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Medela Healthcare has an agreement with ESTS to support the costs of the printing of this Report. Medela Healthcare, however, has no access to the data and information contained in the ESTS database other than the ones published in this report.

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Tom Treasure (UK)

Message from the President of ESTS

Dear ESTS members,
Dear colleagues and friends,

This year we are celebrating the 10th anniversary of the ESTS database which was initiated in 2001 by Mr. Richard Berrisford. Since then it has developed further and has been actively promoted by the database committee, now chaired by Alex Brunelli. Up to date, 190 units throughout Europe are sending in data on their patients on a voluntary basis, with approximately 90 contributing more than 100 cases.

One of the goals of the ESTS database is scientific evaluation on patient's outcome based on a large number of cases. On the other hand the database enables contributing units to measure and compare their surgical performance on an international level. Units that are above the 50th percentile of the composite score will become eligible for a certification. In the past we have decided to use the database as a tool for accreditation of units by the ESTS by checking the quality by peer review.

This year for the first time, six units of the nine units eligible have applied for the process of certification. The peer review will be performed by a professional auditing company (Adamas) as well as an ESTS member (national regent) in order to verify locally the data delivered by these units to the database. We expect to have the first units accredited by this summer. A pilot study performed in units of members of our database committee (Ancona: Alessandro Brunelli; Salamanca: Gonzalo Varela) has proven the validity of the certification process.

Another development over this last year has been the decision to closer cooperate with the database committee of the American Society of Thoracic Surgeons (STS). First steps have been initiated to check further cooperation. A project almost completed is the integration of the data of the French Society of Thoracic and Cardiovascular Surgeons (FSTCVS) to the ESTS database.

In a world where measurement of quality becomes an integral part of our daily work the ESTS database offers a unique chance to demonstrate high performance. We therefore would like to encourage you to participate in this important ESTS project which eventually will be for the benefit of patients throughout Europe.

Gunda Leschber
President European Society of Thoracic Surgeons

Message from the Director of ESTS Database

This is the third annual report of the ESTS online Thoracic Database. It collects data from July 2007 to March 2011. At the time of data analysis approximately 190 units have registered in the Database and contribute 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 two reports, even this one will focus on lung resections only as the most representative procedure of our specialty.

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.

There has been important news in the last year. The online Database has started running on a Dendrite platform. The interface has maintained its clarity and user-friendliness with additional 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 in to 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 2010 have been imported in the ESTS Database and are part of this Annual Report.

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. This year 8 units resulted eligible for certification based on their Composite Performance Score. These units have been invited to submit their application, which includes information about their structural, procedural and professional criteria. Only four units accepted to participate to the program (Antwerp, Belgium; Sagrad Cor/University Hospital Barcelona, Spain; University Hospital, Istanbul, Turkey). These units will be 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 third 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
On behalf of the ESTS Database Committee

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.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.

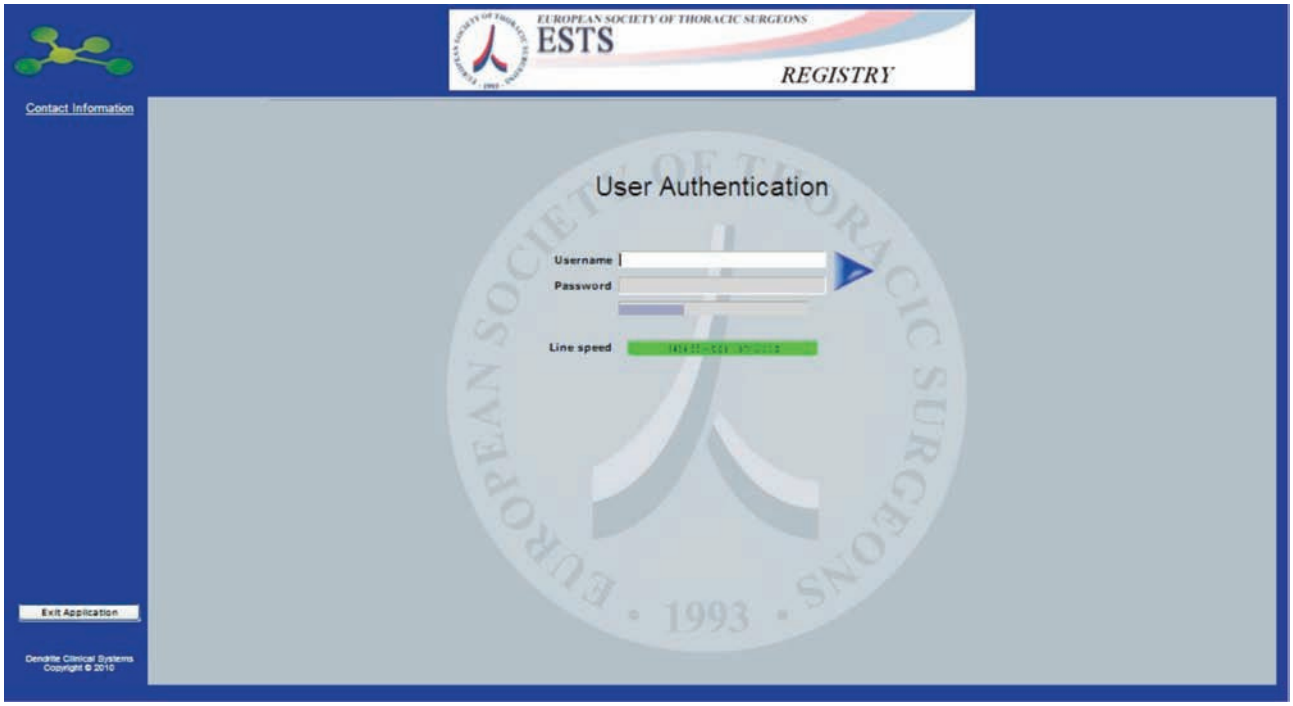
The main reasons for their widespread activity in this field include:
- Bottom-up approach to data management: the range of products and services starts from database and electronic patient records and serves Clinicians daily needs; it escalates to hospital-wide systems, to regional, national and finally 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.

