

Thopaz™



PROVIDING ADVANCED TREATMENT WITH EASE

Thopaz sets new standards for thoracic drainage therapy. The compact system allows early ambulation of patients and provides regulated negative pressure close to the patient's chest, supporting medical professionals in managing the pleural space. Thopaz offers innovative monitoring functions and objective data reading for an easy tracking of the therapy progress.

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Message from the President of ESTS



Dear ESTS members,

The ESTS Database was established 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 46 000 patients providing clinical information on more than 37 000 lung resections. To date, 221 units throughout Europe are sending in data on their patients on a totally free and voluntary basis, with approximately 100 contributing more than 100 cases. The recent integration of the data of the French Society of Thoracic and Cardiovascular Surgeons to the ESTS database is an example of possible cooperation with national registries when they already exist, and the demonstration of a successful import of a huge amount of information. Another prospect for those countries in which thoracic surgery begins to become more individual and to get organized, is to appropriate the ESTS database, even if it means developing it according to national contingencies.

To comprehensively assess surgical performance on an international level is one of our main objectives. Under the leadership of Alessandro Brunelli, the ESTS has developed a composite performance score incorporating processes and outcomes measures available in the database and has applied it to stratify performance of participating units. Those that are above the 50th percentile of the composite score are invited to submit their application to the ESTS Institutional Accreditation Program. Final peer-review assessment is then based upon the required structural/procedural/professional characteristics that are listed at the end of this report. In 2011, Antwerp-Belgium became the first elected institution. Four further European units are under consideration for 2012.

The ESTS Database also offers solid grounds for clinical research. To date, a dozen of publications have been derived from database outcomes, and published in various scientific journals and textbooks. They have significantly advanced understanding in thoracic surgery. Another development over this last year has been the decision to use the ESTS database as support of the ESTS Thymic Tumours data collection. This is another fruitful strategic development to offer to ESTS working groups a scientific platform with increasingly specific variables besides a concise set of core variables.

At the onset of a second decade, the ESTS database is undoubtedly at the end of its beginning. I would like to strongly encourage you to participate in this important project to the benefit of your patients, your practice and your specialty.

Pascal A. Thomas President of the European Society of Thoracic Surgeons

Message from the Director of ESTS Database



This is the fourth annual report of the ESTS Thoracic Database. It collects data from July 2007 to March 2012. At the time of data analysis more than 220 units have registered in the Database and contributed data.

The aim of this report is to provide an overview (albeit still incomplete and preliminary) of the thoracic surgery activity in Europe. As for the first three reports, even this one will focus on lung resections only as the most representative procedure of our specialty and those that are currently taken into consideration for the European Accreditation program.

The structure of the report remains the same of the previous years. The first part represents a summary of the type of procedures performed with a particular focus on the types of lung resection, their diagnoses, the distribution of lung resections by site and side of operation, and the characteristics of the patients operated on according to pulmonary function, ASA and ECOG scores and presence of coronary artery disease.

At the end of the first part, we report the outcomes of operations with the incidence of mortality and cardiopulmonary morbidity in the entire population submitted to lung resection grouped by type of procedure. The second part focuses on the comparative analysis of different European Countries, according to the distribution of patients, procedures and occurrence of unadjusted and risk-adjusted outcome rates. The online Database continues to run on a Dendrite platform, which ensures appropriate levels of software, hardware and data security and backups. Data contribution continues to be free for any ESTS members and for invited contributors.

End-users have the possibility to export their data in their PC for their own purposes. The possibility exists for those units having their own database to import their patients into the ESTS Database. A formal request needs to be sent to ESTS and Dendrite by each December and Dendrite will work on the import, following a standard process (SOP Standard Operating Procedure) available for consultation on the ESTS web site, under the section Database, III rd Party Data Imports.

As anticipated last year, an important agreement has been signed between the French Society of Thoracic and Cardiovascular Surgery (FSTCVS) and ESTS. A convergence has been initiated for data import and future quality initiatives. As to start with, all pulmonary resections collected in the Epithor (the French National Registry) from 2007 to 2011 have been imported in the ESTS Database and are part of this Annual Report.

An important agreement has also been reached between ESTS and The Society of Thoracic Surgeons to collaborate on the general thoracic surgery database issue.

Finally, as announced last year, the ESTS Council has approved a Quality certification program based on self-reported information and data submitted to the ESTS Database. A composite performance score (using both process and outcome indicators) has been already published and has been used as the instrument to rate the participating units according to reference values, which are published at the end in this report for transparency and will be updated regularly. So far the following centers have been accredited by ESTS based on their structural, procedural and professional criteria: Antwerp, Belgium; Sagrad Cor Hospital Barcelona, Spain; University Hospital, Istanbul, Turkey; Salamanca University Hospital, Spain; Ospedali Riuniti Ancona, Italy). These units have been visited by an external team to verify their credentials and for auditing their data submitted to the ESTS Database. More information about the ESTS Institutional Accreditation Program is reported at the end of this report.

We hope you will find this fourth report useful for your clinical and scientific practice and an incentive to join our Database for the future of our specialty in Europe.

Dr. Alessandro Brunelli Director of ESTS Audit and Database



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 190 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.den-drite.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.

PART 1 DATABASE FORMAT AND SUBMISSION OF DATA

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OF THON

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.

3 ~.	ESTS REGISTRY
Contact Information "The database project has been financially supported by Medela HealthCare " medela 🍄	User Authentication
Exit Application Dearlie Clinical Systems Copyright 2210	Line speed 7/2 kapster

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.

200			Patier	nt Search			CONTRACT INST. BAR
Contact Information	Options Add new patient Clear results Show v List 20 results	Search patient Surname Forename NHS Num			Hospital Number Date of birth	Search &	
	Patient Id Hospita	Number	Surname	Forename	NHS Number	Date of birth	Gender

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

3 -2.		Patient Demographic	Summary	WILLIAM DA . 1993 . MARCA
Contact Information	Edit Demographics Pati	ent Search		
Main menu	Test Patient	ILH.S. Humber: Hospital Humber: 888888		: 12 December 1955 : Male
View Letters		(1) Add to Database: ESTSR 👻 Add	(2)	
	Clinical Database	Date Of Entry View Follow	Edit Initial	Add Follow up
		ups ups		
Exit Application Dendrite Clinical Systems Copyright © 2010				

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.

