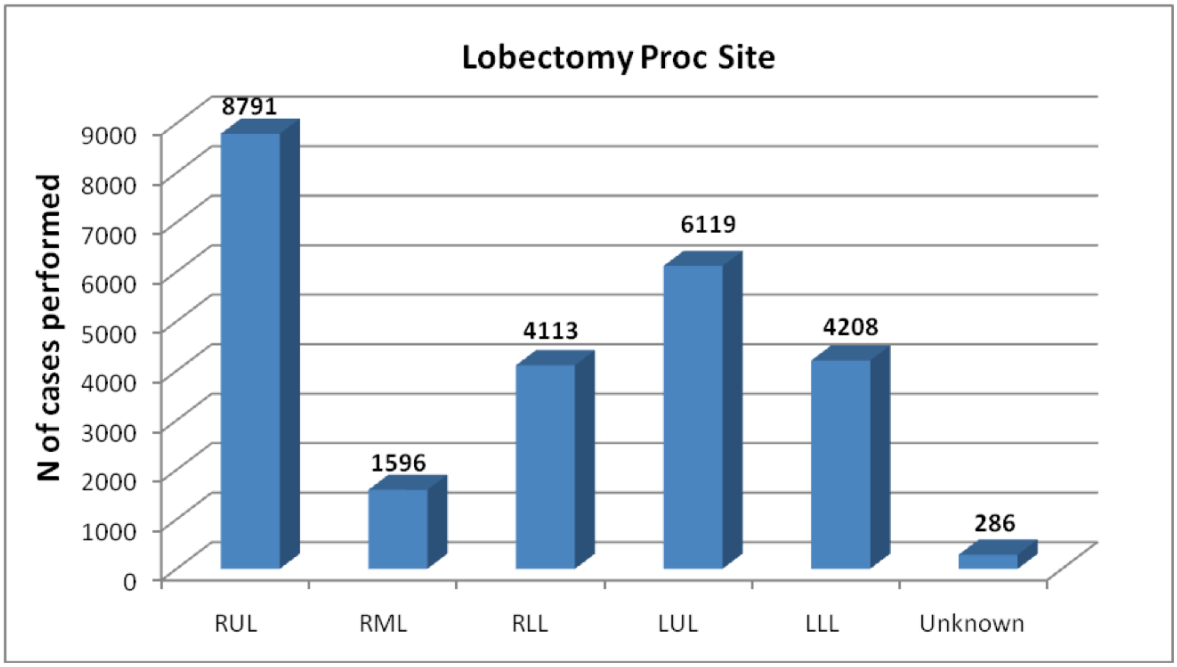
Types of lung resections performed, including all diagnoses

	Occurrences	Percent
Bilobectomy	1671	3.9
Lobectomy	25113	58
Lung Volume Reduction	196	0.5
Pneumonectomy	3843	8.9
Segmentectomy	2404	5.5
Wedge	10080	23.3
Unknown	26	0.1
Total	**43333**	**100.0**



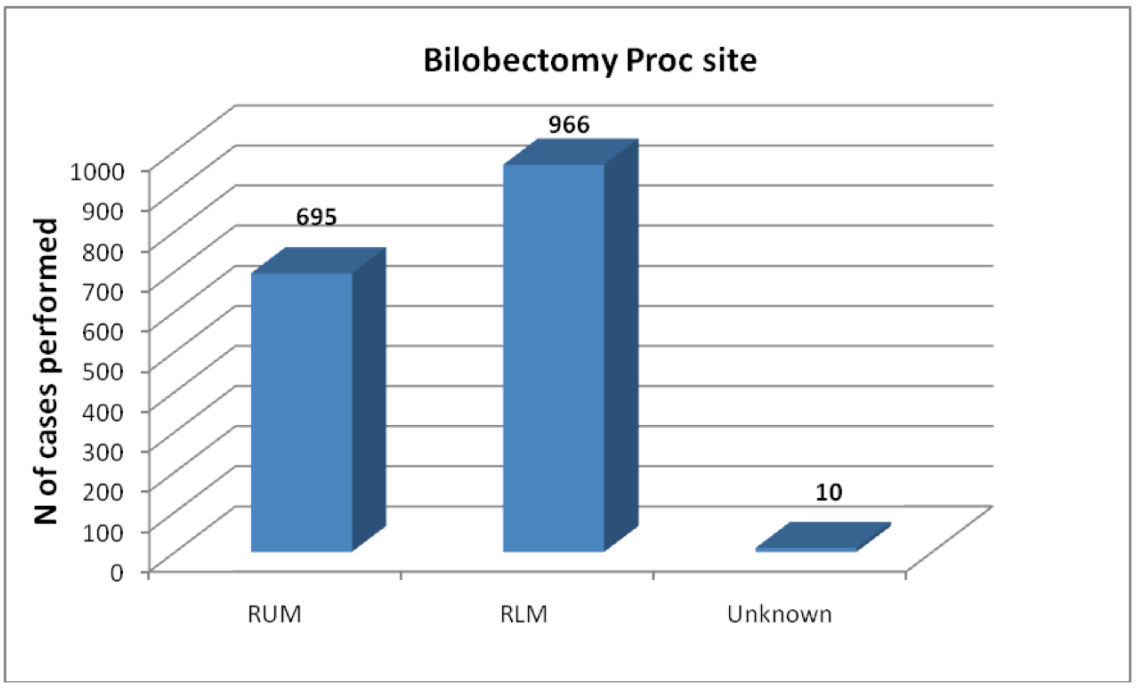
Distribution of lobectomy by site of resection

Lobectomy Procedure Site	Occurrences	Percent
RUL	8791	35
RML	1596	6.4
RLL	4113	16.4
LUL	6119	24.4
LLL	4208	16.8
Unknown	286	1.1
Total	**25113**	**100.0**



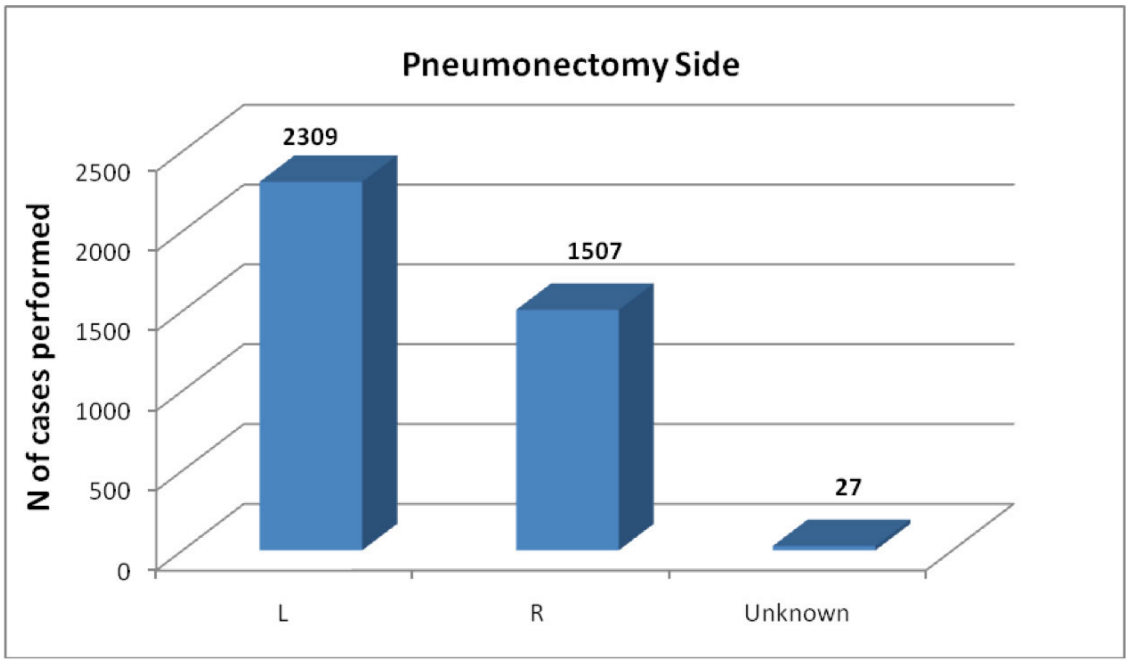
Distribution of bilobectomy by site of resection

Bilobectomy Procedure Site	Occurrences	Percent
RUM	695	41.6
RLM	966	57.8
Unknown	10	0.6
Total	**1671**	**100.0**



Distribution of pneumonectomy by side

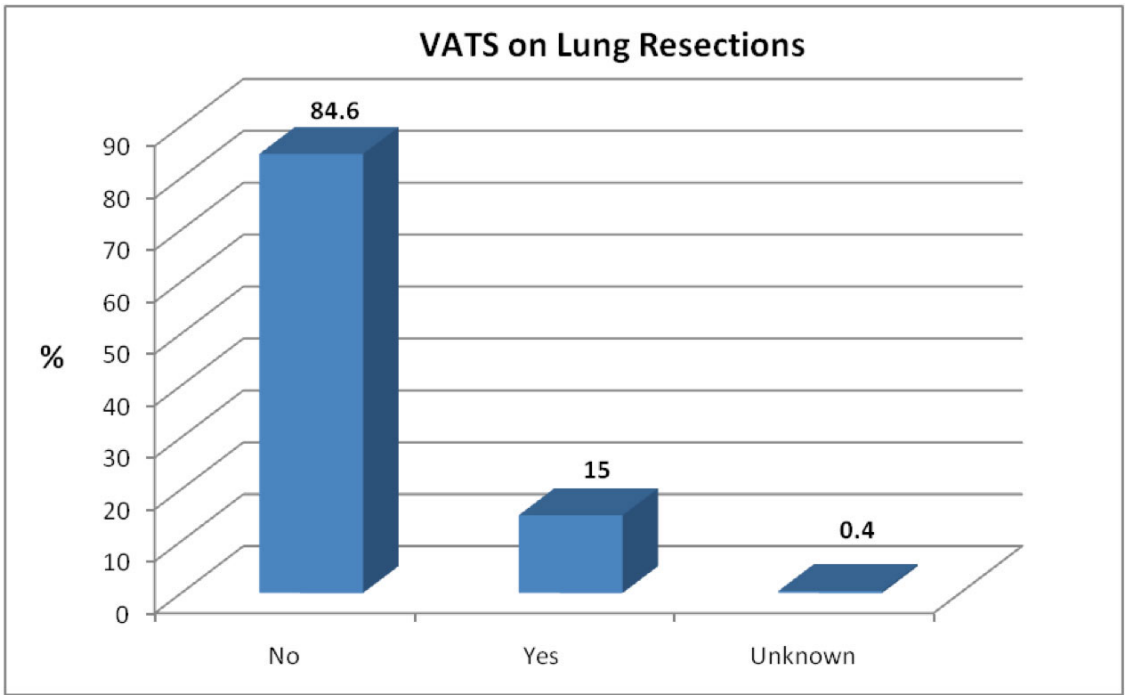
Pneumonectomy Side	Occurrences	Percent
L	2309	60.1
R	1507	39.2
Unknown	27	0.7
Total	**3843**	**100.0**



Pneumonectomy Qualifier	Occurrences	Percent
Alone	2425	63.1
Completion	124	3.2
Intrapericardial	305	7.9
Pleuropneumonectomy	171	4.4
Sleeve Resection	49	1.3
Diaphragm Resection	2	0.1
Atrial Resection	47	1.2
SVC Resection / Reconstruction	77	2
Vertebral resection	39	1
Unknown	604	15.7
Total	**3843**	**100**

VATS as a proportion of all lung resections

	Occurrences	Percent
No VATS (No)	36653	84.6
VATS (Yes)	6517	15
Unknown	163	0.4
Total	**43333**	**100.0**



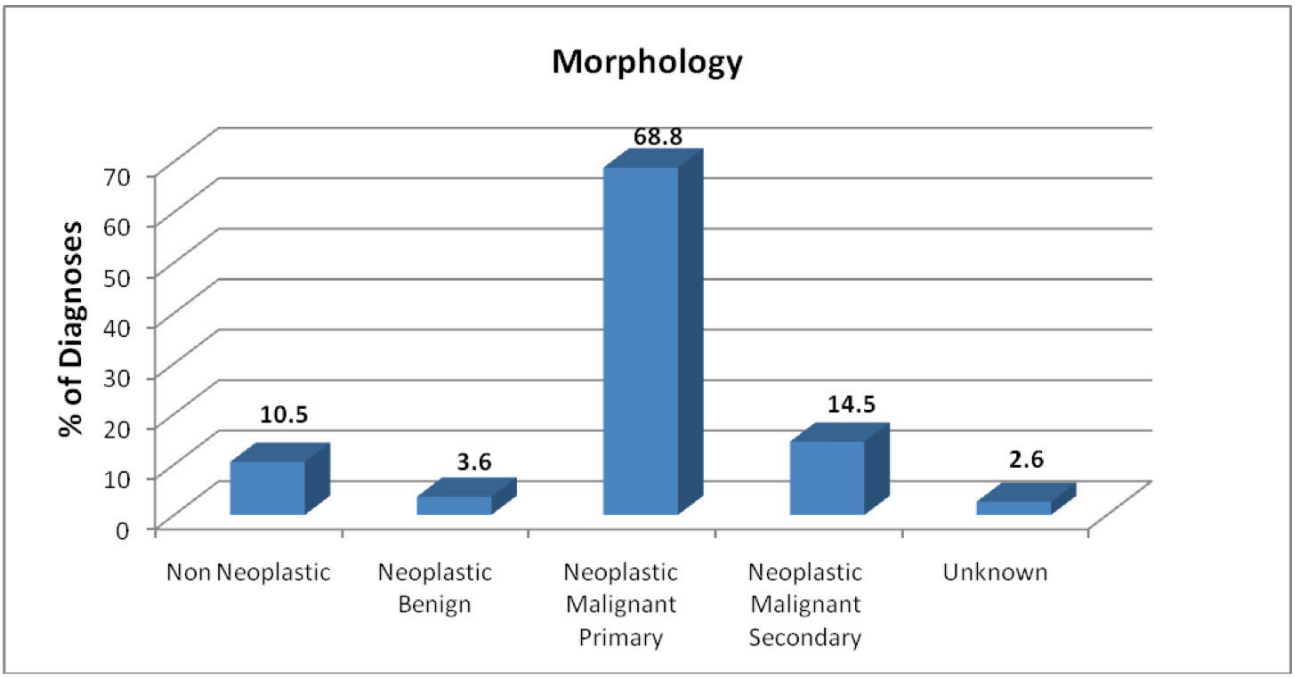
VATS	No	Yes	Yes (%)
2007 - 2009	17749	2121	10.7
2010 - 2012	18783	4361	18.8
Total	**36532**	**6482**	**–**