PART 1
DATABASE FORMAT AND SUBMISSION OF DATA

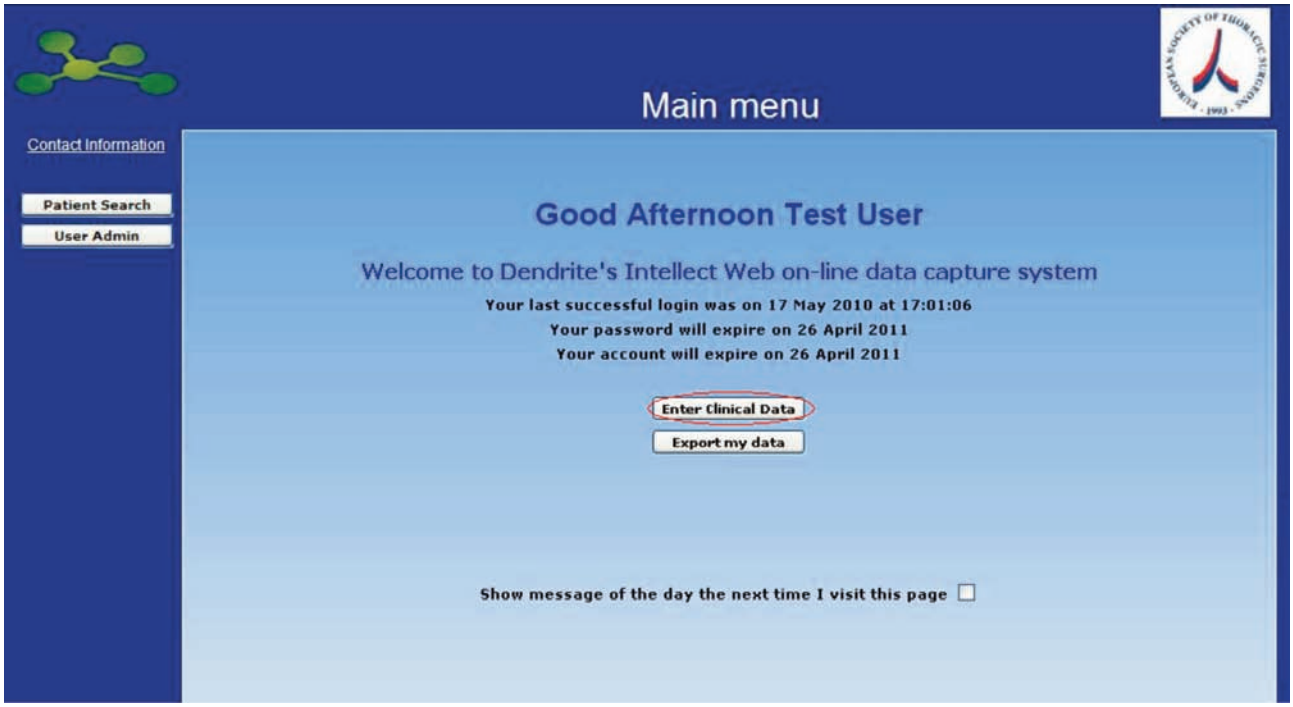
The first step is to request and obtain a login account through the relevant link found in the ESTS homepage (http//www.ests.org) or by directly sending an email to one of the members of the Database Committee. Once you have a valid login account you can proceed through the following data entry interface (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.**