220		()	ESTS	HINGACIC SURGEONS		
	Previous Page	Next Page	Save & Exit	GROUP DETAILS	Page 1 of 4	
Contact Information	Date of Surgery - 02	March 2011 💌		Selecte	d Patient : Test Patient	
Patient Search				JP DETAILS		V
Documents	Date of Surgery	02 March 2011	1			
Wire Letters	Gender	Male 💌				
	Age	55				
Data Summary	Surgeon					
	Other Surgeon					
Audit	Group Definition	Lung	~			
	Lung SUBGROUP	Lung Excision	~			
	Lung Excision - PROCEDURE	Bilobectomy	~			
	BILOBECTOMY - LOBECTOMY - Qualifier	Sleeve		×		
	Bilobectomy PROC SITE	RUM 🛩				
	VATS	Yes 🗸				

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.

		() ESTS	REGISTRY	
	Previous Page Nex	t Page Save & Exit	RISK FACTORS Page 2 o	st 4
Contact Information	Date of Surgery - 02 Marc	h 2011 💙	Select	ted Patient : Test Patient
Patient Search			RISK FACTORS	E
Documents	Urgency	Elective Y		
Wire Letters	ASA		×	
	ECOG	~		
Data Summary	Weight (Kg)	Height (m)	BMI	
Audit	FE¥1 (Litres)		FE¥1% 85	ppoFEV1% 70.83 FVC (Litres)
About	F¥C%	FE	EV1(L)/FVC(L)	DLCO% 77 ppoDLCO% 64.16
		Previous surgery - segments removed Atelectatic segments at operatior Functioning segments resected	n 1	
	¥O2Max (ml/kg/min)	MRC Score		
	Cardiac Co-Morbidity1	Coronary Artery Disease	Card. Co-Morbidity2	M
	Cardiac Co-Morbidity3		~	
Exit Application	Other co-Morbidities1	×	Other co-Morbidities2	<u>×</u>
Exit Application	Other co-Morbidities3	~		

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

	Previous Page	Next Page	Save & Exit	DIAGNO	DSIS AND STAGING	Mage 3 of 4	
ntact Information	Date of Surgery - 02	March 20	11 💌		Select	ed Patient : Test Patient	
Patient Search			DIAGN	OSIS AND	STAGING		
Documents	DIAGNOSIS	Lung Car	ncer (NSCLC)	~			
Wire Letters	Other Diugnosis						
	MORPHOLOGY	Neoplast	tic Malignant Primary	~			
ata Summary	cī	~					
	cN	Y					
Audit	cM	~					
	pT	~					
	pN	~					
	рМ	~					
	pR	~					
	ст		~				
	PET		*				
	Pre-operative Invasive Mediastinal Staging		~				
	Lymphadenectomy				~		
	NEOADJUVANT		*				

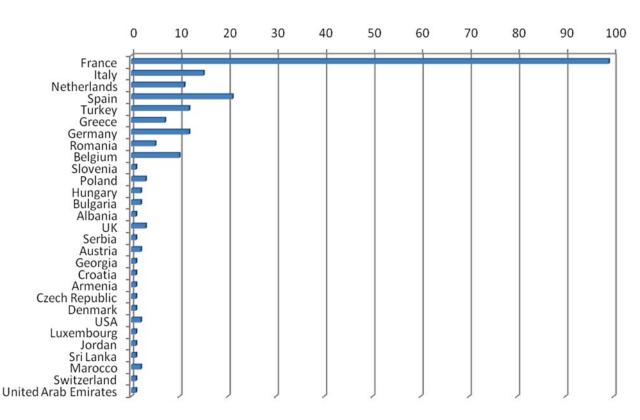
The system auto-calculates for Lung Excision Procedure the Predicted Mortality (%) and Predicted Morbidity (%).

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

200					X	ESTS	REGIST	TRY			
	Previous page	Next	t page Save 8			Exit OUTCOME	Y	Page 4 of 4			
Contact Information	Date of Surgery	- 02 Marc	h 2011	~				Selected Pat	ient : Test Patient		
Patient Search						OUTCO	OME				
Documents	Comp	plication1	ARDS			~					
Wire Letters	Comp	plication2				~					
		plication3				×					
Data Summary	Other Con		_								
	Major cardio com	pulmonary plications	Yes 🜱								
Audit	Predicted mo	rtality %	2.84	ОК		2					
	Predicted mo	rbidity %	12.72	ОК		2					
	DATE of DI	SCHARGE				8					
	Outcome at	Discharge			4						
	Outcome a	t 30 Days			×						
	Cause	of Beath			X						
	DATE	OFDEATH									1
	Operati	ive Death					×				
		Notes									
Exit Application											

	2.84 OK ?
Predicted mortality %	$\Pr_{\substack{\text{(by ESTS Report 2010)}}}^{\text{Pr}edictedMortality} = \frac{e^{z}}{1+e^{z}}$
	z = (-3.22 +1.049*Pneumonect omy+0.928*cardiac comorbidit y-0.0175*PPO Fev1%)
	12.72 OK 2
Predicted morbidity %	$\Pr_{\substack{\text{(by ESTS Report 2010)}}} = \frac{e^{z}}{1 + e^{z}}$
	Z = (-3.52+0.659Pneumonecbmy+0.322*cardiac comorbidity-0.0069*PPOFev1%+0.403*ExtendedResection+0.0319*Age)

N. units enrolled in the ESTS database as of March 2012, subdivided by Country.



N Units

Units contributing to ESTS Database July 2007 - March 2012.

Only units contributing more than 100 patients (as of March 5th 2012) in the registry are shown.