VATS as a proportion of lobectomy

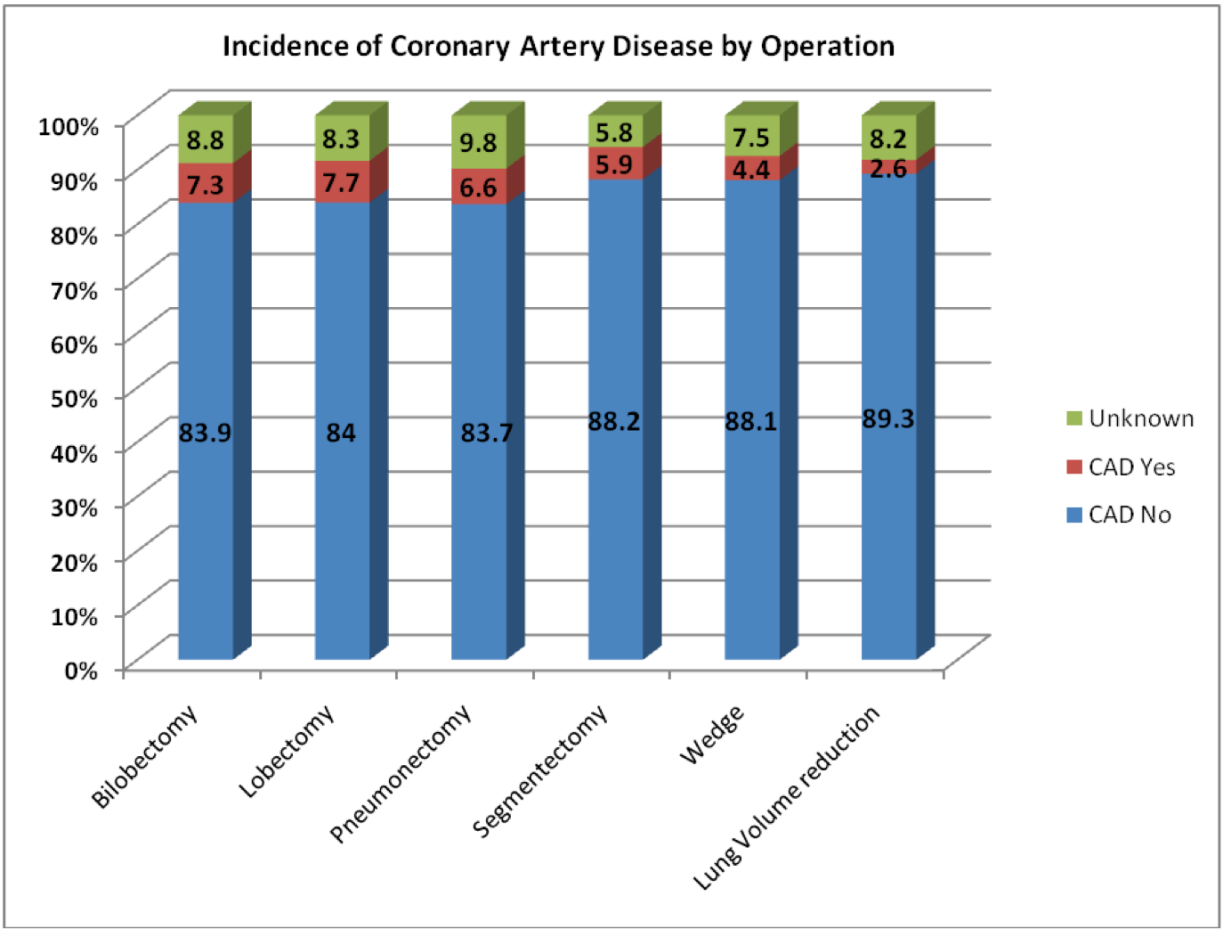
VATS	No	Yes	Yes (%)
2007 - 2009	11296	298	2.6
2010 - 2012	11884	1507	11.3
Total	**23180**	**1805**	**–**

Lung resections pathology

	Occurrences	Percent
Non Neoplastic	4553	10.5
Neoplastic Benign	1539	3.6
Neoplastic Malignant Primary	29824	68.8
Neoplastic Malignant Secondary	6269	14.5
Unknown	1148	2.6
Total	**43333**	**100.0**

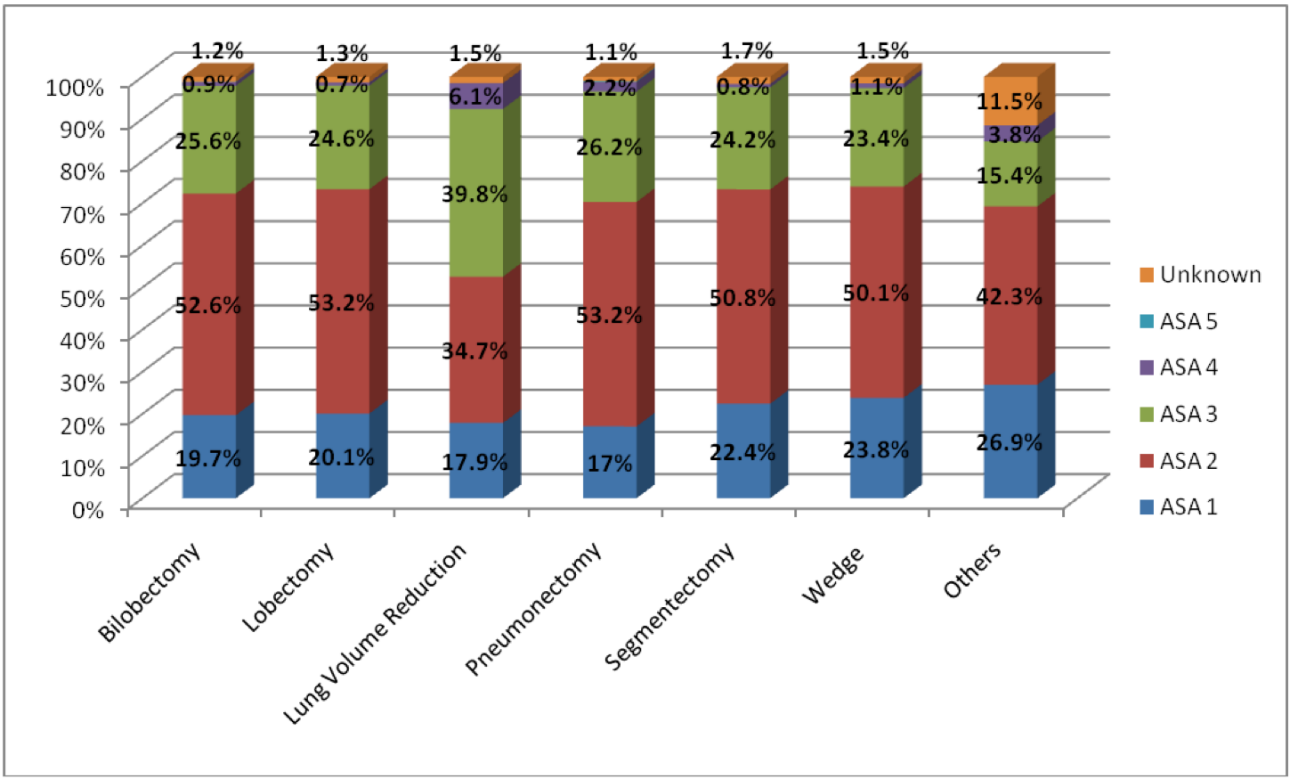


Incidence of coronary artery disease by procedure



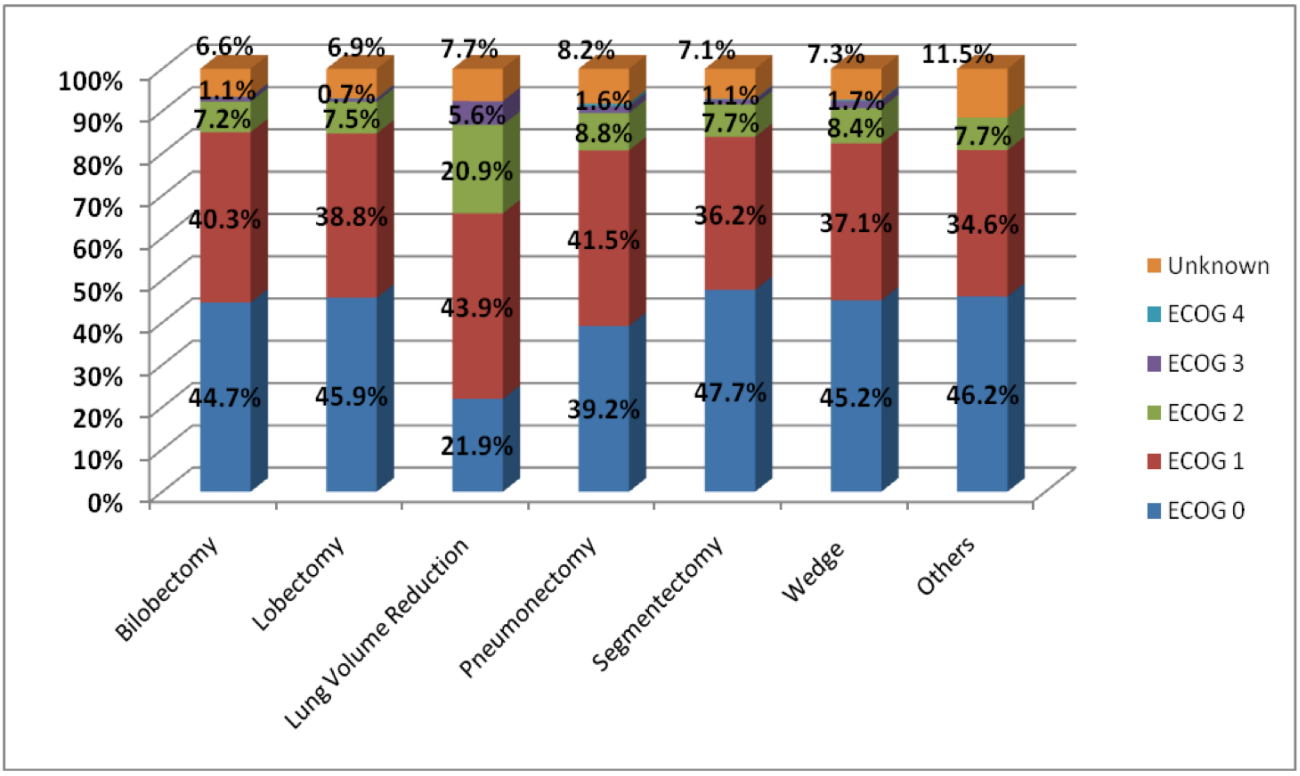
Lung Excision Procedure	CAD No	CAD Yes	Unknown	Total
Bilobectomy	1402	122	147	1671
Lobectomy	21093	1924	2096	25113
Pneumonectomy	3216	252	375	3843
Segmentectomy	2121	143	140	2404
Wedge	8878	448	754	10080
Lung Volume reduction	175	5	16	196
Others	10	0	16	26
Total	**36895**	**2894**	**3544**	**43333**

Distribution of ASA score by type of operation



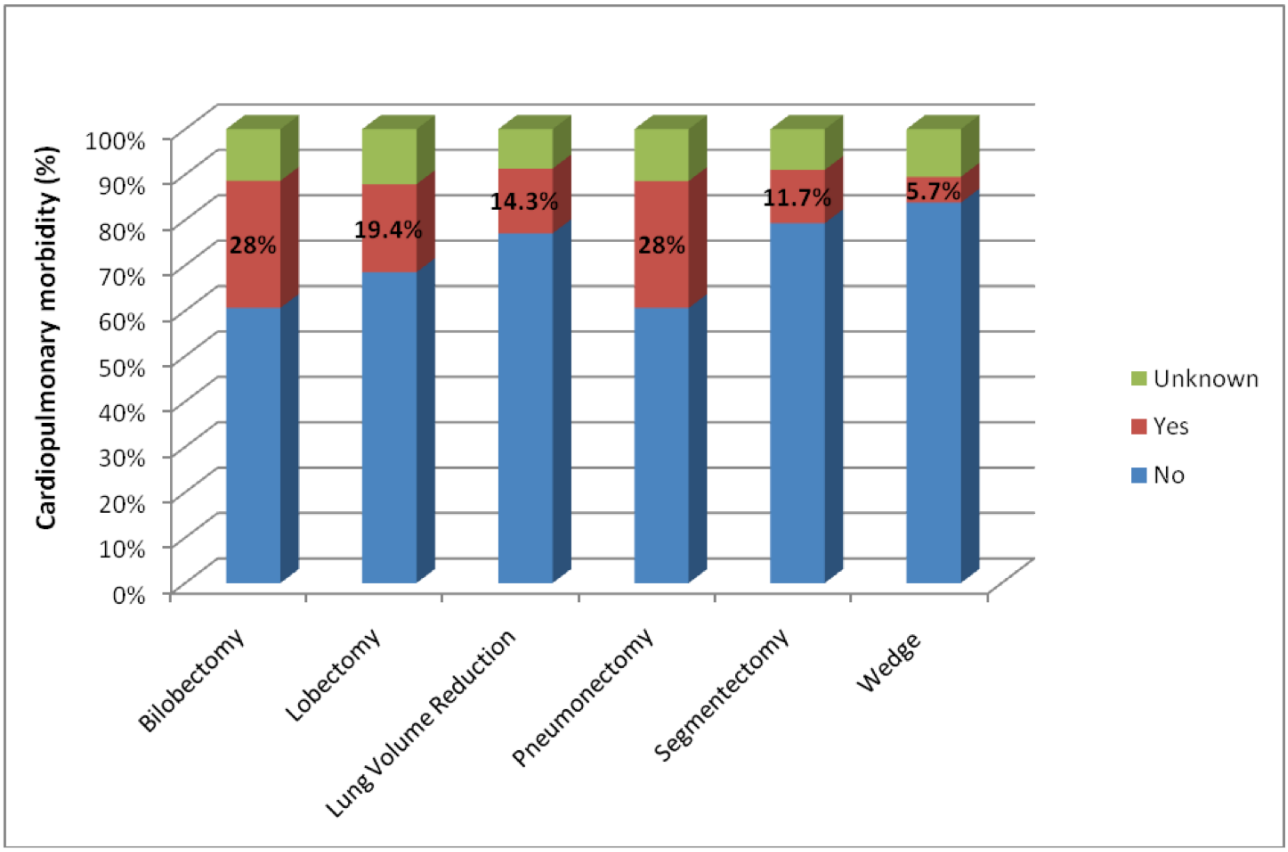
	ASA 1	ASA 2	ASA 3	ASA 4	ASA 5	Unknown	Total
Bilobectomy	329	879	427	15	1	20	1671
Lobectomy	5049	13364	6184	174	5	337	25113
Lung Volume Reduction	35	68	78	12	0	3	196
Pneumonectomy	655	2046	1007	85	8	42	3843
Segmentectomy	539	1222	582	20	0	41	2404
Wedge	2403	5052	2355	113	2	155	10080
Others	7	11	4	1	0	3	26
Total	**9017**	**22642**	**10637**	**420**	**16**	**601**	**43333**