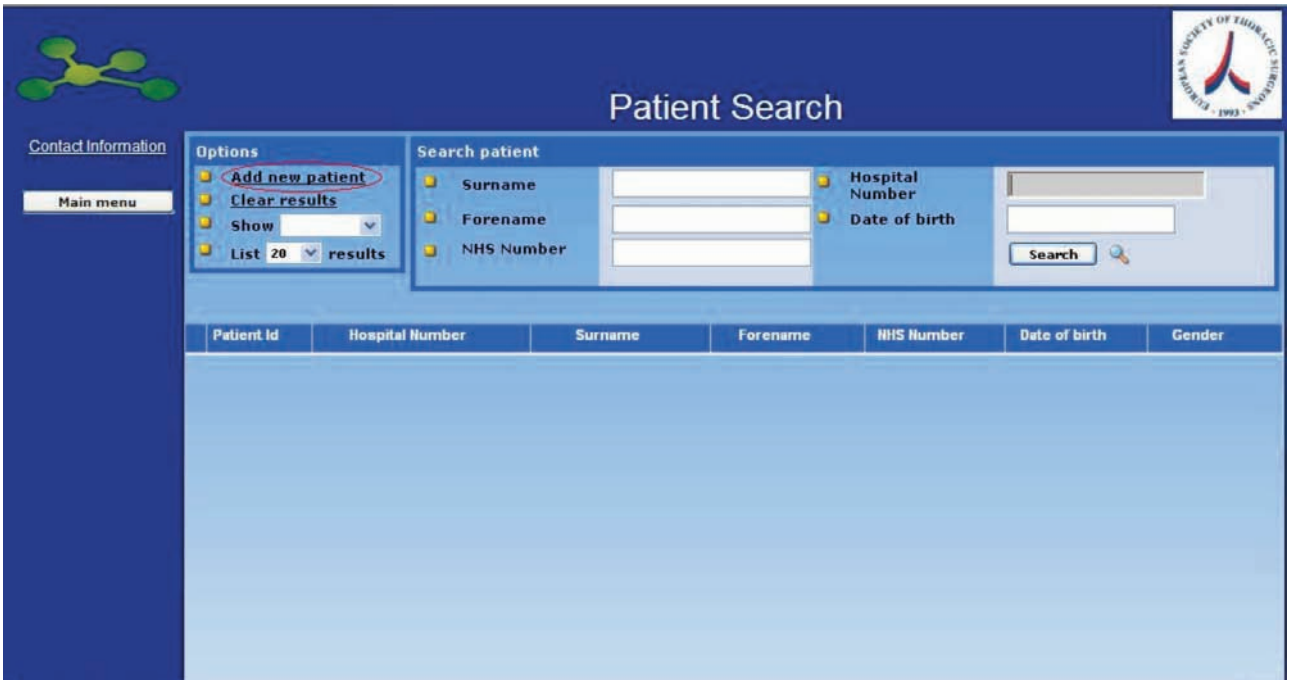


Once you have logged in you are presented with the Database main menu, from which you can add new data, view or edit a procedure, modify your account details, and export your data in Excel for your own purposes.