INSTITUTION	CITY	COUNTRY
CH du pays d'Aix		FRANCE
VUMC Dept of Surgery	AMSTERDAM	NETHERLANDS
Ospedali Riuniti Ancona	ANCONA	ITALY
University Hospital of Antwerp	ANTWERP	BELGIUM
EVANGELISMOS	ATHENS	GREECE
Hygeia Hospital	ATHENS	GREECE
CHG Avignon	AVIGNON	FRANCE
Hospital Clinic	BARCELONA	SPAIN
Sagrat Cor University Hospital	BARCELONA	SPAIN
CHG Bayonne	BAYONNE	FRANCE
CHU Jean Minjoz Besançon	BESANCON	FRANCE
Clinique Ambroise Paré	BEUVRY	FRANCE
Clinique Saint Privat Béziers	BEZIERS	FRANCE
CMC du Cèdre Rouen 1	BOIS GUILLAUME	
Discipline Chirurgiche, Rianimatorie e dei Trapianti Univ. Bologna		ITALY
Clinique Bordeaux Nord	BORDEAUX	FRANCE
Amphia Hospital	BREDA	NETHERLANDS
Cliniques Universitares Saint-Luc	BRUSSELS	BELGIUM
Hopital Academique Erasme	BRUSSELS	BELGIUM
Institute of Oncology Bucharerst	BUCHAREST	ROMANIA
Marius Nasta Institute of Pneumonology	BUCHAREST	ROMANIA
CH René Dubos - Pontoise	CERGY PONTOISE	
Centre Hospitalier de Chambéry	CHAMBERY	FRANCE
HIA Percy	CLAMART	FRANCE
CHU Gabriel Montpied CF	CLERMONT FERRAND	FRANCE
University Of Debrecen	DEBRECEN	HUNGARY
CHU du Bocage Dijon	DIJON	FRANCE
County Emergency Hospital	DROBETA-TURNU SEVERIN	ROMANIA
Royal Devon & Exeter NHS Foundation Trust	EXETER	UK
Scienze Chir. Sezione Chirurgia Toracica - Osped. Riun. Univ. Foggia	FOGGIA	ITALY
San Martino - Genoa	GENOVA	ITALY
CHU Michallon Grenoble	GRENOBLE	FRANCE
Kennemer Gasthuis	HAARLEM	NETHERLANDS
HG Vall d'Hebron	HEBRON	SPAIN
Istanbul School of Medicine	ISTANBUL	TURKEY
Istanbul University, Cerrahpasa Medical Faculty	ISTANBUL	TURKEY
Sureyyapasa Chest Disease & Thoracic Surgery Hospital	ISTANBUL	TURKEY
Hôpital St Louis	LA ROCHELLE	FRANCE
Clinique Petit Col Moulin Le Havre	LE HAVRE	FRANCE
Marie Lannelongue Hospital	LE PLESSIS ROBINSON	FRANCE
V. Fazzi Hospital	LECCE	ITALY
University of Leuven	LEUVEN	BELGIUM
CHU Calmette Lille	LILLE	FRANCE
Polyclinique du Bois	LILLE	FRANCE
CHU Dupuytren	LIMOGES	FRANCE
CHU Louis Pradel Lyon	LYON	FRANCE
Clinique St Louis Lyon	LYON	FRANCE

INSTITUTION	CITY	COUNTRY
H. Clinico San Carlos	MADRID	SPAIN
Hospital general Universitario Gregorio Maranon	MADRID	SPAIN
Clinique de la Louvière	MARCQ en BAROEUL	FRANCE
CHU Nord Marseille	MARSEILLE	FRANCE
Médipole Gentilly Maxeville	MAXEVILLE	FRANCE
Hôpital Belle-Isle Metz	METZ	FRANCE
Az. Ospedaliera San Paolo	MILANO	ITALY
Fondazione ospedale Maggiore Policlinico	MILANO	ITALY
Maria Hilf Kliniken	MONCHENGLADBACH	GERMANY
CHU de Montpellier	MONTPELLIER	FRANCE
Clinique du Millénaire	MONTPELLIER	FRANCE
CMC de la Baie de Morlaix	MORLAIX	FRANCE
CHU Central de Nancy	NANCY	FRANCE
CHU de Nantes	NANTES	FRANCE
Clinique St Augustin - Nantes	NANTES	FRANCE
Nouvelle Clinique Nantaise	NANTES	FRANCE
Clinica Universitaria De Navarra	NAVARRA	SPAIN
CHU Pasteur Nice	NICE	FRANCE
Clinique Saint Georges	NICE	FRANCE
CHR de la Source	ORLEANS	FRANCE
HEGP Paris	PARIS	FRANCE
Hôtel Dieu Paris	PARIS	FRANCE
IMM Paris	PARIS	FRANCE
Marie Lannelongue Hospital	PARIS	FRANCE
University Hospital Parma	PARMA	ITALY
CHG Pau	PAU	FRANCE
CHU Haut Lévêque Bordeaux	PESSAC	FRANCE
CHU Lyon Sud	PIERRE BENITE	FRANCE
CHU de Poitiers	POITIERS	FRANCE
Clinique Quimper sud	QUIMPER	FRANCE
Clinique Courlancy Reims	REIMS	FRANCE
CHU Pontchaillou	RENNES	FRANCE
CHU Charles Nicolle Rouen	ROUEN	FRANCE
Clinique du Val D'or	SAINT CLOUD	FRANCE
CH Privé Saint Grégoire	SAINT GREGOIRE	FRANCE
Hopital yves le Foll	SAINT-BRIEUC	FRANCE
University Hospital Salamanca	SALAMANCA	SPAIN
HHUU VIRGEN DEL ROCIO	SEVILLA	SPAIN
University Hospital Siena	SIENA	ITALY
Clinique Belledonne Grenoble	ST MARTIN D'HERES	
CHU de Strasbourg	STRASBOURG	FRANCE
Clinique St Odile	STRASBOURG	FRANCE
Clinique Bénigne Joly	TALANT	FRANCE
AHEPA UNIVERSITY HOSPITAL	THESSALONIKI	GREECE
Clinical Muncipal Emergency Hospital	TIMISOARA	ROMANIA
University Hospital of Lung Diseases "Shefqet Ndroqi"	TIRANA	ALBANIA
CHU Larrey Toulouse	TOULOUSE	FRANCE
CHU Trousseau Tours	TOURS	FRANCE
General University Hospital Valencia	VALENCIA	SPAIN
CH Jean Bernard	VALENCIENNES	FRANCE
Clinique Océane	VANNES	FRANCE

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.
- 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 <u>one</u> of the following:

- New or progressive <u>and</u> persistent infiltrate.
- Consolidation.
- Cavitation.
- And at least **<u>one</u>** of the following:
- Fever (>38EC or >100.4EF) with no other recognized cause.
- Leukopenia (<4000 WBC/mm³) or leukocytosis (≥12,000 WBC/mm³).
- For adults \geq 70 years old, altered mental status with no other recognized cause.

And at least **<u>two</u>** 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., $PaO_2/FiO_2 \le 240$), 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:

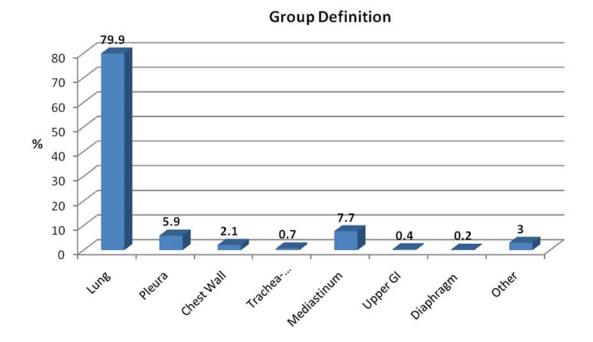
- 1. increase of serum creatinine to greater than 2.0, and 2-fold the preoperative creatinine level.
- 2. a new requirement for dialysis postoperatively.

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.