Distribution of ECOG score by type of operation



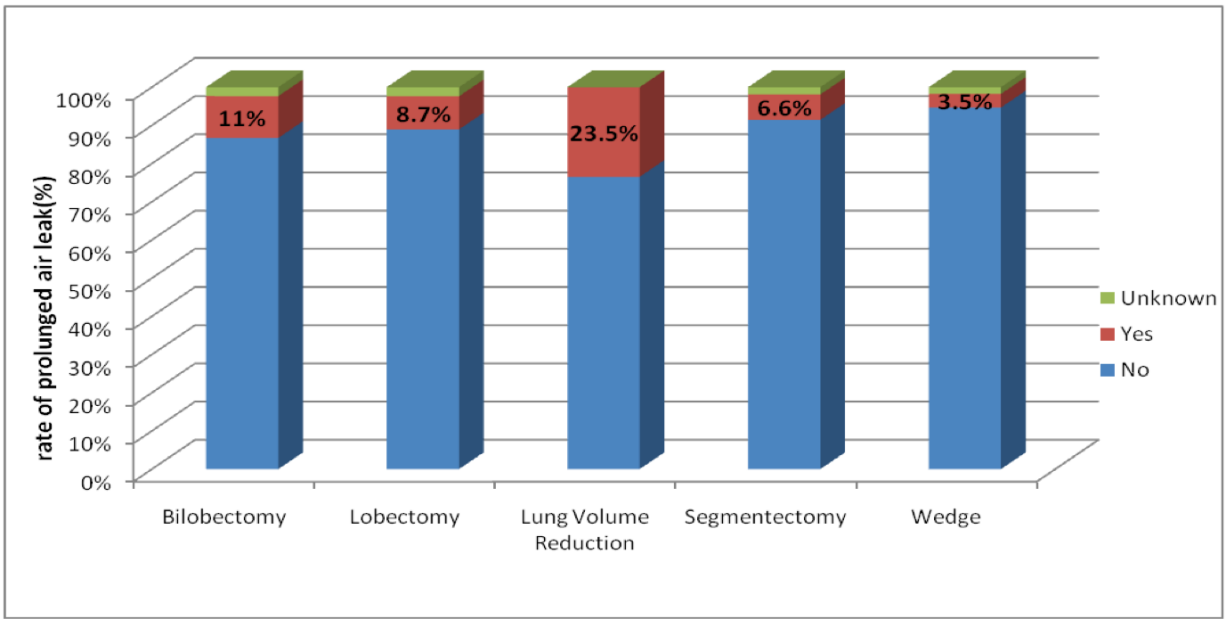
	ECOG 0	ECOG 1	ECOG 2	ECOG 3	ECOG 4	Unknown	Total
Bilobectomy	747	673	121	18	1	111	1671
Lobectomy	11520	9748	1886	188	34	1737	25113
Lung Volume Reduction	43	86	41	11	0	15	196
Pneumonectomy	1507	1595	339	62	25	315	3843
Segmentectomy	1147	870	185	26	5	171	2404
Wedge	4560	3742	842	170	30	736	10080
Others	12	9	2	0	0	3	26
Total	**19536**	**16723**	**3416**	**475**	**95**	**3088**	**43333**

Cardiopulmonary morbidity rate in different types of lung resections



	CM No	CM Yes	Unknown	Total
Bilobectomy	1013	468	190	1671
Lobectomy	17200	4869	3044	25113
Lung Volume Reduction	151	28	17	196
Pneumonectomy	2329	1075	439	3843
Segmentectomy	1906	282	216	2404
Wedge	8447	574	1059	10080
Unknown	2	8	16	26
Total	**31048**	**7304**	**4981**	**43333**

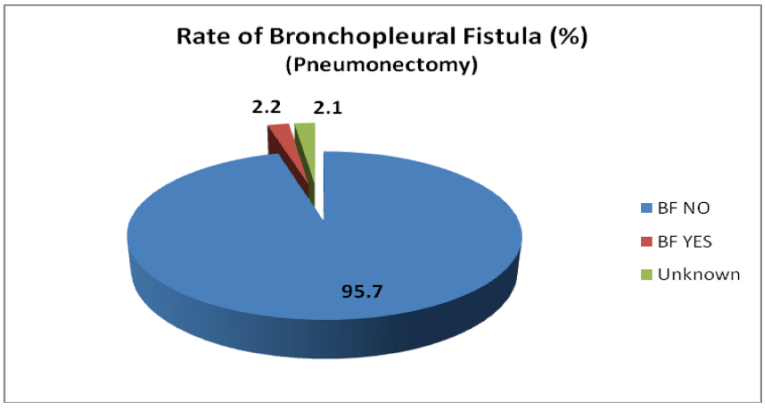
Incidence of prolonged air leak (> 5days) in different types of lung resections



Lung Excision - PROCEDURE	Air Leak > 5 days		
	No	Yes	Unknown
Bilobectomy	86.7%	11.0%	2.3%
Lobectomy	88.9%	8.7%	2.4%
Lung Volume Reduction	76.5%	23.5%	0.0%
Segmentectomy	91.5%	6.6%	1.9%
Wedge	94.7%	3.5%	1.8%
Total	**91.1%**	**6.8%**	**2.1%**

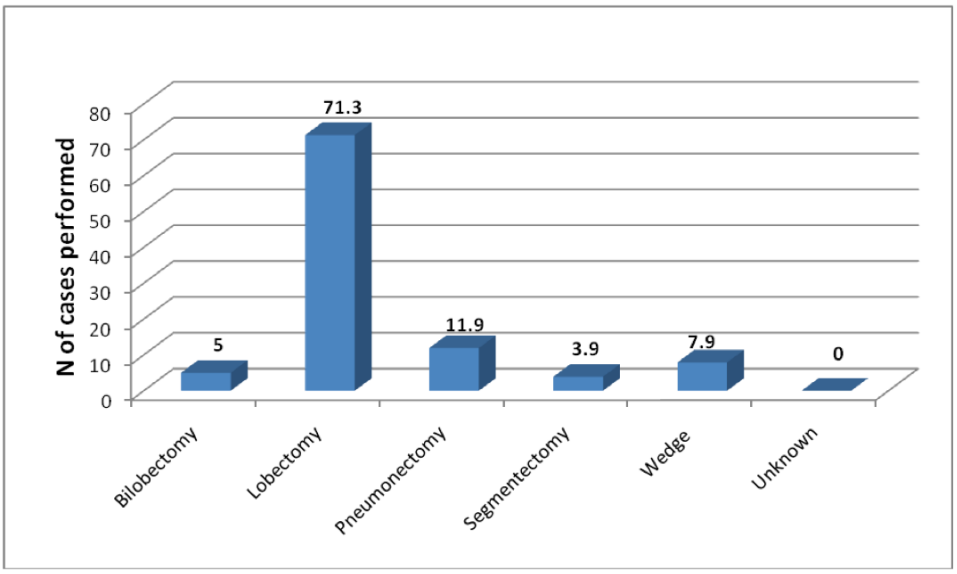
Incidence of bronchopleural fistula (BPF) in pneumonectomy

	BPF No	BPF Yes	Unknown	Total
Pneumonectomy (N)	3677	85	81	3843
Pneumonectomy (%)	95.7	2.2	2.1	100.0



Lung resection for primary lung cancer: Types of procedures

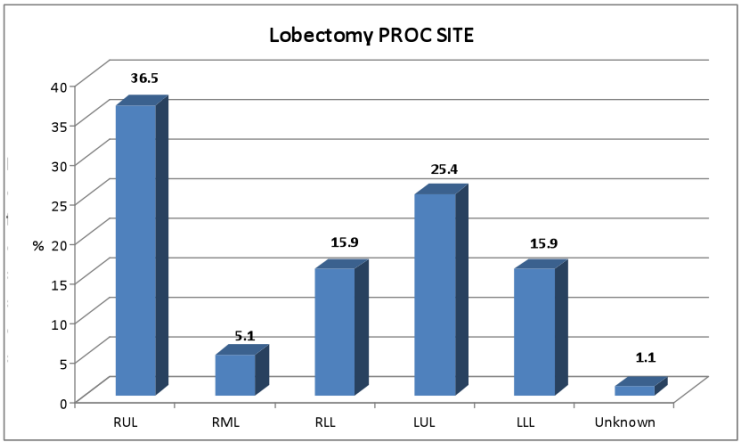
	Occurrences	Percent
Bilobectomy	1478	5
Lobectomy	21262	71.3
Pneumonectomy	3537	11.9
Segmentectomy	1170	3.9
Wedge	2363	7.9
Unknown	14	0
Total	**29824**	**100.0**



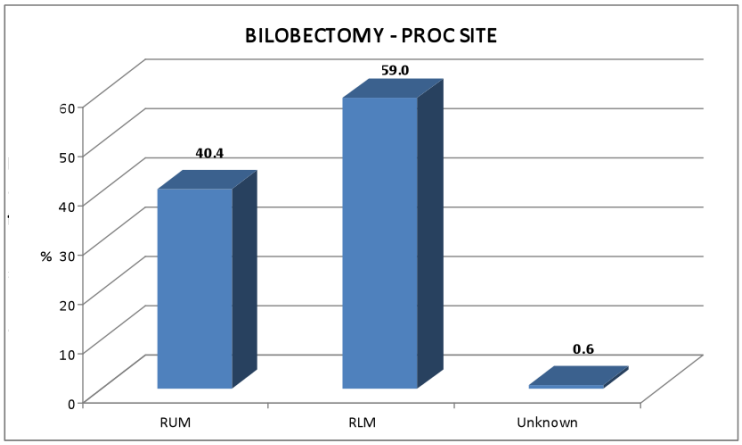
Bilobectomy – Lobectomy qualifier	Occurrences	Percent
Alone	20360	68.3
Chest Wall	610	2.1
Superior Sulcus Tumor	224	0.8
Sleeve	889	3.0
Diaphragm Resection	15	0.1
Atrial Resection	13	0.0
SVC Resection / Reconstruction	42	0.1
Vertebral Resection	112	0.4
Unknown	7559	25.4
Total	**29824**	**100.0**

Distribution of lobectomy/bilobectomy by site of resection

Lobectomy procedure site	Occurrences	Percent
RUL	7767	36.5
RML	1086	5.1
RLL	3387	15.9
LUL	5397	25.4
LLL	3390	15.9
Unknown	235	1.1
Total	**21262**	**100.0**



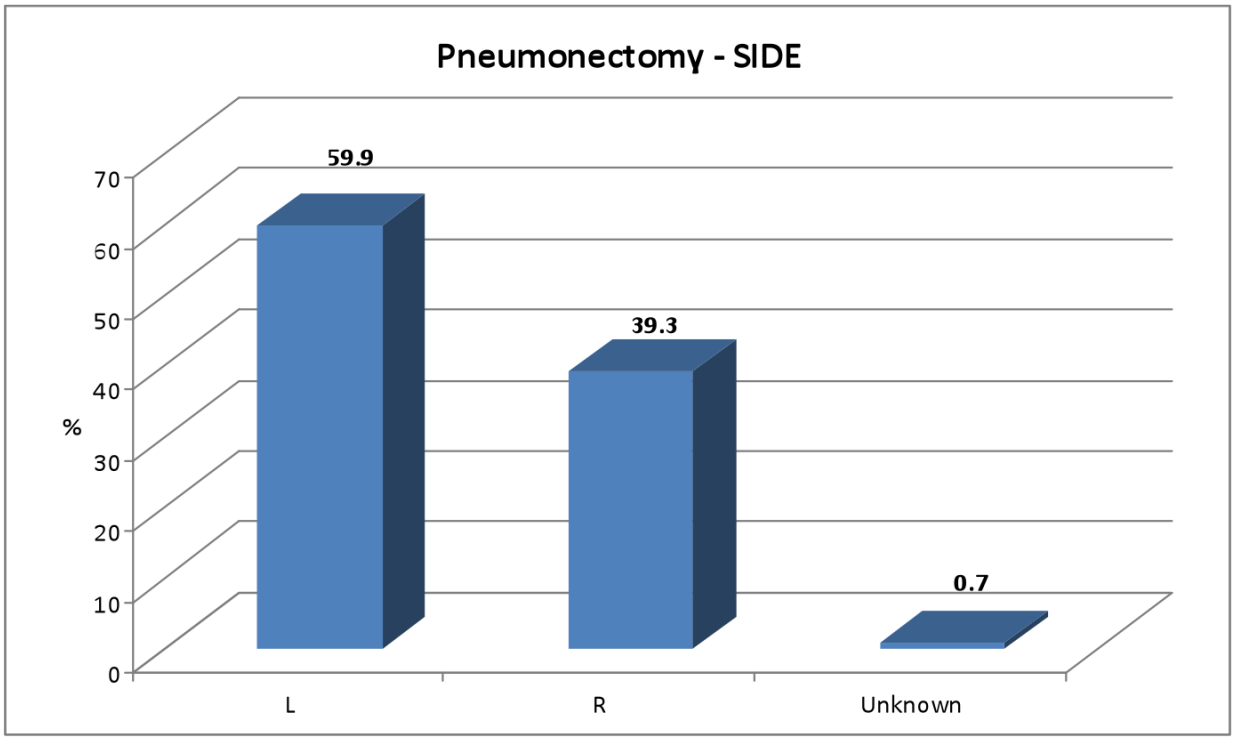
Bilobectomy procedure site	Occurrences	Percent
RUM	597	40.4
RLM	872	59.0
Unknown	9	0.6
Total	**1478**	**100.0**



Distributions of pneumonectomy

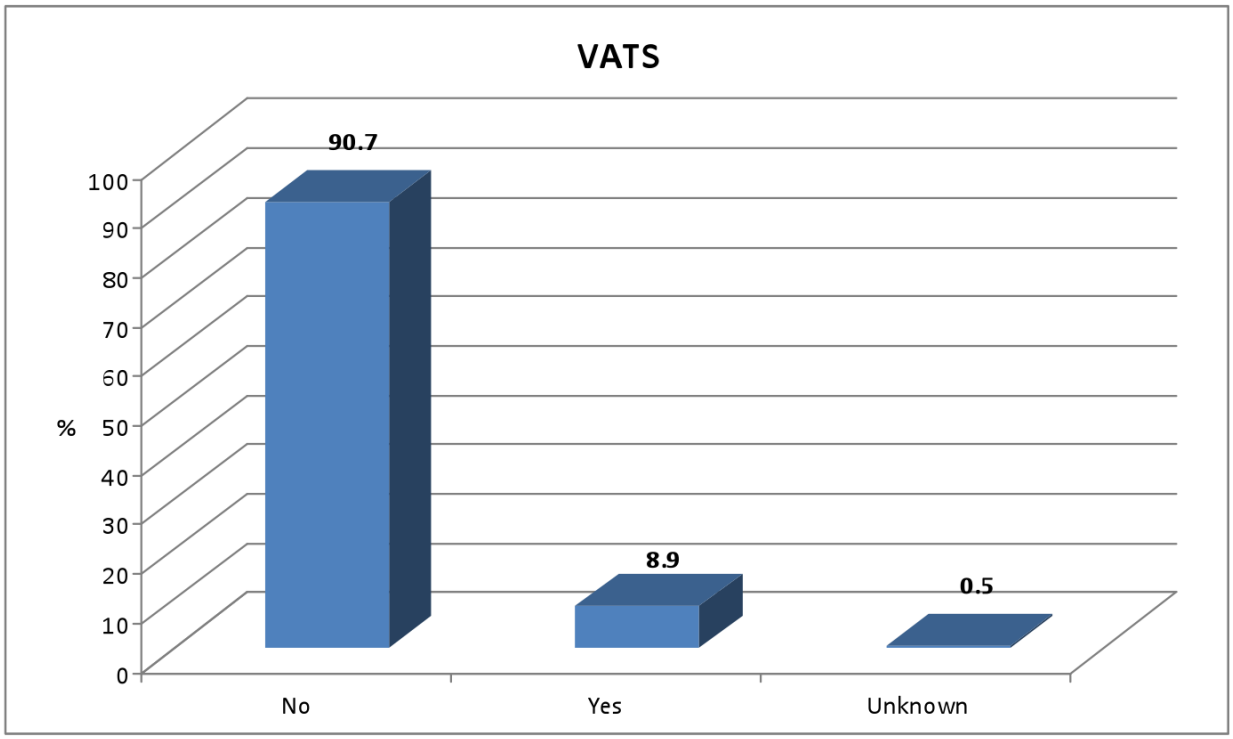
Pneumonectomy Qualifier	Occurrences	Percent	Cum.
Alone	2259	75.7	75.68
Completion	96	3.2	78.89
Intrapericardial	275	9.2	88.11
Pleuropneumonectomy	143	4.8	92.9
Sleeve Resection	48	1.6	94.51
Diaphragm Resection	2	0.1	94.57
Atrial Resection	47	1.6	96.15
SVC Resection / Reconstruction	77	2.6	98.73
Vertebral resection	38	1.3	100
Total	**2985**	**100.0**	**–**