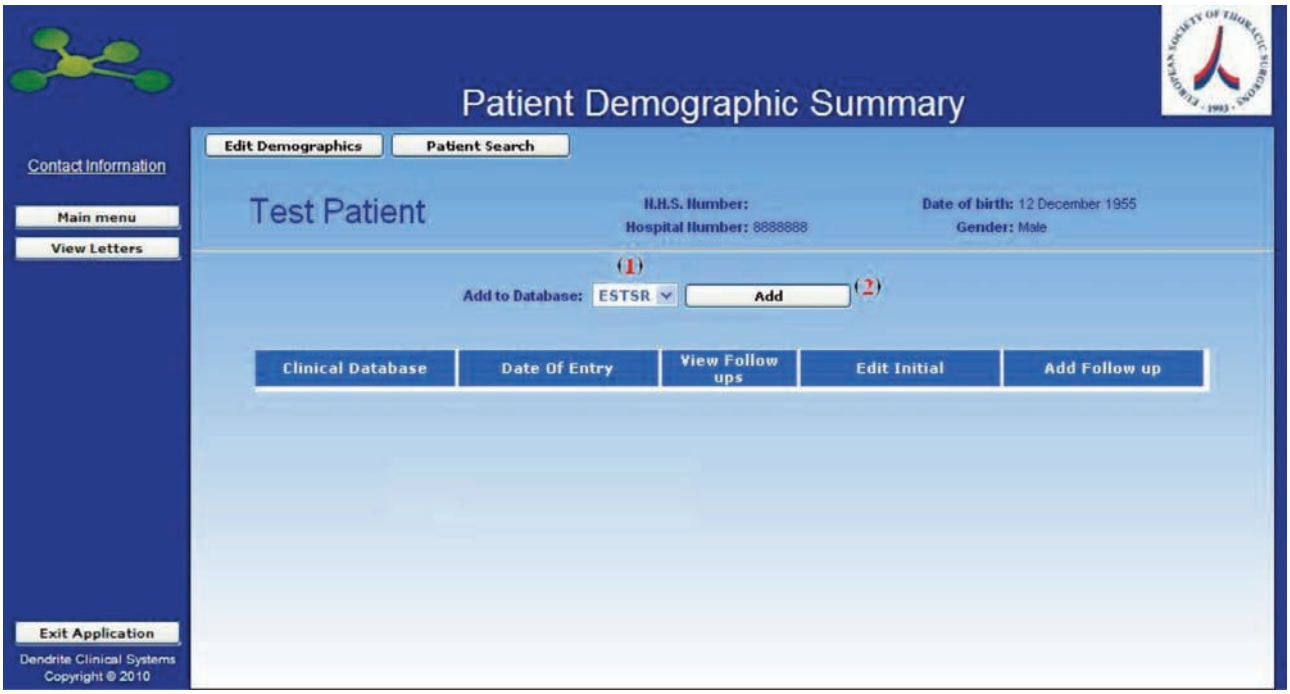


Clicking on the Enter Clinical Data button opens the next screen "Patient Search", where it is possible to search for patients already in the database or add new patients.

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.

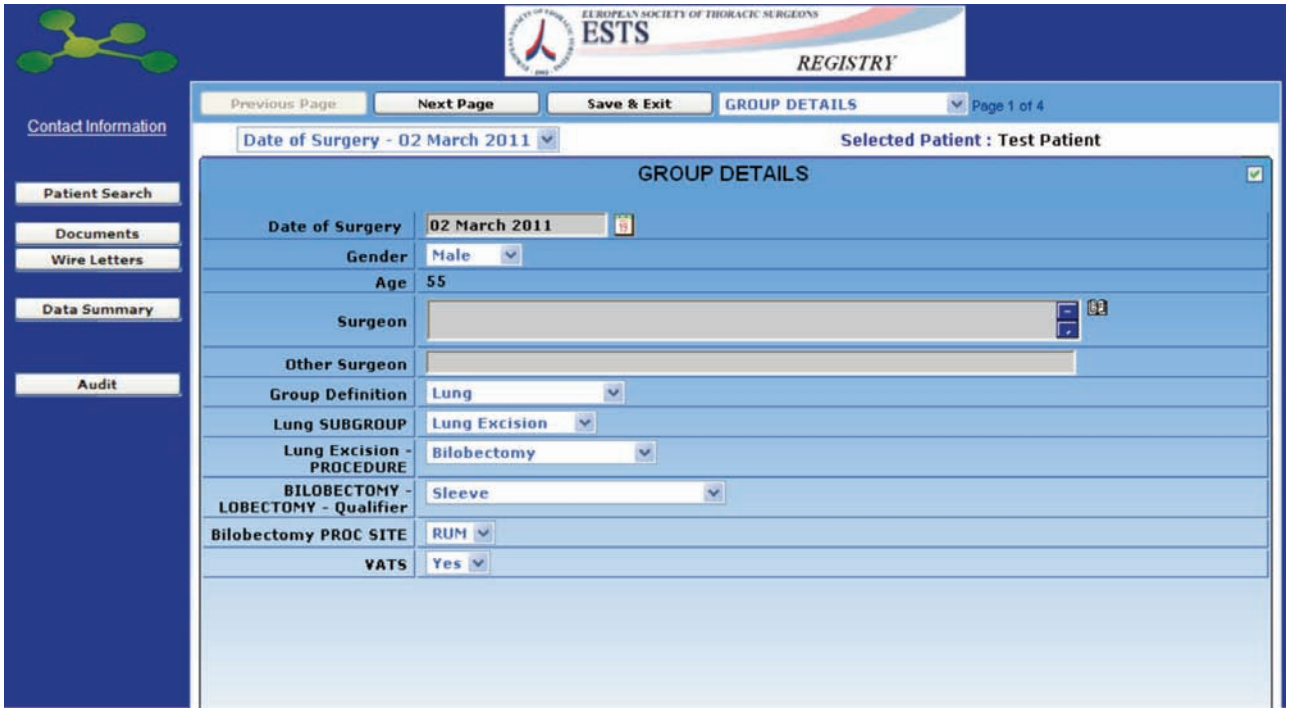


The newly created patient is ready to be entered into the database.