Group Definitions

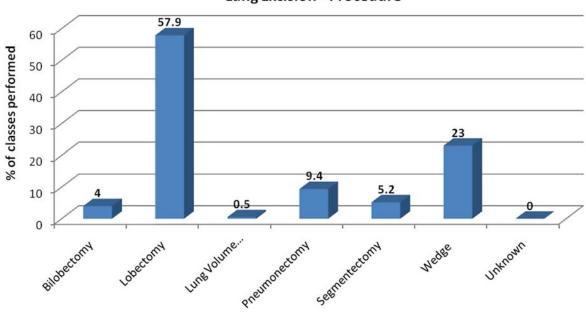
Ans	wer	Occurrences	Percent
0	Lung	36718	79.9
1	Pleura	2731	5.9
2	Chest Wall	958	2.1
3	Trachea - Bronchus	341	0.7
4	Mediastinum	3537	7.7
5	Upper GI	179	0.4
6	Diaphragm	100	0.2
	Other	1373	3.1
		45937	

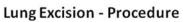


Types of lung resections performed (tot. 34879), including all diagnoses

Lung Excision Procedure

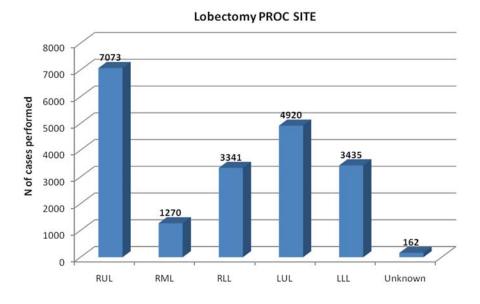
Ans	wer	Occurrences	Percent
0	Bilobectomy	1386	4.0
1	Lobectomy	20201	57.9
2	Lung Volume Reduction	on 162	0.5
3	Pneumonectomy	3294	9.4
4	Segmentectomy	1805	5.2
5	Wedge	8018	23.0
	Unknown	13	0.0
		34879	





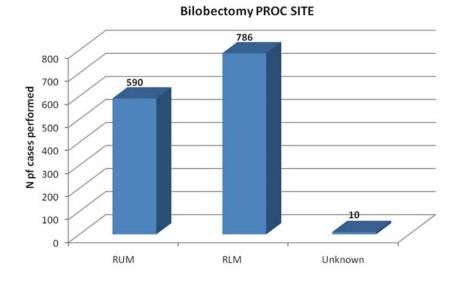
Distribution of lobectomies/bilobectomies (21587 cases) by site of resection

Lob	Lobectomy Proc Site						
Answer		Occurrences	Percent				
0	RUL	7073	35.0				
1	RML	1270	6.3				
2	RLL	3341	16.5				
3	LUL	4920	24.4				
4	LLL	3435	17.0				
	Unknown	162	0.8				
		20201					



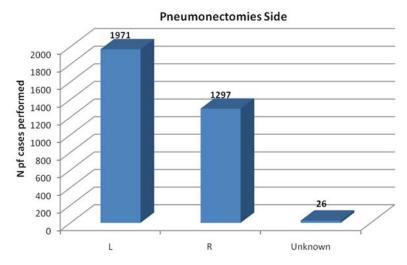
Bilobectomy Proc Site

Answer		Occurrences	Percent	
0	RUM	590	42.6	
1	RLM	786	56.7	
	Unknown	10	0.7	
		1386		



Distribution of pneumonectomies

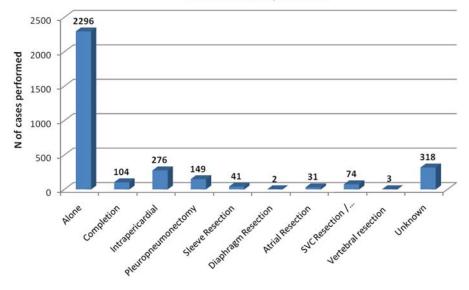
Pne	Pneumonectomy Side							
Answer		Occurrences	Percent					
0	L	1971	59.8					
1	R	1297	39.4					
	Unknown	26	0.8					
		3294						



Pneumonectomy Qualifier

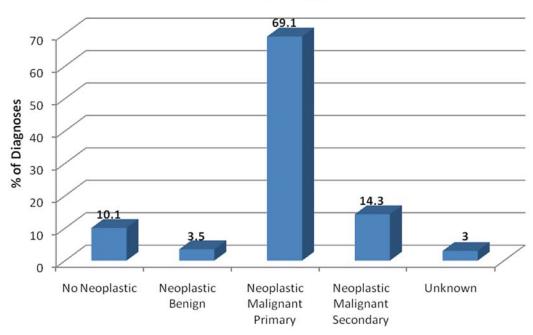
Answer	Occurrences	Percent
Alone	2296	69.7
Completion	104	3.2
Intrapericardial	276	8.4
Pleuropneumonectomy	149	4.5
Sleeve Resection	41	1.2
Diaphragm Resection	2	0.1
Atrial Resection	31	0.9
SVC Resection /Reconstruct	tion 74	2.2
Vertebral resection	3	0.1
Unknown	318	9.7
	3294	

Pneumonectomy Qualifier



Diagnoses of all lung resections

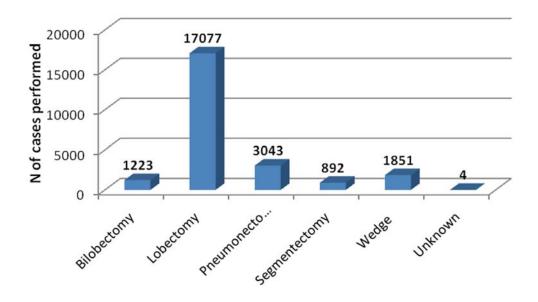
Answer Oc		rrences	Percent
0	Non Neoplastic	3531	10.1
1	Neoplastic Benign	1232	3.5
2	Neoplastic Malignant Primary	24090	69.1
3	Neoplastic Malignant Secondary	4989	14.3
	Unknown	1037	3.0
		34879	

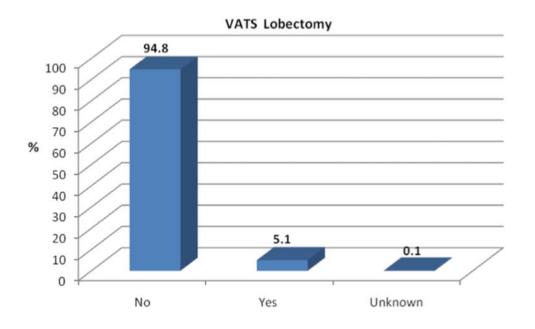


Morphology

Lung resection for Primary Lung Cancer: Types of procedures (total 24090)