Pneumonectomy side	Occurrences	Percent
L	2120	59.9
R	1391	39.3
Unknown	26	0.7
Total	**3537**	**100.0**



Distribution of VATS procedures in total lung resections

VATS	Occurrences	Percent
No	27043	90.7
Yes	2638	8.9
Unknown	143	0.5
Total	**29824**	**100.0**

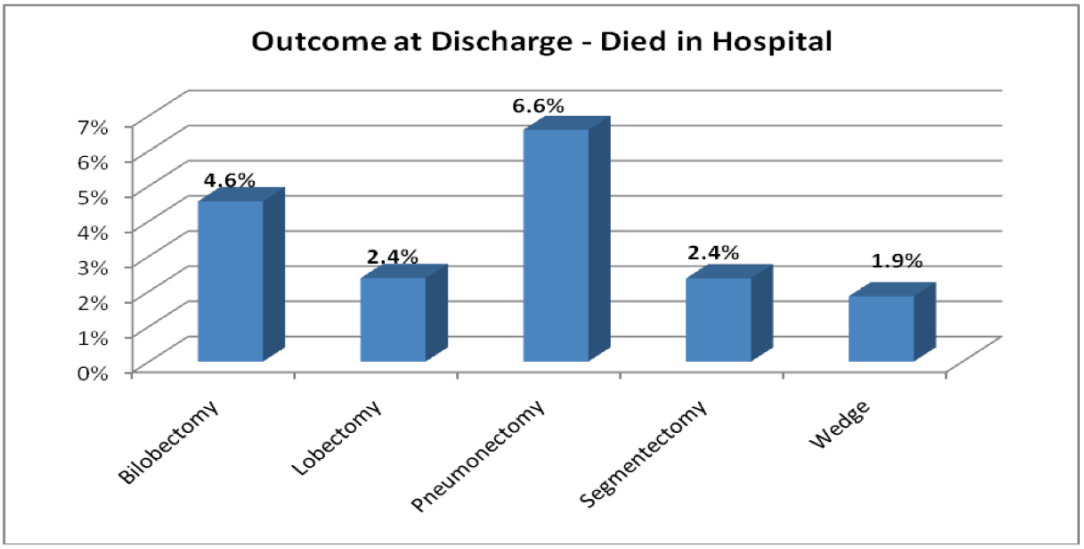


Distributions of VATS procedures in lobectomy/bilobectomy

VATS	Occurrences	Percent
No	21171	93.1
Yes	1539	6.8
Unknown	30	0.1
Total	**22740**	**100.0**

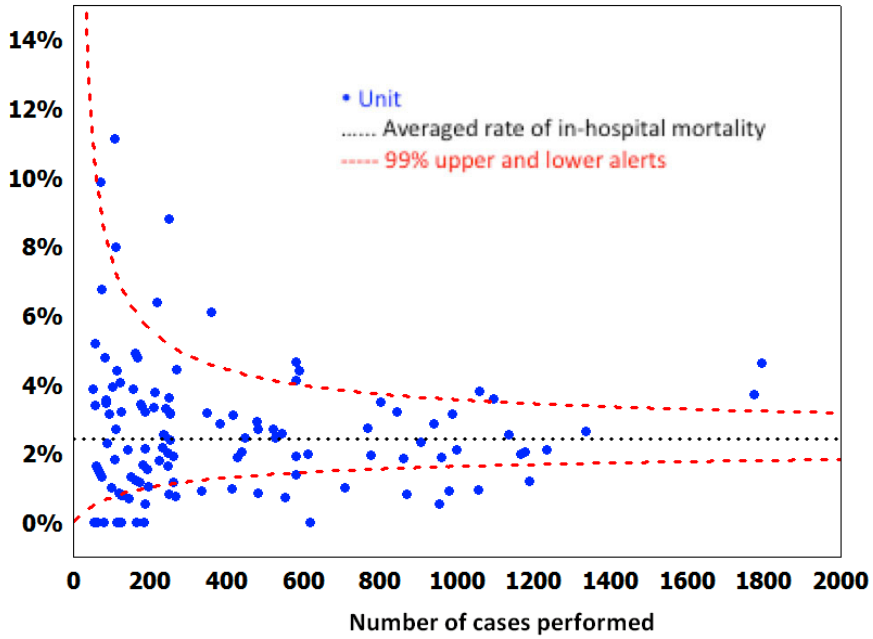
Unadjusted in-hospital mortality rates in primary lung cancer resections

Outcome at Discharge - Died in Hospital	Occurrences	Died in Hospital	Percent
Bilobectomy	1447	66	4.6%
Lobectomy	20582	489	2.4%
Pneumonectomy	3457	228	6.6%
Segmentectomy	1140	27	2.4%
Wedge	2314	43	1.9%
Total	**28940**	**853**	**2.9%**



Overall unadjusted in-hospital mortality calculated in the total dataset

(Only centers with yearly major resections N>50 were included)

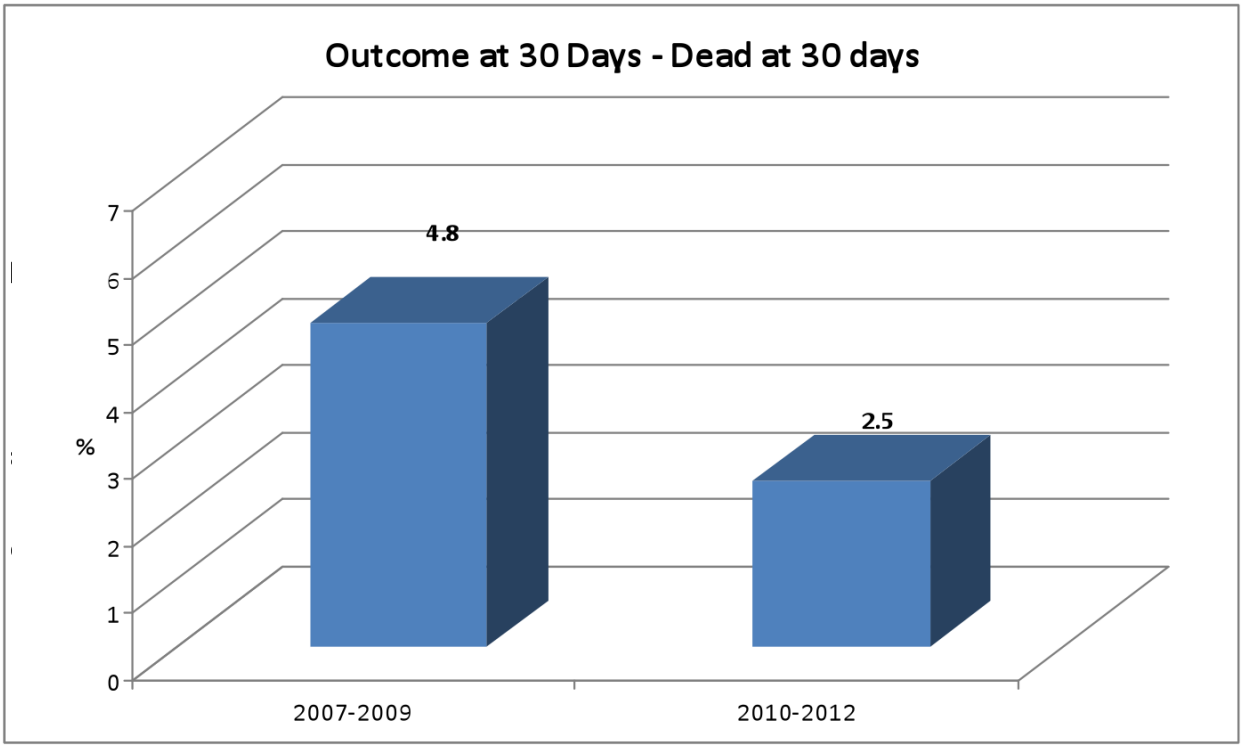


Comparisons of outcomes between 2007-2009 *vs* 2010-2012 in the total dataset*

** : due to missing data 30-day mortality was only evaluated in 23,830 patients.*

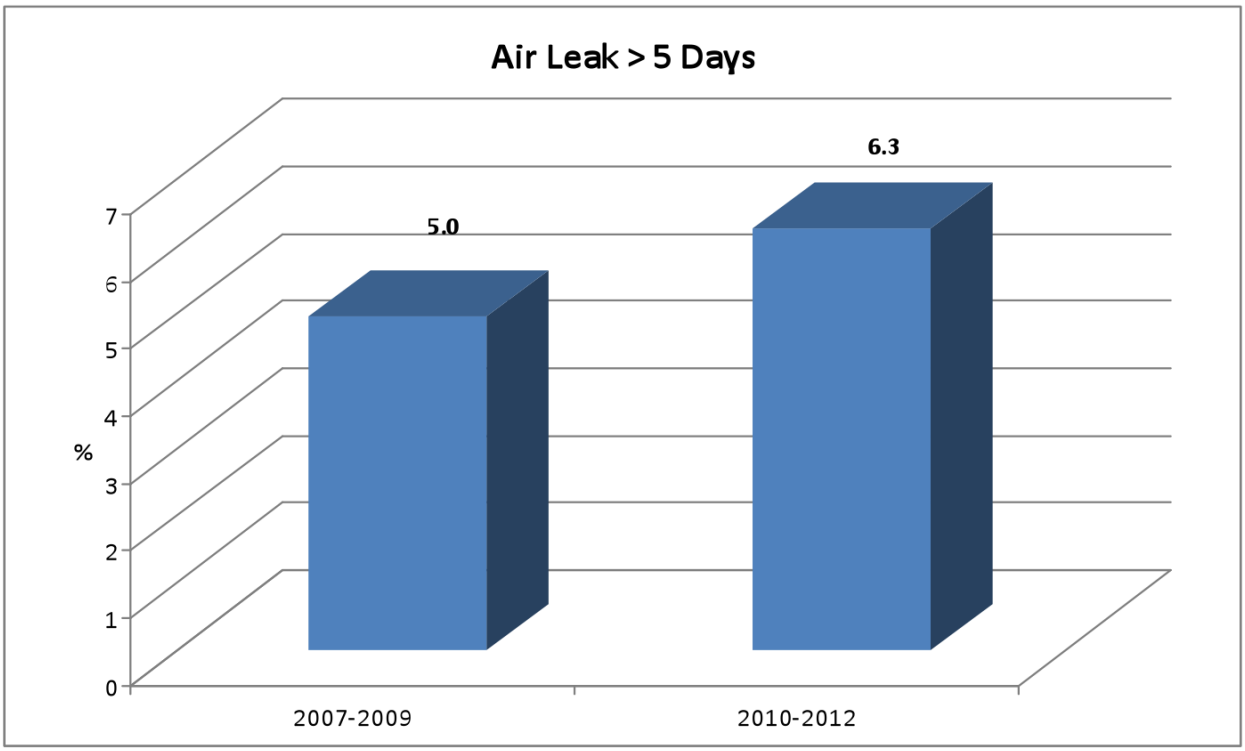
Cumulative non-adjusted 30-day mortality

Cumulative non-adjusted 30-day mortality	Alive	Died	Died Percent
2007-2009	13009	658	4.8
2010-2012	9912	251	2.5
Total	**22921**	**909**	**3.8**



Prolonged air leak

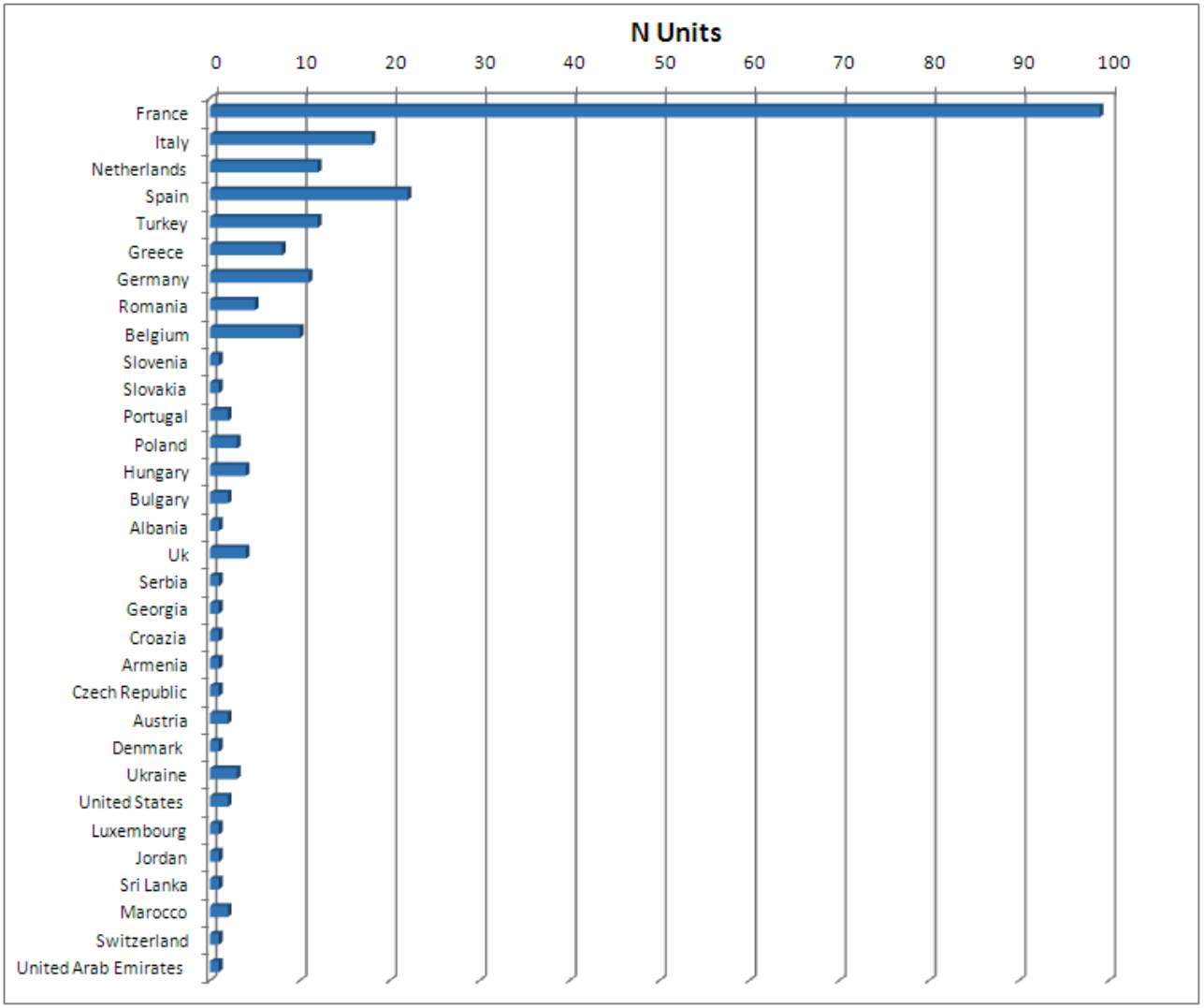
Air leak > 5 Days	No	Yes	Yes (%)
2007-2009	24921	1300	5.0
2010-2012	29179	1959	6.3
Total	**54100**	**3259**	**6.0**