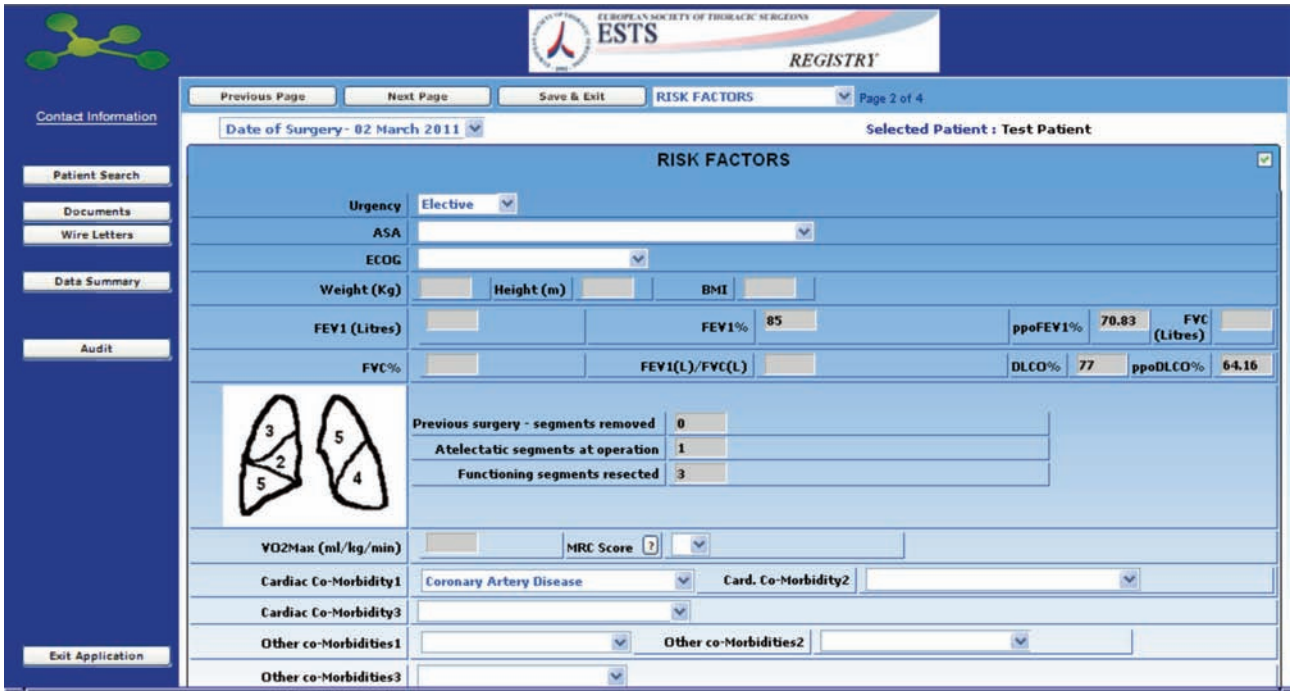


Now it is possible to select the available Database (1) (in our case there is only the one named ESTSR) and add the patient to the chosen Database by clicking on the button (2).