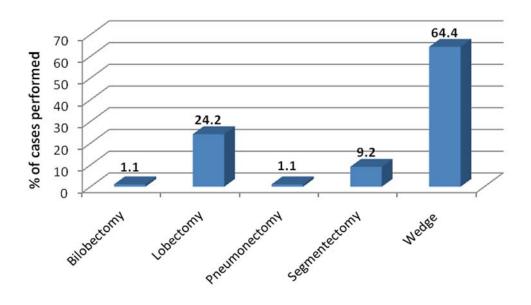
Answer		Occurrences	Percent
0	Bilobectomy	1223	5.1
1	Lobectomy	17077	70.9
3	Pneumonectomy	3043	12.6
4	Segmentectomy	892	3.7
5	Wedge	1851	7.7
	Unknown	4	0.0
		24090	



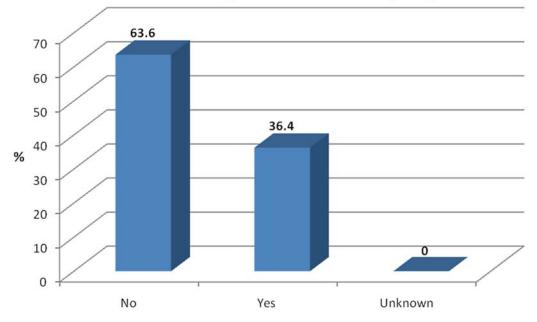


Lung resection for secondary malignant disease: Types of procedures (total 4989)

Ans	wer	Occurrences	Percent
0	Bilobectomy	54	1.1
1	Lobectomy	1208	24.2
3	Pneumonectomy	56	1.1
4	Segmentectomy	458	9.2
5	Wedge	3212	64.4
	Unknown	1	0.0
		4989	

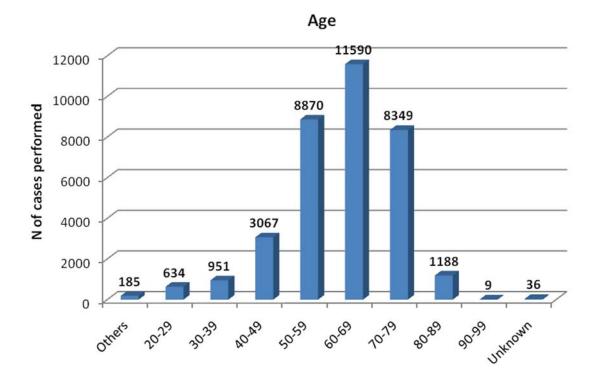


% of VATS wedge resections for Secondary Malignant disease



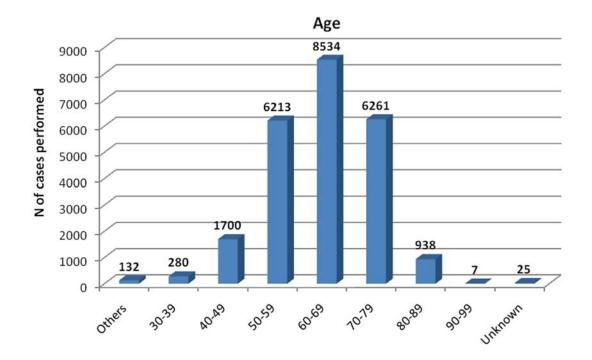
Patients age distribution in all types of lung resection

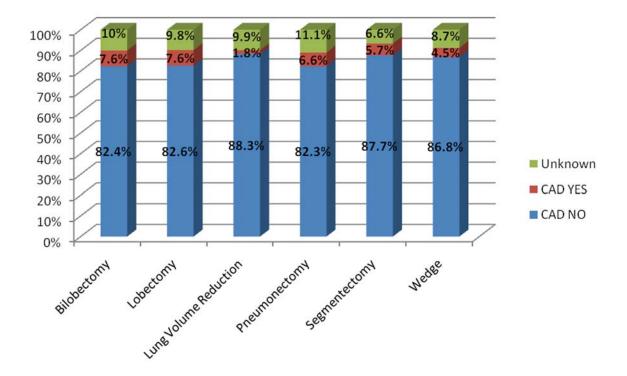
Answer	Occurrences	Percent
Others	185	0.5
20-29	634	1.8
30-39	951	2.7
40-49	3067	8.8
50-59	8870	25.4
60-69	11590	33.2
70-79	8349	23.9
80-89	1188	3.4
90-99	9	0.0
Unknown	36	0.1



Patients age distribution in lung resection for Malignant Primary Neoplastic disease

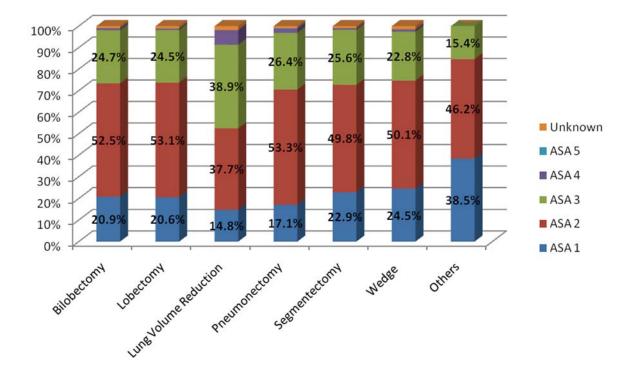
Answer	Occurrences	Percent
Others	132	0.5
30-39	280	1.2
40-49	1700	7.1
50-59	6213	25.8
60-69	8534	35.4
70-79	6261	26.0
80-89	938	3.9
90-99	7	0.0
Unknown	25	0.1





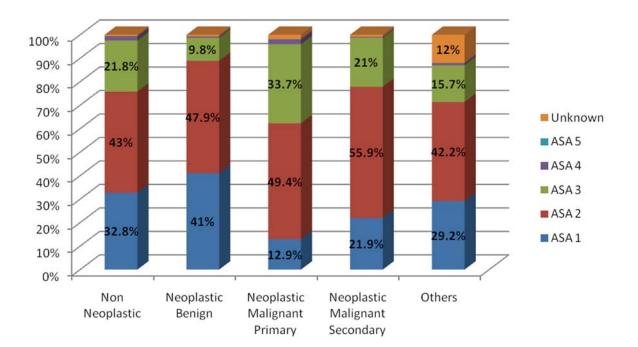
Incidence of Coronary Artery Disease by operation

	CAD NO	CAD YES	Unknown	Total
Bilobectomy	1142	105	139	1386
%	82.40	7.58	10.03	100.00
Lobectomy	16684	1535	1982	20201
%	82.59	7.60	9.81	100.00
Lung Volume Reduction	143	3	16	162
%	88.27	1.85	9.88	100.00
Pneumonectomy	2712	218	364	3294
%	82.33	6.62	11.05	100.00
Segmentectomy	1582	103	120	1805
%	87.65	5.71	6.65	100.00
Wedge	6960	358	700	8018
%	86.80	4.46	8.73	100.00
Unknown	6	0	7	13