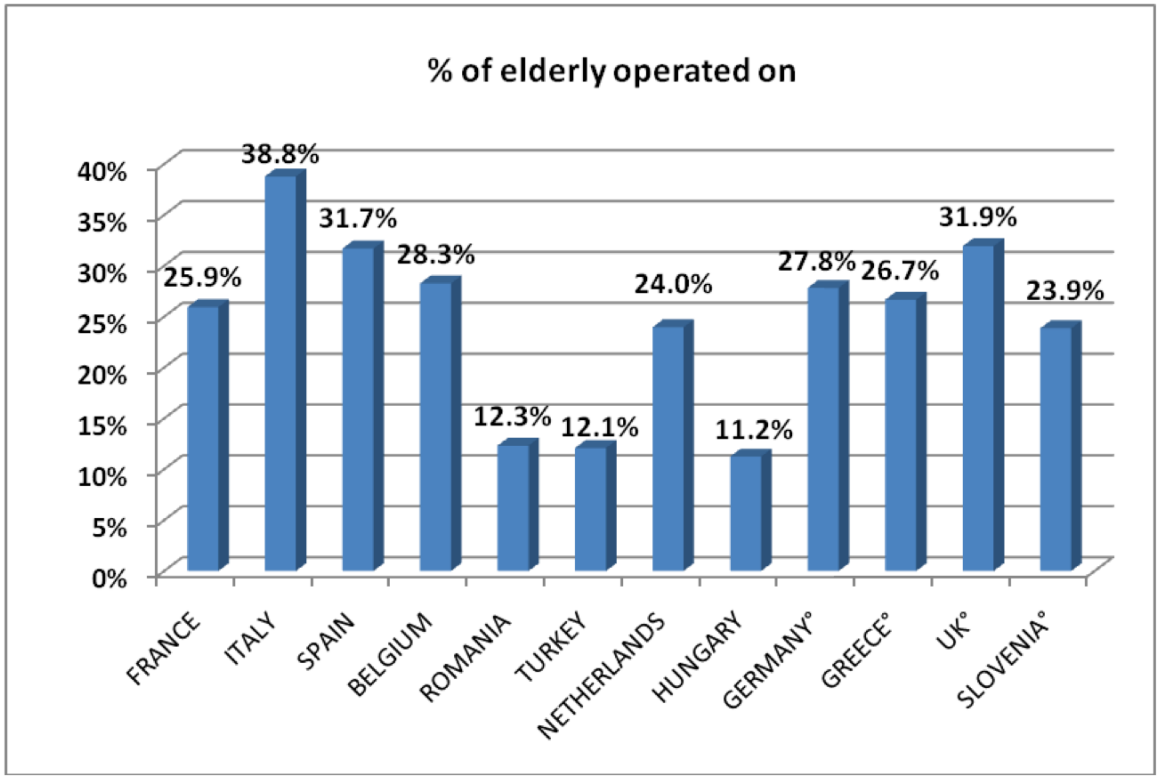
PART 2
NATION-SPECIFIC ACTIVITY
&
COMPARATIVE ANALYSIS
BETWEEN CONTRIBUTING COUNTRIES

Only Countries contributing more than 100 lung resections were included

Number of units enrolled in the ESTS database as of March 2013, by country

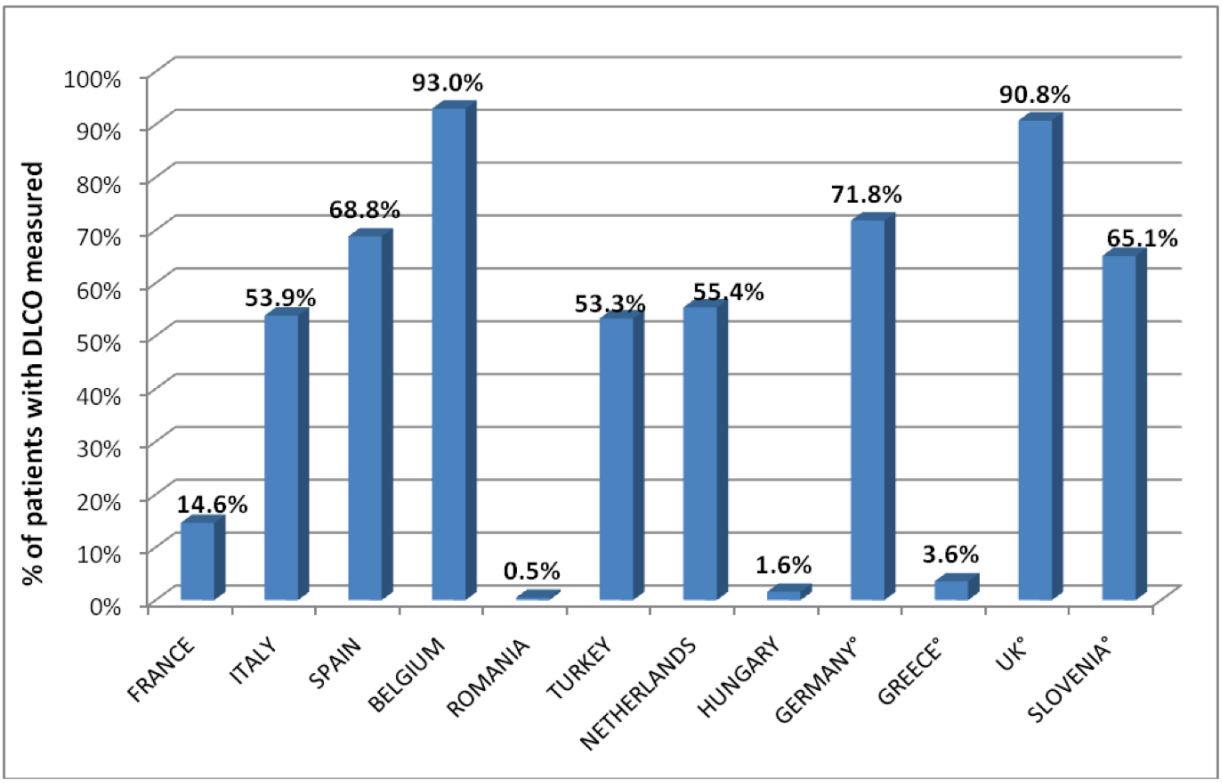


Proportion of elderly patients (older than 70 years of age) operated on in different European countries



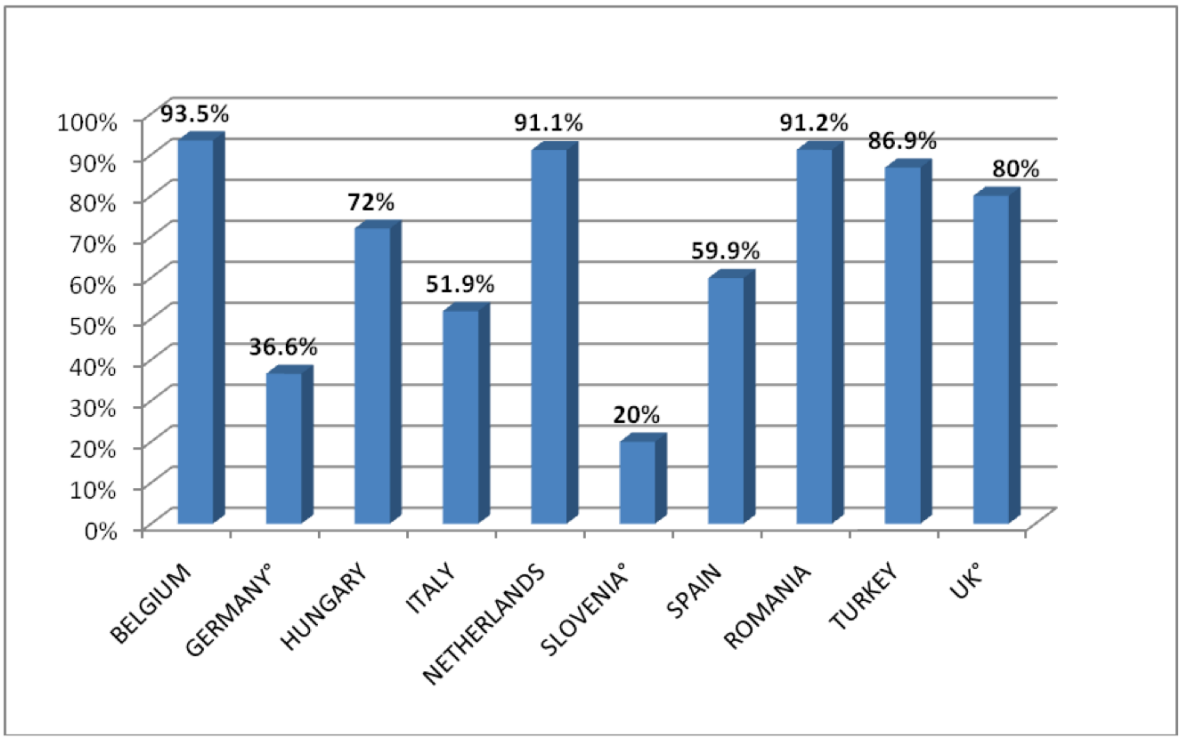
(°): Country with less than 500 patients included, results must be interpreted with caution

Percentage of patients submitted to major anatomic lung resections with preoperative measurement of DLCO in different European Countries.



(°): Country with less than 500 patients included, results must be interpreted with caution

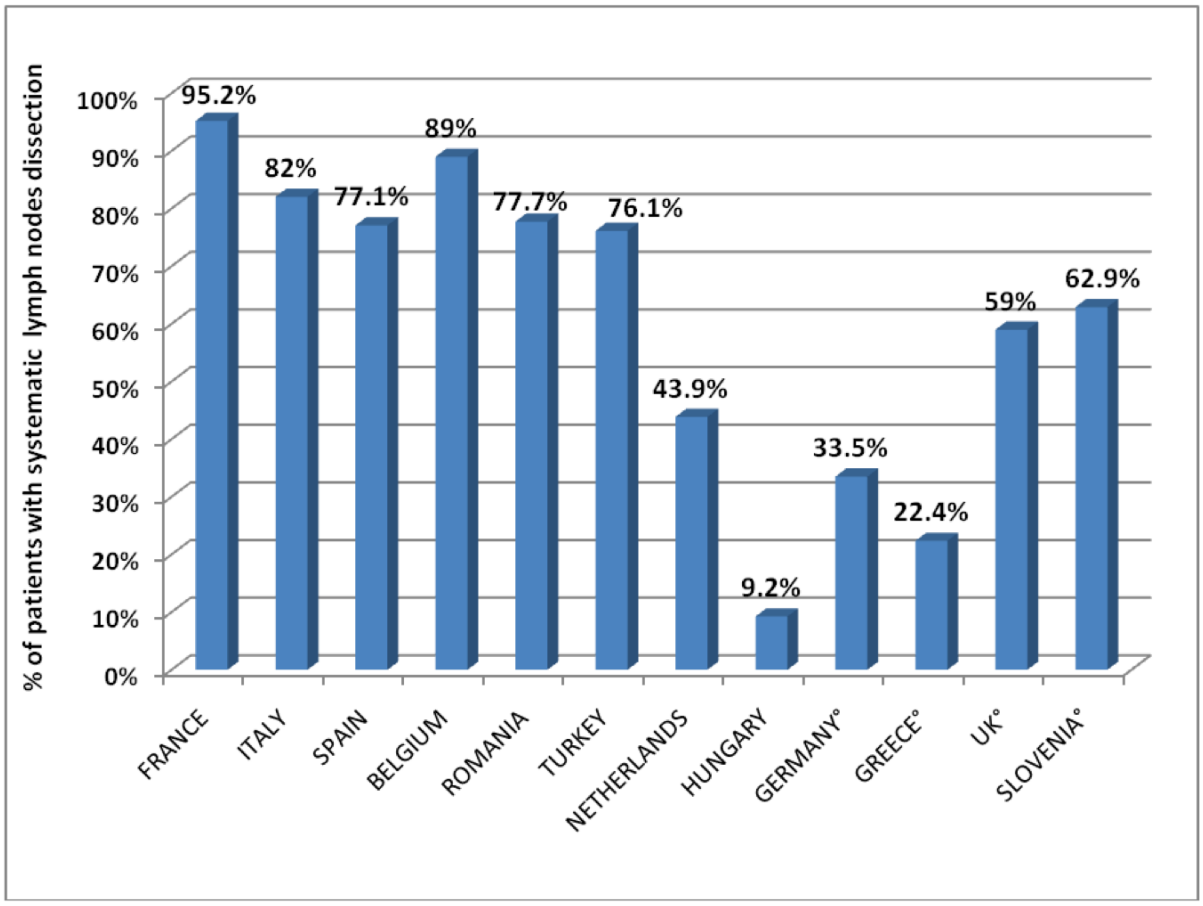
Percentage of patients with primary neoplastic disease and suspicious clinical N2 stage (enlarged >1cm mediastinal nodes at CT scan or PET positive mediastinal nodes) who underwent at least one preoperative invasive mediastinal staging procedure (EBUS, EUS, mediastinoscopy, mediastinotomy, VATS, TEMLA etc.)



(°): Country with less than 500 patients included, results must be interpreted with caution

Percentage of patients submitted to lymph node dissection during major lung resection for malignant primary neoplastic disease grouped by Countries

Lymph node dissection more extended than sampling alone or selected biopsy (as defined and recommended by the ESTS guidelines for intraoperative mediastinal staging) in lung cancer patients was a frequent procedure in all countries.
This variable will be included in the composite performance score (CPS) used for the ESTS quality certification program.