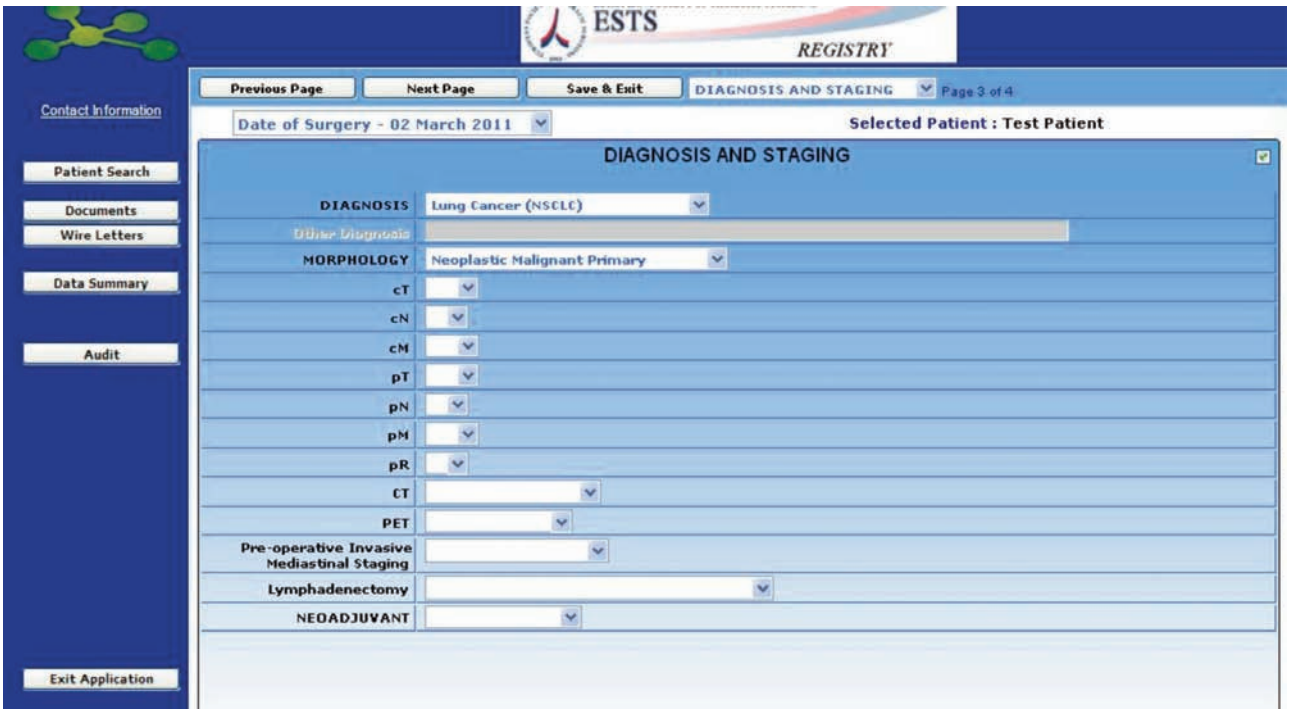
Once you have clicked the Add Button, the first page of the selected Registry will appear. Now you can start inserting clinical data as showed in next page.



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.