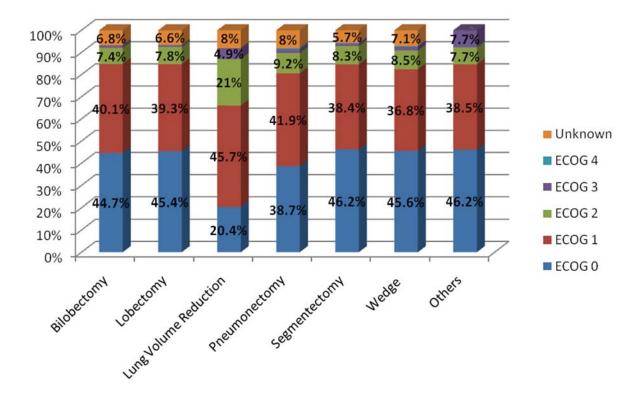
Distribution of ASA score by type of operation

	ASA 1	ASA 2	ASA 3	ASA 4	ASA 5	Unknown	Total
Bilobectomy	289	728	343	12	1	13	1386
Lobectomy	4161	10730	4947	133	3	227	20201
Lung Volume							
Reduction	24	61	63	11	0	3	162
Pneumonectomy	564	1757	869	65	8	31	3294
Segmentectomy	413	899	462	14	0	17	1805
Wedge	1967	4017	1825	89	1	119	8018
Others	5	6	2	0	0	0	13
Total	7423	18198	8511	324	13	410	34879



Distribution of ASA score in wedge resections grouped by diagnosis

	ASA 1	ASA 2	ASA 3	ASA 4	ASA 5	Unknown	Total
Non Neoplastic	596	783	396	33	0	11	1819
Neoplastic Benign	330	385	79	4	0	6	804
Neoplastic							
Malignant Primary	239	914	624	38	1	35	1851
Neoplastic							
Malignant Secondary	705	1795	674	11	0	27	3212
Others	97	140	52	3	0	40	332
Total	1967	4017	1825	89	1	119	8018



Distribution of ECOG score by type of operation

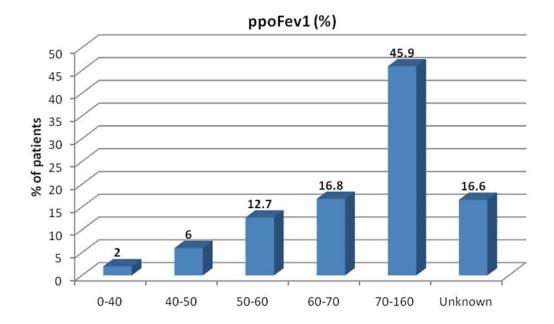
	ECOG 0	ECOG 1	ECOG 2	ECOG 3	ECOG 4	Unknown
Bilobectomy	619	556	102	15	0	94
Lobectomy	9171	7945	1567	151	27	1340
Lung Volume Redu	ction 33	74	34	8	0	13
Pneumonectomy	1274	1380	302	56	18	264
Segmentectomy	834	693	150	20	5	103
Wedge	3656	2949	683	136	23	571
Others	6	5	1	1	0	0

Automatic calculation of split lung function

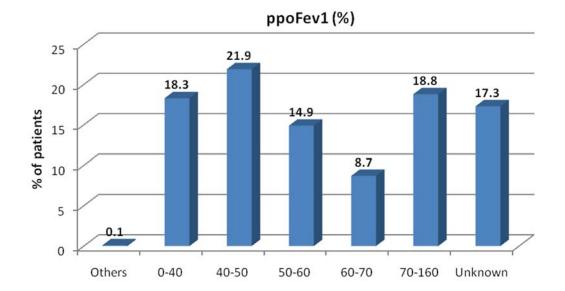
The calculation of Predicted Postoperative Forced Expiratory Volume in one second (ppoFEV1) and Predicted Postoperative Carbon Monoxide Lung Diffusion Capacity (ppoDLCO) in this version of the online Database has been standardized through the introduction of a ppoFEV1 calculator (see image and example below) taking into account the number of functioning and non functioning segments removed at operation.

	Preop FEV1 %	85
13/15	Previous surgery - segments remove	d 0
	Atelectatic segments at operation	1
	Functioning segments resected	β
	Atelectatic segments resected	1
	Atelectatic segments restored by pro	ocedure 0
	Cal	culate Result
	Predicted post-op FEV1 %	

Distribution of ppoFEV1% in lobectomy/bilobectomy patients



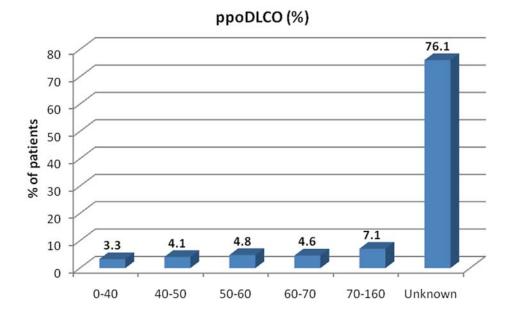
Answer	Occurrences	Percent
0-40	424	2.0
40-50	1302	6.0
50-60	2747	12.7
60-70	3633	16.8
70-160	9898	45.9
Unknown	3583	16.6



Distribution of ppoFEV1% in pneumonectomy patients

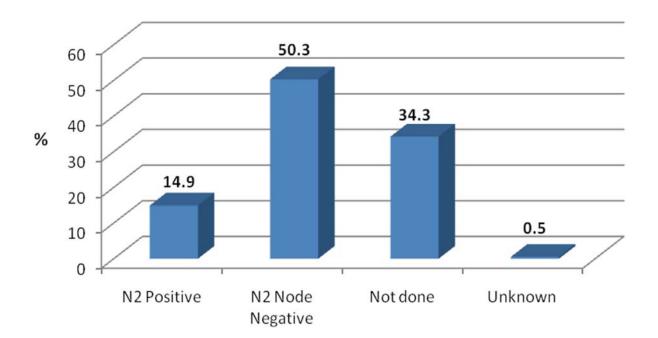
Answer	Occurrences	Percent
Others	2	0.1
0-40	604	18.3
40-50	720	21.9
50-60	491	14.9
60-70	286	8.7
70-160	620	18.8
Unknown	571	17.3
	3294	

Distribution of ppoDLCO% in major lung resections (lobectomy and pneumonectomy)