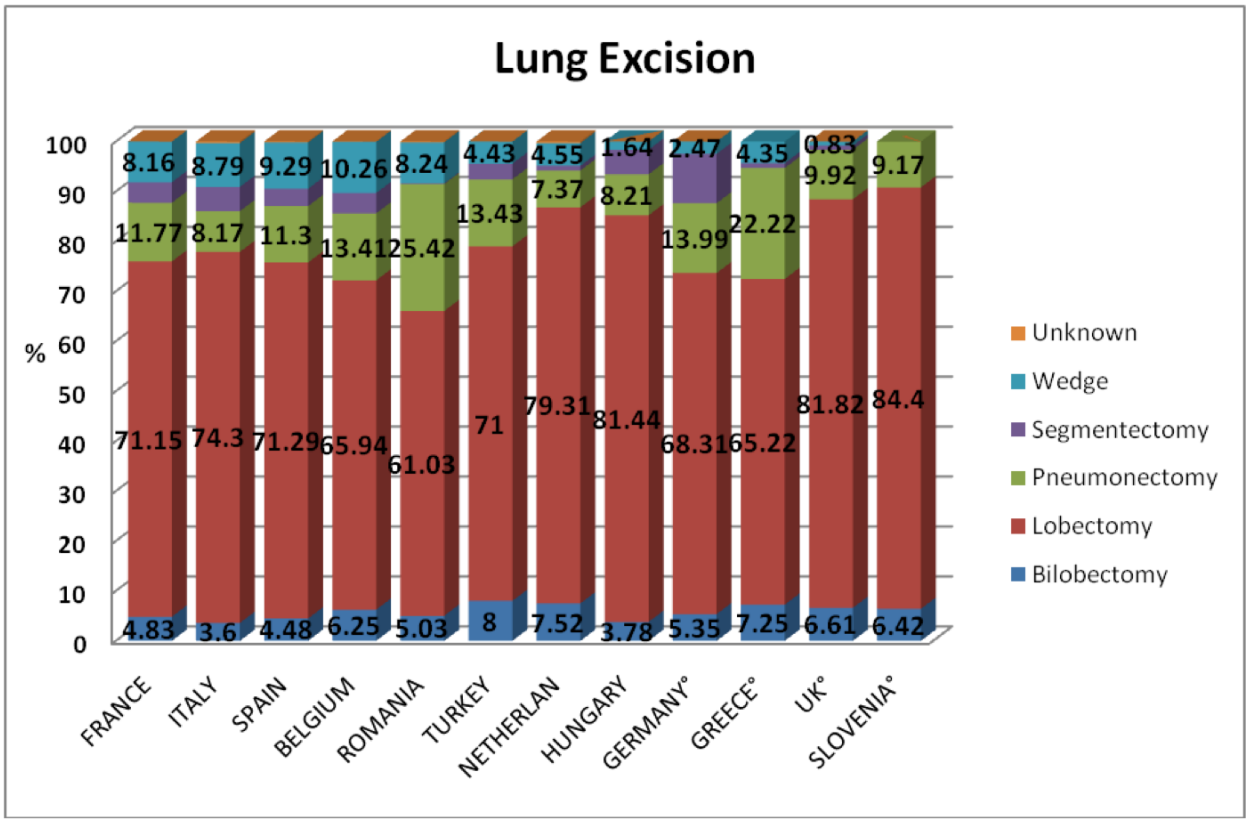


(°): Country with less than 500 patients included, results must be interpreted with caution

Primary lung cancer per contributing nations

Percentage of lung excision procedures

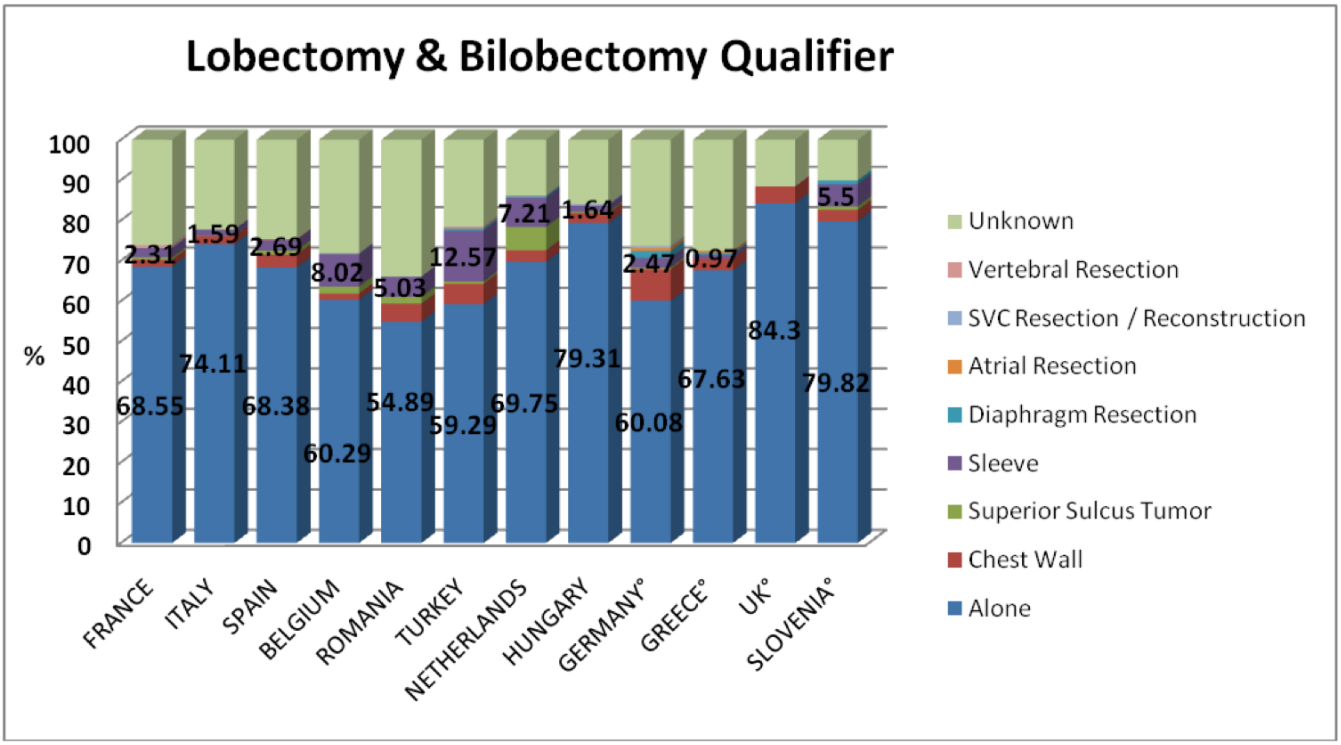
	Bilobectomy	Lobectomy	Pneumonectomy	Segmentectomy	Wedge	Unknown
FRANCE	4.83	71.15	11.77	4.09	8.16	0
ITALY	3.6	74.3	8.17	4.85	8.79	0.29
SPAIN	4.48	71.29	11.3	3.47	9.29	0.17
BELGIUM	6.25	65.94	13.41	4.08	10.26	0.07
ROMANIA	5.03	61.03	25.42	0.14	8.24	0.14
TURKEY	8	71	13.43	3.14	4.43	0
NETHERLANDS	7.52	79.31	7.37	0.94	4.55	0.31
HUNGARY	3.78	81.44	8.21	4.93	1.64	0
GERMANY°	5.35	68.31	13.99	9.88	2.47	0
GREECE°	7.25	65.22	22.22	0.97	4.35	0
UK°	6.61	81.82	9.92	0.83	0.83	0
SLOVENIA°	6.42	84.4	9.17	0	0	0



(°): Country with less than 500 patients included, results must be interpreted with caution

Percentage of lobectomy – bilobectomy

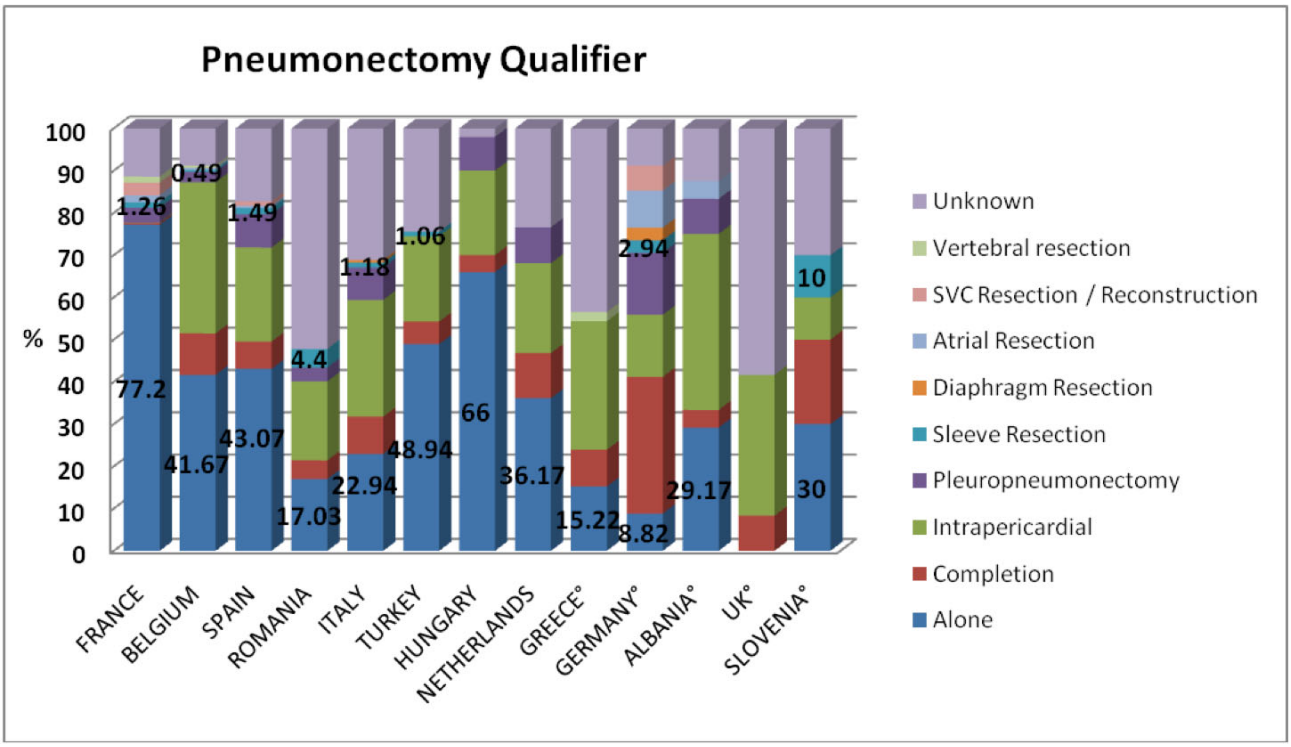
Qualifier	Alone	Chest Wall	Superior Sulcus Tumor	Sleeve	Diaphragm Resection	Atrial Resection	SVC Resec/Recon	Vertebral Resection	Unknown
FRANCE	68.55	1.68	0.58	2.31	0	0.03	0.17	0.52	26.15
ITALY	74.11	1.97	0.05	1.59	0	0	0	0	22.29
SPAIN	68.38	3.13	1.01	2.69	0	0.11	0.06	0	24.62
BELGIUM	60.29	1.58	1.71	8.02	0.13	0.07	0.13	0	28.07
ROMANIA	54.89	4.47	1.68	5.03	0	0	0	0	33.94
TURKEY	59.29	5	0.57	12.57	0.57	0.14	0.14	0.29	21.43
NETHERLANDS	69.75	2.82	5.8	7.21	0.47	0	0	0.16	13.79
HUNGARY	79.31	2.46	0.33	1.64	0	0	0.33	0	15.93
GERMANY°	60.08	7.82	0.41	2.47	1.65	0.82	0.41	0	26.34
GREECE°	67.63	2.9	0	0.97	0.48	0.48	0	0	27.54
UK°	84.3	4.13	0	0	0	0	0	0	11.57
SLOVENIA°	79.82	2.75	0.92	5.5	0.92	0	0	0	10.09



(°): Country with less than 500 patients included, results must be interpreted with caution

Percentage of pneumonectomy (qualifier)

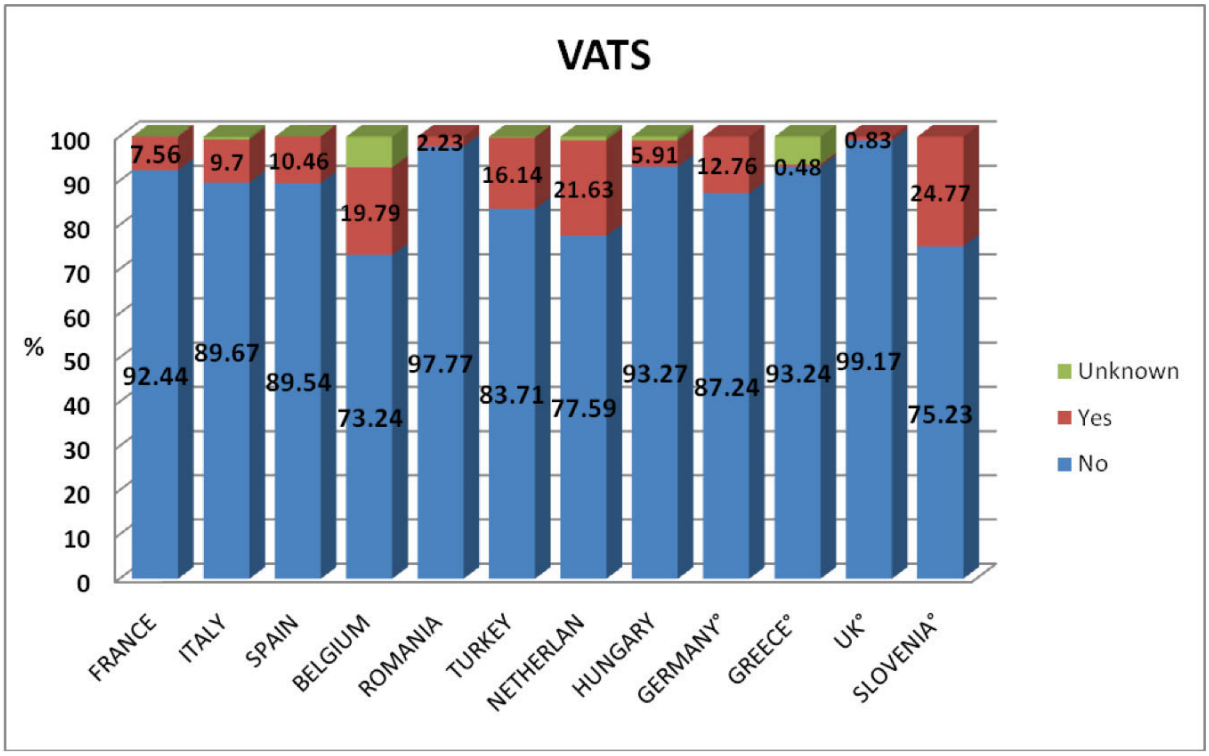
	Alone	Completion	Intrapericardial	Pleuro-Pneumonectomy	Sleeve resection	Diaphragm resection	Atrial resection	SVC Resection Reconstruction	Vertebral resection	Unknown
FRANCE	77.2	0.37	0.12	3.58	1.26	0	1.67	2.97	1.43	11.4
BELGIUM	41.67	9.8	35.78	2.45	0.49	0	0.49	0	0.49	8.82
SPAIN	43.07	6.44	22.28	7.92	1.49	0	0.5	0.99	0	17.33
ROMANIA	17.03	4.4	18.68	3.3	4.4	0	0	0	0	52.2
ITALY	22.94	8.82	27.65	7.65	1.18	0.59	0	0	0	31.18
TURKEY	48.94	5.32	20.21	0	1.06	0	0	0	0	24.47
HUNGARY	66	4	20	8	0	0	0	0	0	2
NETHERLANDS	36.17	10.64	21.28	8.51	0	0	0	0	0	23.4
GREECE°	15.22	8.7	30.43	0	0	0	0	0	2.17	43.48
GERMANY°	8.82	32.35	14.71	14.71	2.94	2.94	8.82	5.88	0	8.82
ALBANIA°	29.17	4.17	41.67	8.33	0	0	4.17	0	0	12.5
UK°	0	8.33	33.33	0	0	0	0	0	0	58.33
SLOVENIA°	30	20	10	0	10	0	0	0	0	30



(°): Country with less than 500 patients included, results must be interpreted with caution