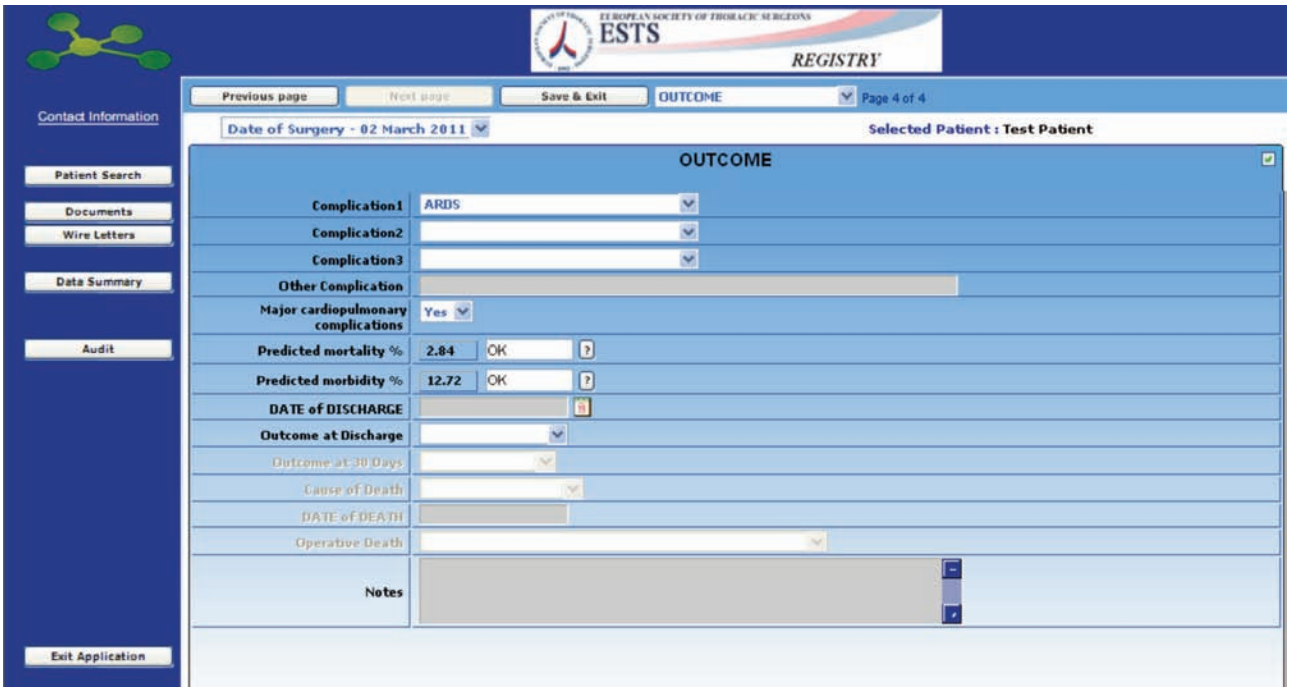


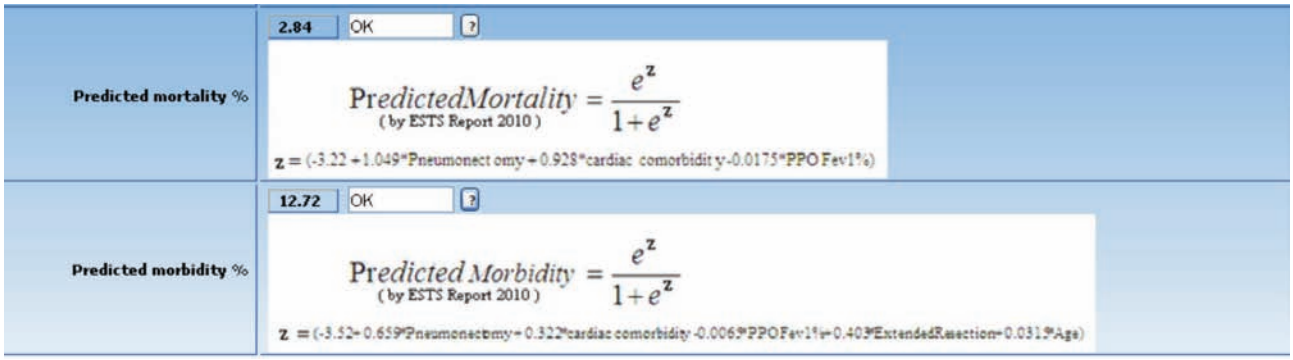
In addition to risk factors, diagnosis and staging details can be added in a following section.



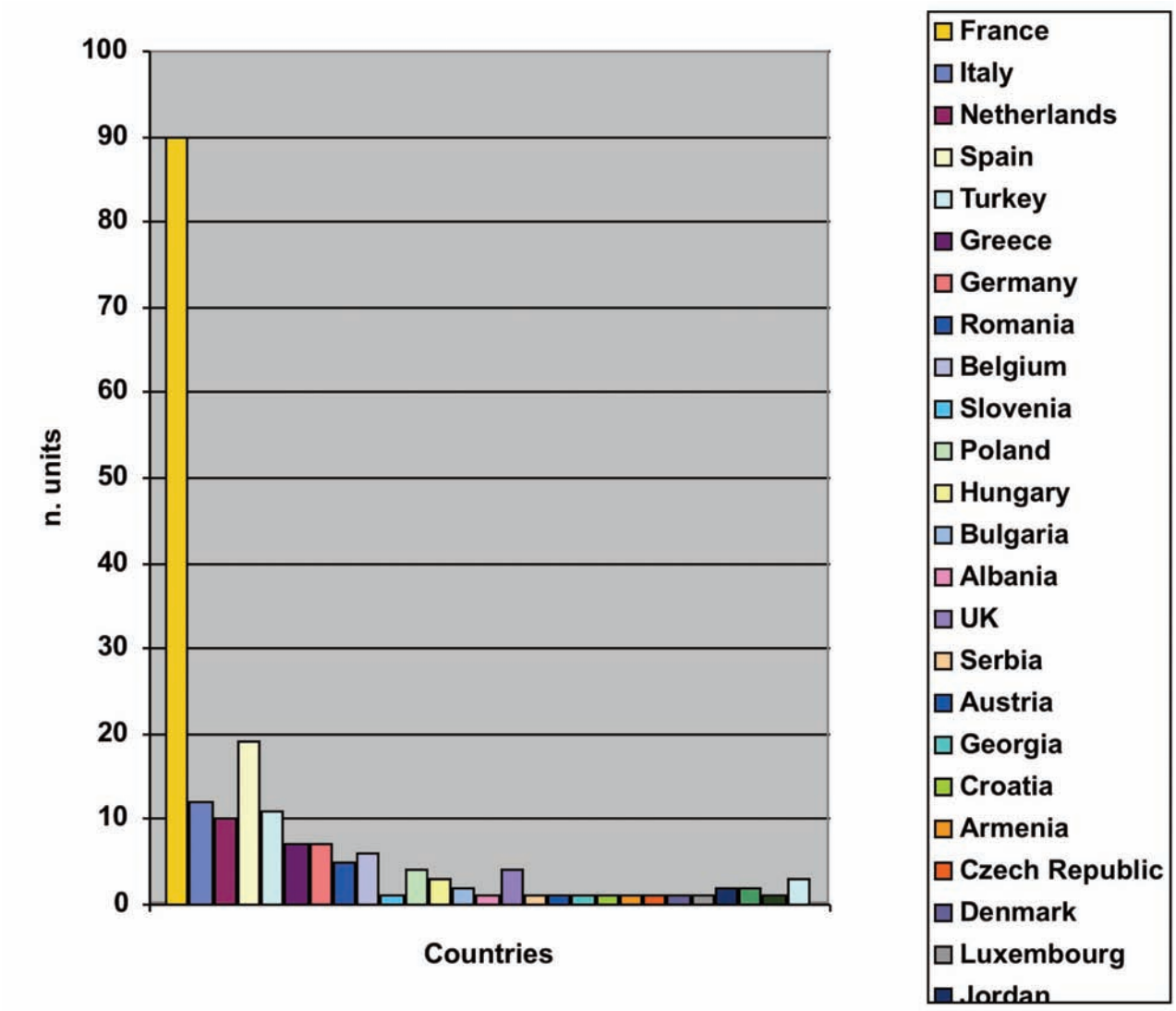
The system auto-calculates for Lung Excision Procedure the Predicted Mortality (%) and Predicted Morbidity (%).