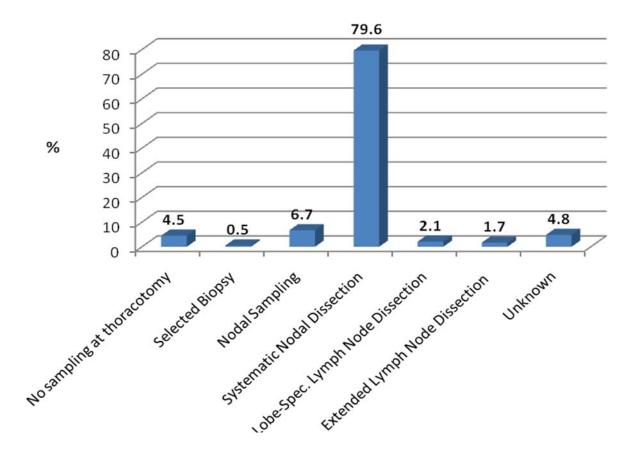
Answer	Occurrences	Percent
Others	4	0.0
0-40	816	3.3
40-50	1021	4.1
50-60	1189	4.8
60-70	1140	4.6
70-160	1772	7.1
Unknown	18939	76.1
	24881	

Incidence of invasive mediastinal staging performed in all types of lung resections in patients with enlarged mediastinal nodes at CT scan or PET positive mediastinal nodes and primary lung cancer



Type of intraoperative mediastinal nodal staging in lung resection for malignant primary neoplastic disease

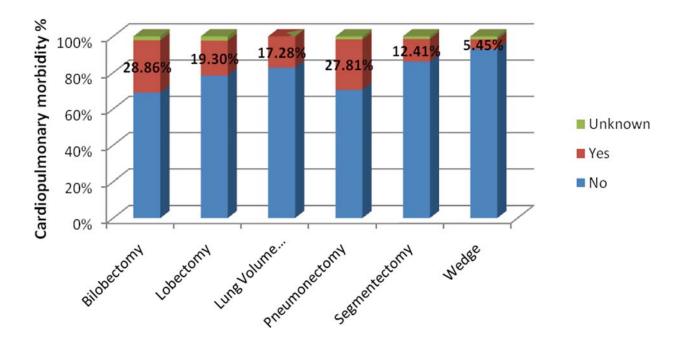
(according to the ESTS guidelines on intraoperative mediastinal staging. Lardinois D et al. ESTS guidelines for intraoperative lymph node staging in non small cell lung cancer. Eur J Cardiothorac Surg 2007; 32:1-8)



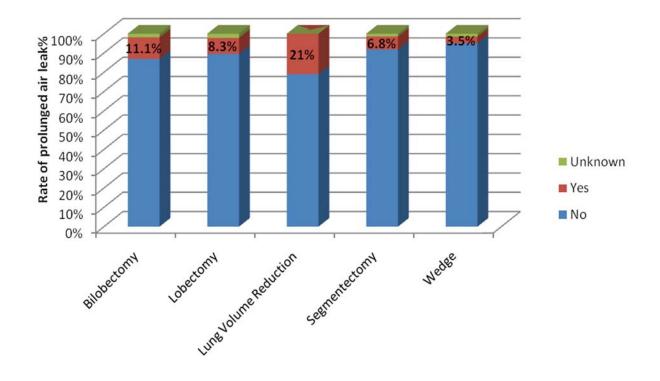
Cardiopulmonary Morbidity rate in different types of lung resections

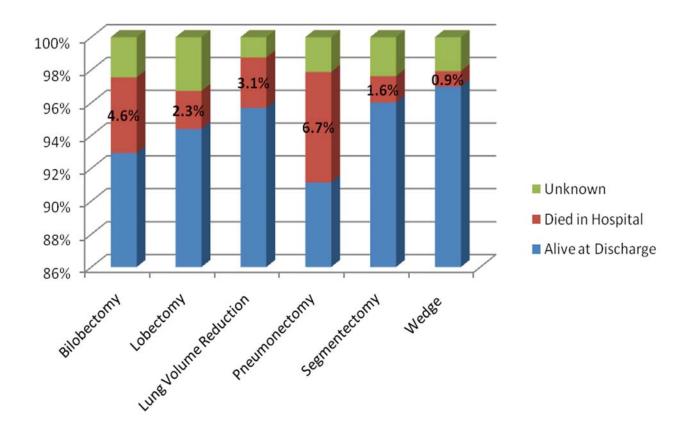
The cardiopulmonary complications included for this analysis are the followings: respiratory failure and mechanical ventilation for more than 24 hours, reintubation at any time in the postoperative period, pneumonia, atelectasis requiring bronchoscopy, pulmonary embolism, pulmonary edema, supraventricular arrhythmia requiring treatment, ventricular arrhythmia, acute myocardial ischemia, stroke, renal insufficiency, cardiac failure.

These complications are those occurring while the patient are in the hospital.



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





Unadjusted in-hospital Mortality rates in different types of lung resections

PART 2 COMPARATIVE ANALYSIS BETWEEN DIFFERENT COUNTRIES

FTHOR

Only Countries contributing more than 100 lung resections were included

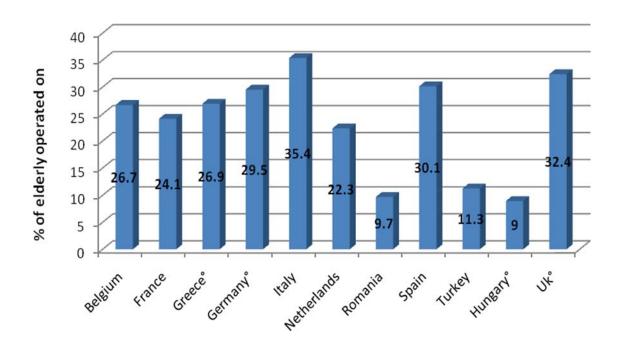
1993

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

From analysing the graph below, there is a wide difference between Countries in terms of proportion of elderly patients operated on, ranging from as low as 9% to as high as 35% of the total. Reasons inherent to geographical, social, cultural, and referral patterns may explain this difference.

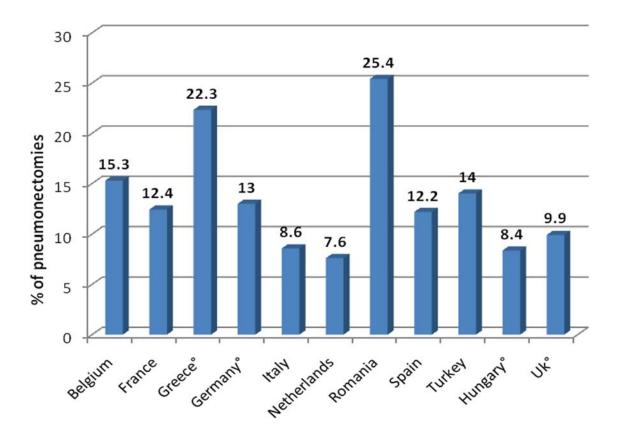
(°): Country with less than 500 patients included, results must be interpreted with caution.