Percentage of VATS

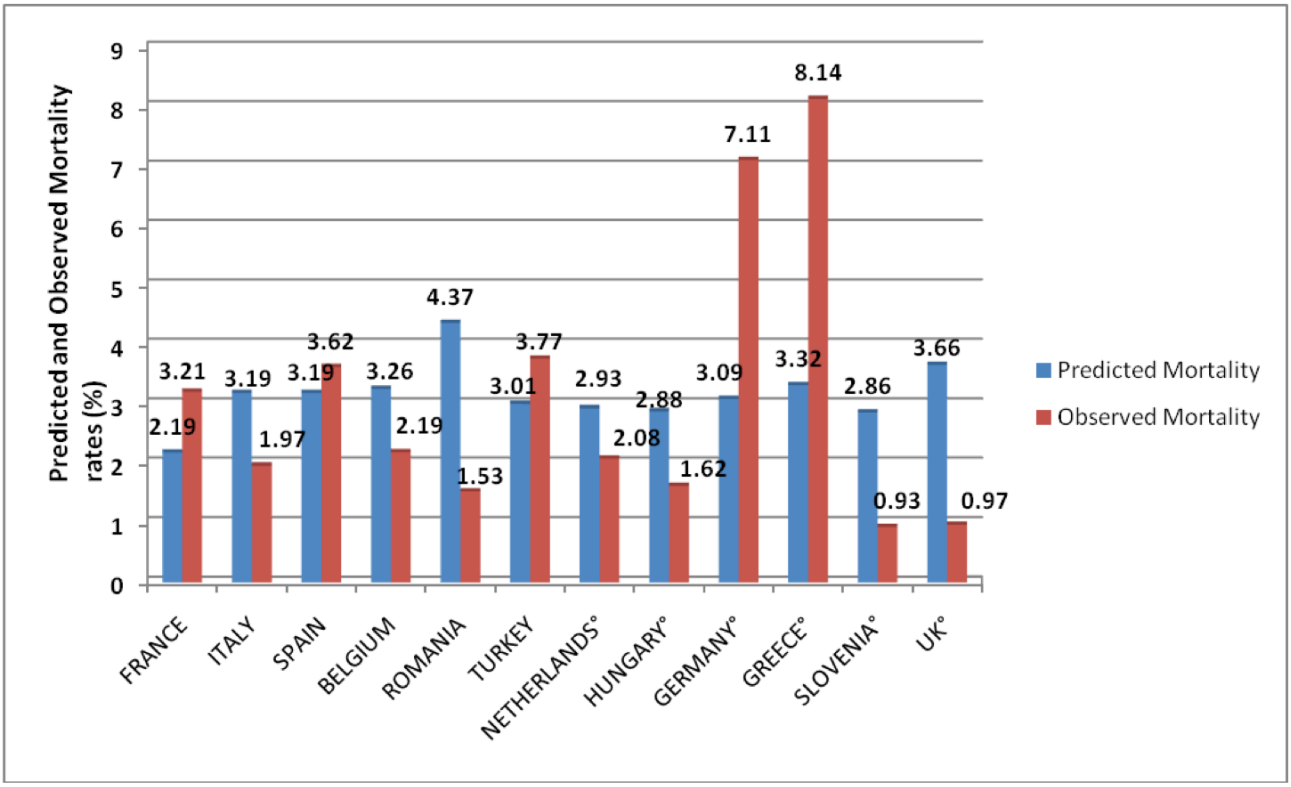
	No	Yes	Unknown
FRANCE	92.44	7.56	0
ITALY	89.67	9.7	0.62
SPAIN	89.54	10.46	0
BELGIUM	73.24	19.79	6.97
ROMANIA	97.77	2.23	0
TURKEY	83.71	16.14	0.14
NETHERLANDS	77.59	21.63	0.78
HUNGARY	93.27	5.91	0.82
GERMANY°	87.24	12.76	0
GREECE°	93.24	0.48	6.28
UK°	99.17	0.83	0
SLOVENIA°	75.23	24.77	0



(°): Country with less than 500 patients included, results must be interpreted with caution

Observed versus predicted in-hospital mortality rates of major lung resections in different European Countries

(risk adjustment according to Brunelli A et al. The European Thoracic Database project: Composite Performance Score to measure quality of care major lung resection. Eur J Cardiothorac Surg 2009; 35: 769-774).



Predicted and Observed Mortality rates (%)	Predicted Mortality	Observed Mortality
FRANCE	2.19	3.21
ITALY	3.19	1.97
SPAIN	3.19	3.62
BELGIUM	3.26	2.19
ROMANIA	4.37	1.53
TURKEY	3.01	3.77
NETHERLANDS°	2.93	2.08
HUNGARY°	2.88	1.62
GERMANY°	3.09	7.11
GREECE°	3.32	8.14
SLOVENIA°	2.86	0.93
UK°	3.66	0.97

(°): Country with less than 500 patients included, results must be interpreted with caution

PART 3
APPENDICES

Appendix 1: Units contributing to ESTS Database July 2007 - February 2013

Only units contributing more than 100 patients (as of February 21th 2013) in the registry are shown

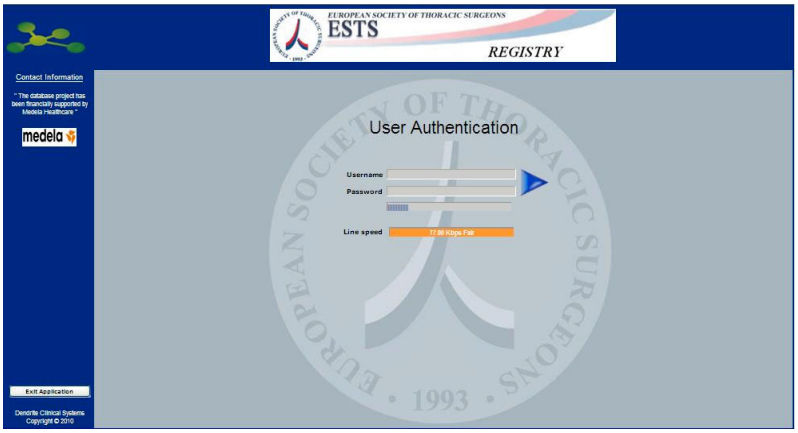
COUNTRY	CITY	INSTITUTION
ALBANIA	TIRANA	University Hospital of Lung Diseases "Shefqet Ndroqi"
BELGIUM	ANTWERP	University Hospital of Antwerp
BELGIUM	BRUSSELS	Cliniques Universitaires Saint- Luc
BELGIUM	BRUSSELS	Hopital Academique Erasme
BELGIUM	LEUVEN	University Hospitals Leuven
FRANCE	AVIGNON	CHG - Avignon
FRANCE	BAYONNE	CHG - Bayonne
FRANCE	BESANÇON	CHU Jean Minjoz
FRANCE	BEUVRY	Clinique Ambroise Paré
FRANCE	BOIS GUILLAUME	CMC du Cèdre
FRANCE	BORDEAUX	CHU Haut Lévêque
FRANCE	BORDEAUX	Clinique Bordeaux Nord
FRANCE	CAEN	CHU Côte de Nacre Caen
FRANCE	CERGY PONTOISE	CH René Dubos
FRANCE	CHAMBÉRY	CH - Chambèry
FRANCE	CLAMART	HIA Percy
FRANCE	CLERMONT FERRAND	CHU Gabriel Montpied
FRANCE	DIJON	CHU du Bocage
FRANCE	ERMONT	Clinique Claude Bernard
FRANCE	GRENOBLE	CHU Michallon
FRANCE	GRENOBLE	Clinique Belledonne
FRANCE	LA ROCHELLE	Hôpital St Louis
FRANCE	LE HAVRE	Clinique Petit Col Moulin
FRANCE	LE PLESSIS ROBINSON	Marie Lannelongue Hospital
FRANCE	LILLE	CHU Calmette
FRANCE	LILLE	Clinique de la Louvière
FRANCE	LILLE	Polyclinique du Bois
FRANCE	LYON	CHU Lyon Sud
FRANCE	LYON	Clinique St Louis
FRANCE	LYON	Hôpital privé Jean Mermoz
FRANCE	MARSEILLE	CHU Ste Marguerite
FRANCE	MARSEILLE	HIA Alphonse LAVERAN
FRANCE	MAXEVILLE	Médipole Gentilly
FRANCE	MEAUX	CH - Meaux
FRANCE	METZ	Hôpital Belle-Isle
FRANCE	MONTPELLIER	CHU de Montpellier
FRANCE	MONTPELLIER	Clinique du Millénaire
FRANCE	MORLAIX	CMC de la Baie de Morlaix
FRANCE	NANCY	CHU Central de
FRANCE	NANTES	CHU - Nantes
FRANCE	NANTES	Clinique St Augustin
FRANCE	NANTES	Nouvelle Clinique Nantaise
FRANCE	NICE	CHU Pasteur
FRANCE	NICE	Clinique Saint Georges
FRANCE	NIMES	Clinique les Franciscaines
FRANCE	PARIS	HEGP
FRANCE	PARIS	Hôtel Dieu
FRANCE	PARIS	IMM
FRANCE	PAU	CHG - Pau
FRANCE	POITIERS	CHU - Pointers
FRANCE	QUIMPER	Clinique Quimper sud

INSTITUTION		CITY	COUNTRY
FRANCE	REIMS	Clinique Courlancy	
FRANCE	ROUEN	CHU Charles Nicolle	
FRANCE	SAINT BRIEUC	Hopital yves le Foll	
FRANCE	SAINT CLOUD	Clinique du Val D'or	
FRANCE	SAINT ETIENNE	CH Privé de la Loire	
FRANCE	SAINT ETIENNE	CHU - Saint Etienne	
FRANCE	SAINT GRÉGOIRE	CH Privé Saint Grégoire	
FRANCE	STRASBOURG	CHU - Strasbourg	
FRANCE	STRASBOURG	Clinique St Odile	
FRANCE	TALANT	Clinique Bénigne Joly	
FRANCE	TOULOUSE	CHU Larrey	
FRANCE	TOULOUSE	Clinique Pasteur	
FRANCE	TOURS	CHU Trousseau	
FRANCE	VALENCIENNES	Clinique Teissier	
FRANCE	VANNES	Clinique Océane	
GERMANY	BREMEN	Klinikum Bremen-Ost - Bremen	
GERMANY	MONCHENGLADBACH	Maria Hilf Kliniken	
GREECE	ATHENS	Evangelismos	
GREECE	ATHENS	Hygeia Hospital	
GREECE	THESSALONIKI	Ahepa University Hospital	
HUNGARY	BUDAPEST	National Institute of Oncology	
HUNGARY	DEBRECEN	University Of Debrecen	
HUNGARY	SZEGED	University of Szeged, Department of Surgery	
ITALY	ANCONA	Ospedali Riuniti Ancona	
ITALY	BOLOGNA	Discipline Chirurgiche, Rianimatorie e dei Trapianti Univ. di Bologna	
ITALY	FOGGIA	Scienze Chir. Sezione Chirurgia Toracica Osped. Riun. Univ. di Foggia	
ITALY	GENOVA	San Martino - Genoa	
ITALY	LECCE	V. Fazzi Hospital	
ITALY	MILANO	Az. Ospedaliera San Paolo	
ITALY	MILANO	Fondazione ospedale Maggiore Policlinico	
ITALY	PARMA	University Hospital Parma	
ITALY	SIENA	University Hospital Siena	
NETHERLANDS	AMSTERDAM	VUMC Dept of Surgery	
NETHERLANDS	BREDA	Amphia Hospital	
NETHERLANDS	HAARLEM	Kennemer Gasthuis	
PORTUGAL	LISBON	Santa Martha Hospital, Lisbon	
ROMANIA	BUCHAREST	Institute of Oncology Bucharerst	
ROMANIA	BUCHAREST	Marius Nasta Institute of Pneumonology	
ROMANIA	DROBETA-TURNU SEVERIN	County Emergency Hospital	
ROMANIA	TIMISOARA	Clinical Muncipal Emergency Hospital	
SLOVAKIA	BRATISLAVA	University Hospital Bratislava, Slovacchia	
SLOVENIA	LJUBLJANA	University Medical Centre Ljubljana	
SPAIN	BARCELONA	Hospital Clinic	
SPAIN	BARCELONA	Sagrat Cor University Hospital	
SPAIN	HEBRON	HG Vall d'Hebron	
SPAIN	MADRID	H. Clinico San Carlos	
SPAIN	MADRID	Hospital general Universitario Gregorio Maranon	
SPAIN	NAVARRA	Clinica Universitaria De Navarra	
SPAIN	SALAMANCA	University Hospital Salamanca	
SPAIN	SEVILLA	HHUU Virgen del Rocio	
SPAIN	VALENCIA	General University Hospital Valencia	
TURKEY	BURSA	Uludag University, School of Medicine	
TURKEY	ISTANBUL	Istanbul School of Medicine	
TURKEY	ISTANBUL	Istanbul University, Cerrahpasa Medical Faculty	
TURKEY	ISTANBUL	Sureyyapasa Chest Disease & Thoracic Surgery Hospital	
UK	EXETER	Royal Devon & Exeter NHS Foundation Trust	

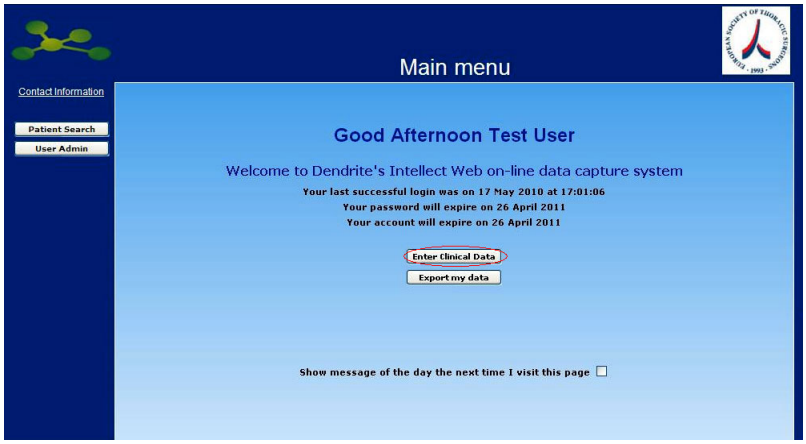
Appendix 2: Database format and submission of data

The first step is to request and obtain a login account through the relevant link found in the ESTS homepage (http//www.ests.org) or by directly sending an email to one of the members of the Database Committee. Once you have a valid login account you can proceed through the following data entry interface (accessible through https://ests.dendrite.it/csp/ests/intellect/login.csp).
The intellect Web logon screen shown below has been engineered to provide enhanced security facilities:

- Limiting users to 3 logon attempts before locking the user-account
- Giving information on previously successful and unsuccessful logon attempts
- Requiring users to have an eight-character password that contains at least one uppercase character, one lowercase character and one digit.



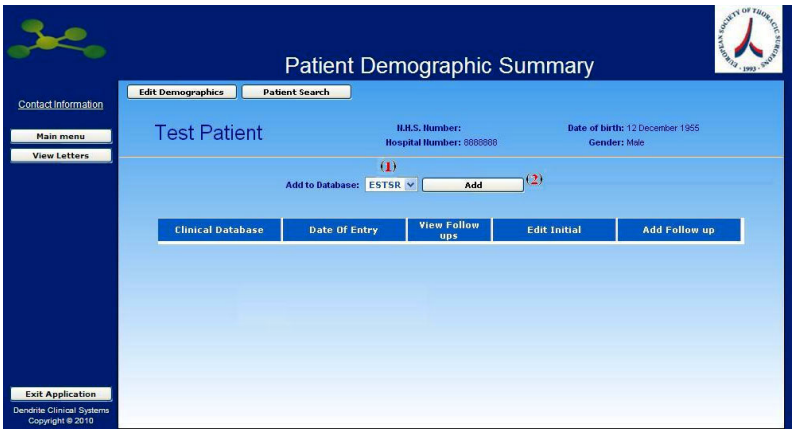
Once you have logged in you are presented with the Database main menu, from which you can add new data, view or edit a procedure, modify your account details, and export your data in Excel for your own purposes.



Clicking on the Enter Clinical Data button opens the next screen “Patient Search”, where it is possible to search for patients already in the database or add new patients.

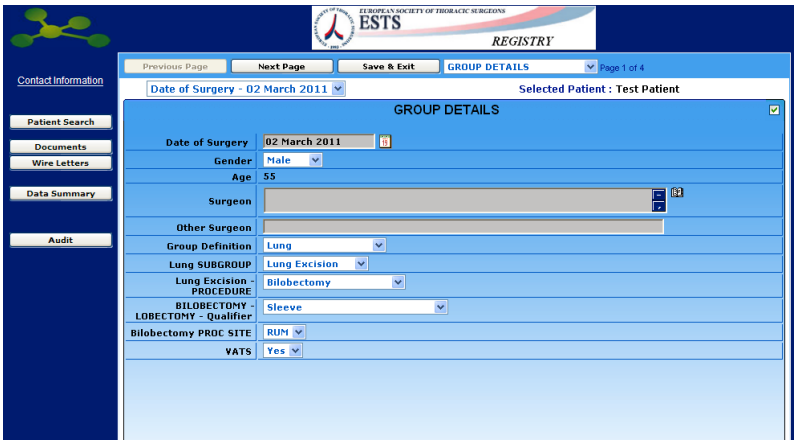
Clicking on the link Add New Patient, that can be found at the left of the screen in the section Options, you will be required to fill in the minimum data required to register a New Patient.

The newly created patient is ready to be entered into the database.

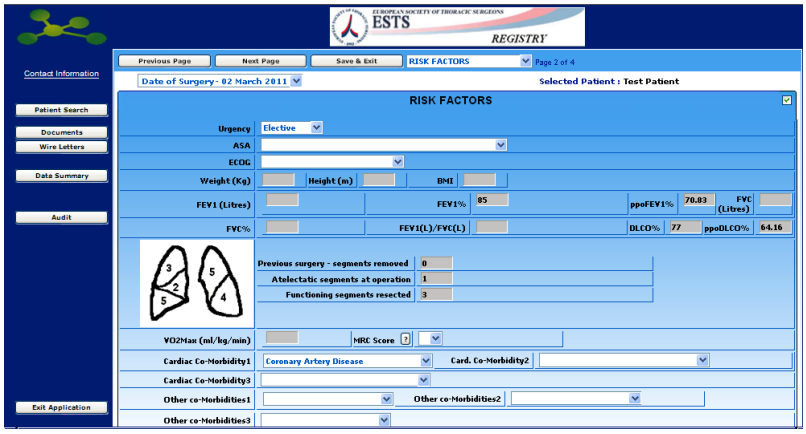


Now it is possible to select the available Database (**1**) (in our case there is only the one named ESTSR) and add the patient to the chosen Database by clicking on the button (**2**).

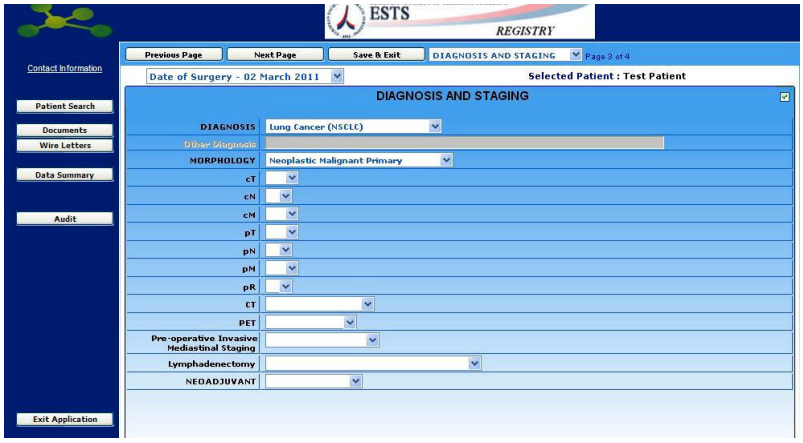
Once you have clicked the Add Button, the first page of the selected Registry will appear. Now you can start inserting clinical data as showed in next page.



The Database is an all-purpose database designed for all general thoracic surgery procedures, but specifically focused on lung resections for which a number of additional items can be selected, including risk-scores, cardiopulmonary function data and calculation of predicted postoperative pulmonary function through a standardized calculator.

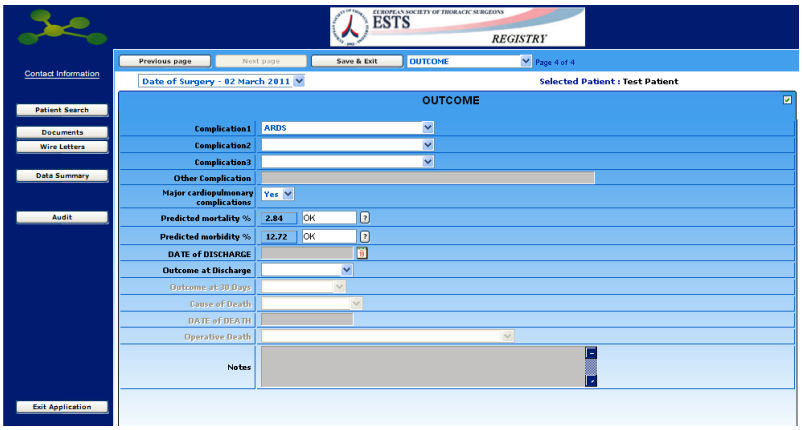


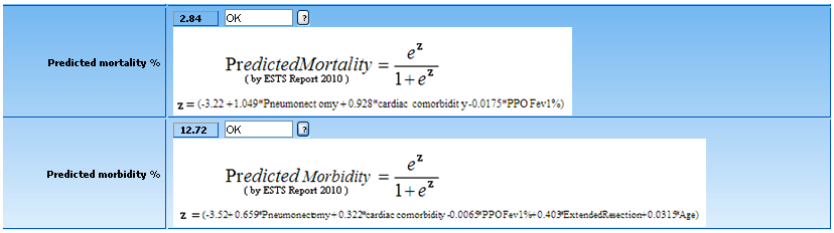
In addition to risk factors, diagnosis and staging details can be added in a following section.



The system auto-calculates for Lung Excision Procedure the Predicted Mortality(%) and Predicted Morbidity (%)

Early outcomes, including in-hospital morbidity, in-hospital and 30-days mortality should be specified in the final section, before submitting the data.





Appendix 3: Definition of major cardiopulmonary complications listed in the database

ARDS: Adult respiratory distress syndrome defined according to the American-European consensus conference. All of the following criteria should be met:

1. Acute onset.
2. Arterial hypoxemia with PaO2/FIO2 ratio lower than 200 (regardless PEEP level).
3. Bilateral infiltrates at chest radiograph or CT scan.
4. No clinical evidence of left atrial hypertension or pulmonary artery occlusive pressure < 18 mmHg.
5. Compatible risk factors.

Atrial Arrhythmia: new onset of atrial fibrillation/flutter (AF) requiring medical treatment or cardioversion. Does not include recurrence of AF which had been present preoperatively.

Ventricular Arrhythmia: sustained ventricular tachycardia or ventricular fibrillation that has been clinically documented and treated by ablation therapy, implantable cardioverter defibrillator, permanent pacemaker, pharmacologic treatment or cardioversion.

Bronchoscopy for atelectasis: postoperative atelectasis documented clinically or radiographically that needed bronchoscopy.

Pneumonia: defined according to the last CDC criteria. Two or more serial chest radiographs with at least **one** of the following:

- New or progressive and persistent infiltrate.
- Consolidation.
- Cavitation.

And at least **one** of the following:

- Fever (>38EC or >100.4EF) with no other recognized cause.
- Leukopenia (<4000 WBC/mm^3) or leukocytosis (≥12,000 WBC/mm^3).
- For adults ≥70 years old, altered mental status with no other recognized cause.

And at least **two** of the following:

- New onset of purulent sputum, or change in character of sputum, or increased respiratory secretions, or increased suctioning requirements.
- New onset or worsening cough, or dyspnea, or tachypnea.
- Rales or bronchial breath sounds.

Worsening gas exchange (e.g. O_2 desaturations (e.g., $PaO_2/FiO_2 \leq 240$), increased oxygen requirements, or increased ventilator demand).

Pulmonary embolism: confirmed by V/Q scan, angiogram or CT scan.

DVT: deep venous thrombosis confirmed by Doppler study, contrast study or other study and that required treatment.

Myocardial infarct: evidenced by one of the following criteria:

1. transmural infarction diagnosed by the appearance of a new Q wave in two or more contiguous leads on ECG.
2. Subendocardial infarction (non Q wave) evidenced by clinical, angiographic electrocardiographic signs.
3. Laboratory isoenzyme evidence of myocardial necrosis.

Renal failure: defined as the onset of new renal failure in the postoperative period according to one of the following criteria:

1. increase of serum creatinine to greater than 2.0, and 2-fold the preoperative creatinine level.
2. a new requirement for dialysis postoperatively.

Neurological complication: occurrence of one of the following central neurologic postoperative events not present preoperatively:

1. a central neurologic deficit persisting postoperatively for more than 72 hours.
2. a transient neurologic deficit (transient ischemic attack or reversible ischemic neurological deficit) with recovery within 72 hours.
3. a new postoperative coma persisting at least 24 hours and caused by anoxic/ischemic and/or metabolic encephalopathy, thromboembolic event or cerebral bleed.

Appendix 4: ESTS institutional accreditation program

The ESTS Council has approved an Institutional Accreditation program open to all thoracic surgery units participating to the ESTS Database.
The aim of the program is to set standards of good clinical practice across Europe with the intent to improve the quality of care possibly according to published guidelines.
To be certified units must participate to the ESTS Database since at least 2 years and have contributed a sufficient number of patients. This pre-requisite is necessary to calculate a reliable Composite Performance Score, which is the metrics used to evaluate the Institutional performance.
A recent document from the STS Quality Measurement task force elegantly explained the conceptual framework and the statistical consideration in the development of Composite Performance Scores in Cardiac Surgery.

Based on a similar methodology, ESTS has recently developed and published a Composite Performance Score (CPS) for lung surgery (Brunelli A et al. The European Thoracic Database project: Composite Performance Score to measure quality of care major lung resection. Eur J Cardiothorac Surg 2009; 35: 769-774).

The method consists in developing standardized outcome and process indicators covering all temporal domains of the lung resection care. The indicators were selected based on their evidence-based level. For the preoperative domain, we selected the proportion of patients with DLCO measured before major lung resection, and the proportion of patients with clinically suspicious N2 nodes at CT scan or PET scan submitted to some type of preoperative mediastinal invasive staging. For the intraoperative domain, we selected the proportion of patients with primary neoplastic disease submitted to major anatomic resections and at least lobe-specific nodal dissection. For the postoperative domain, we selected the risk-adjusted in-hospital cardiopulmonary and mortality rates.
Each of these indicators has been rescaled according to their standard deviation in the entire population to obtain individual standardized indicators. These were then summed to obtain the composite score for each unit.
To derive the regression models for morbidity and mortality, univariate screening of the following variables: age, gender, BMI, type of resection, ppoFEV1, induction therapy, extended resection, presence of cardiac co-morbidity. Variables with p-level<0.1 were used as independent predictors in backward logistic regression analysis validated by bootstrap resampling technique. Only significant ($p<0.05$) and reliable (bootstrap significancy frequency >50%) were retained in the final model.

Updated logistic regression equation for mortality (c-index 0.74; Hosmer Lemeshow statistics, p=0.9)
Logit: -3.22 + 1.049Xpneumonectomy (coded as 1 vs. 0 lobectomy) + 0.928Xcardiac comorbidity (coded as 1 and including CAD, any previous cardiac surgery, history and treatment for arrhythmia, congestive heart failure, hypertension) -0.0175XppoFEV1%.

Updated logistic regression equation for cardiopulmonary morbidity (c-index 0.66; Hosmer-Lemeshow statistics, p=0.4)
Logit: -3.52 + 0.659Xpneumonectomy + 0.403Xextended resection (coded as 1 and including chest wall resection, pleuropneumonectomy, completion operation, intrapericardial operation) + 0.322Xcardiac comorbidity -0.0065XppoFEV1% + 0.0315Xage.
Standardized scores are calculated by subtracting the observed risk-adjusted outcome or process incidence minus the average observed outcome or process incidence. The difference is then divided by the standard deviation of the observed outcome or process in the entire population. The 50th percentile

of the CPS, which is the threshold selected by the Database Committee as a minimum criteria for accreditation, is 0.404. In the future, an automatic function will be implemented in the ESTS Database, which will allow the end-users to calculate their own CPS.

In addition to their CPS, units must have certain structural, procedural and professional characteristics to be certified. These characteristics needs to be assessed and audited along a sample of data submitted to the database. To this purpose, ESTS has subcontracted an external auditing Company, which together with a thoracic surgeon will visit the applicant units and produce a report, which will be evaluated by the Database Committee. If the report will be judged satisfactory, the Accreditation will be granted by the ESTS Council.

The following are the required structural/procedural/professional characteristics (based and modified from Klepetko W and coll. Structure of General Thoracic Surgery in Europe: By The EACTS/ESTS Working Group on Structures in Thoracic Surgery. Eur J Cardiothorac Surg 2001; 20:663-668.

Hospital & Departmental structural criteria

- Dedicated staff and institutional resources.
- 1 fully equipped operating room per 300-400 major thoracic procedures per year.
- Access to ICU with experience in thoracic surgical cases.
- Dedicated GTS ward, with full supporting paramedical staff and specialized chest physiotherapists.
- The size of the unit should reflect the procedural volume and postoperative management policy.
- Access to outpatient facilities and radiology.
- GTS must have easy access to support facilities that must include: hematological, microbiological and biochemical labs, respiratory pathophysiology lab, endoscopic examinations (bronchoscopy, esophagoscopy), cardiologic examination, cardiopulmonary exercise test, radiology including C scan and PET, cytology, histopathology and frozen section analysis.
- In-house facilities for research and education (meeting room, medical libraries, email and internet).

Procedures Volume

A suggested minimum volume of 150 +/- 50 major thoracic procedures per year is recommended.
For esophageal resections a minimum volume of 20 +/- 5 procedures per year is recommended.
For lung transplant a minimum volume of 10 procedures per year is recommended.

Qualification of surgeons

All surgeons must be qualified to perform thoracic surgery according to individual national or European legislation.
The Head of the unit must have a minimum experience of 5 years of clinical practice as qualified thoracic surgeon.

Costs

The costs for the inspection and auditing (7,000 Euros) are the individual Unit's responsibility.
The accreditation will be valid for a 36 months period. After this period the unit must apply for revalidation.
ESTS accreditation will provide a number of benefits to certified institutions:

1. Accredited units will be announced during the ESTS Annual meeting and their names listed in the ESTS home page and ESTS Annual Report.
2. Participation to ESTS quality improvement initiatives.
3. Participation to high-profile scientific projects supported by the ESTS scientific committee.
4. Accredited units may propose their own clinical research projects based on data present in the ESTS database. The research projects will be then reviewed by the database committee and, if accepted, the unit will be granted full access to the data in the ESTS database needed for analysis.

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