Percentage of pneumonectomies (out of major anatomic resections) for malignant primary neoplastic disease in different European Countries

It has been reported that a low proportion of pneumonectomy to lobectomy procedures indicate a good practice, as the gold-standard operation for lung cancer should be lobectomy, the one that would warrant radicality with an acceptable sacrifice of functioning lung tissue. The graph below shows a great variability in practice between different Countries. The percentage of pneumonectomies (including only major anatomic pulmonary resections only) varied from as low as 8% to as high as 25%.

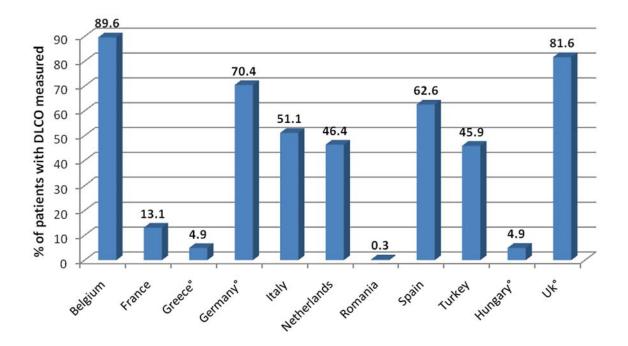
(°): Country with less than 500 patients included, results must be interpreted with caution.



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

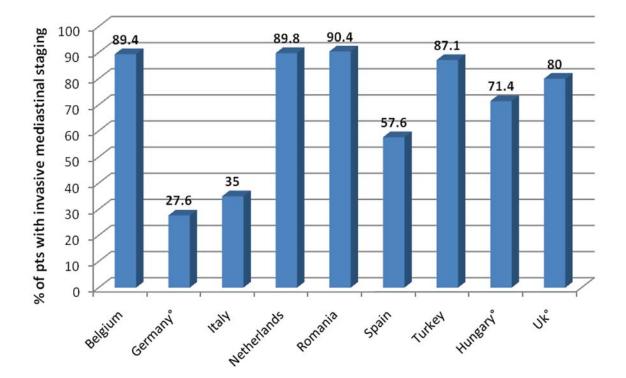
According to the recently published ERS-ESTS guidelines for evaluation of fitness in lung resection candidates, DLCO should be systematically measured before operation. In fact it does not correlate with FEV1 and a substantial proportion of patients with normal FEV1 may have low values of DLCO. The graph shows a great variability of practice in different 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.)

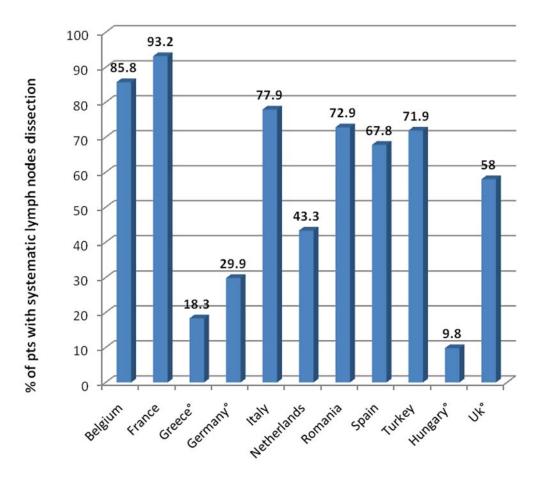
This parameter is one of the process variables used in the Composite Performance Score. The average rate of invasive mediastinal staging in all patients was 61%. There was a great variability between European Countries (from 13% to 90% of patients).



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

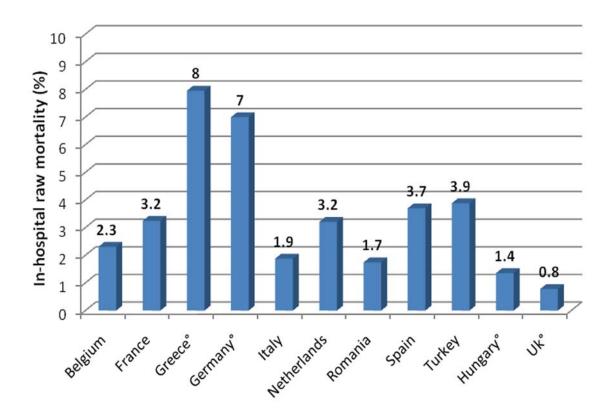
Lymph node dissection more extended than sampling alone or selected biopsy (as defined and recommended by the ESTS guidelines for intraoperative mediastinal staging) in lung cancer patients was a frequent procedure in all Countries.

This variable will be included in the composite performance score used for the ESTS quality certification program.



In-hospital raw mortality rates of major lung resections in different European Countries

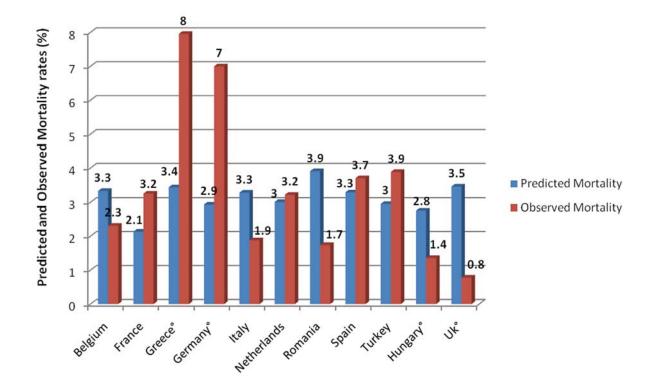
The analysis of raw mortality rates does not take into consideration the characteristics of the patients operated on and the extent of procedures. Most of the Countries display mortality rates between 1% and 4%.



In-hospital raw mortality	%
Belgium	2.3
France	3.2
Greece°	8.0
Germany°	7.0
Italy	1.9
Netherlands	3.2
Romania	1.7
Spain	3.7
Turkey	3.9
Hungary°	1.4
Uk°	0.8

Observed versus predicted 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
Belgium	3.3	2.3
France	2.1	3.2
Greece°	3.4	8.0
Germany°	2.9	7.0
Italy	3.3	1.9
Netherlands	3.0	3.2
Romania	3.9	1.7
Spain	3.3	3.7
Turkey	3.0	3.9
Hungary°	2.8	1.4
Uk°	3.5	0.8

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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