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





N. units enrolled in the ESTS database as of March 2011, subdivided by Country.



Units contributing to ESTS Database July 2007 - March 2011.

Only units contributing more than 100 patients (as of March 18th 2011) in the registry are shown.

INSTITUTION	CITY	COUNTRY
CH du pays d'Aix	Aix En Provence	FRANCE
VUMC Dept of Surgery	Amsterdam	NETHERLANDS
Ospedali Riuniti Ancona	Ancona	ITALY
University Hospital of Antwerp	Antwerp	BELGIUM
Evangelismos	Athens	GREECE
CHG Avignon	Avignon	FRANCE
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	FRANCE
Discipline Chirurgiche, Rianimatorie e dei Trapianti	Bologna	ITALY
Clinique Bordeaux Nord	Bordeaux	FRANCE
Amphia Hospital	Breda	NETHERLANDS
Cliniques Universitares Saint- Luc	Brussels	BELGIUM
Hopital Academique Erasme	Brussels	BELGIUM
Marius Nasta Institute of Pneumonology	Bucharest	ROMANIA
CH René Dubos - Pontoise	Cergy Pontoise	FRANCE
Centre Hospitalier de Chambéry	Chambery	FRANCE
HIA Percy	clamart	FRANCE
CHU Gabriel Montpied CF	Clermont Ferrand	FRANCE
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	Foggia	ITALY
San Martino - Genoa	Genova	ITALY
CHU Michallon Grenoble	Grenoble	FRANCE
Kennemer Gasthuis	Haarlem	NETHERLANDS
Istanbul School of Medicine	Istambul	TURKEY
Sureyyapasa Chest Disease & Thoracic Surgery Hospital	Istambul	TURKEY
Hôpital St Louis	La Rochelle	FRANCE
V. Fazzi Hospital	Lecce	ITALY
Clinique Petit Col Moulin Le Havre	Le Havre	FRANCE
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
H. Clinico San Carlos	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

INSTITUTION	CITY	COUNTRY
Fondazione ospedale Maggiore Policlinico	Milano	ITALY
Maria Hilf Kliniken	Monchengladbach	GERMANY
Clinique du Millénaire	Montpellier	FRANCE
CHU de Montpellier	Montpellier	FRANCE
CMC de la Baie de Morlaix	Morlaix	FRANCE
CHU Central de Nancy	Nancy	FRANCE
CHU de Nantes	Nantes	FRANCE
Nouvelle Clinique Nantaise	Nantes	FRANCE
Clinique St Augustin - Nantes	Nantes	FRANCE
Clinica Universitaria De Navarra	Navarra	SPAIN
Clinique Saint Georges	Nice	FRANCE
CHU Pasteur Nice	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
University Hospital Salamanca	Salamanca	SPAIN
Clinique du Val D'or	Saint Cloud	FRANCE
CH Privé Saint Grégoire	Saint Gregoire	FRANCE
Hopital yves le Foll	Saint Brieuc	FRANCE
University Hospital Siena	Siena	ITALY
Clinique Belledonne Grenoble	St Martin D'Heres	FRANCE
Clinique St Odile	Strasbourg	FRANCE
CHU de Strasbourg	Strasbourg	FRANCE
University of Szeged	Szeged	HUNGARY
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.
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:

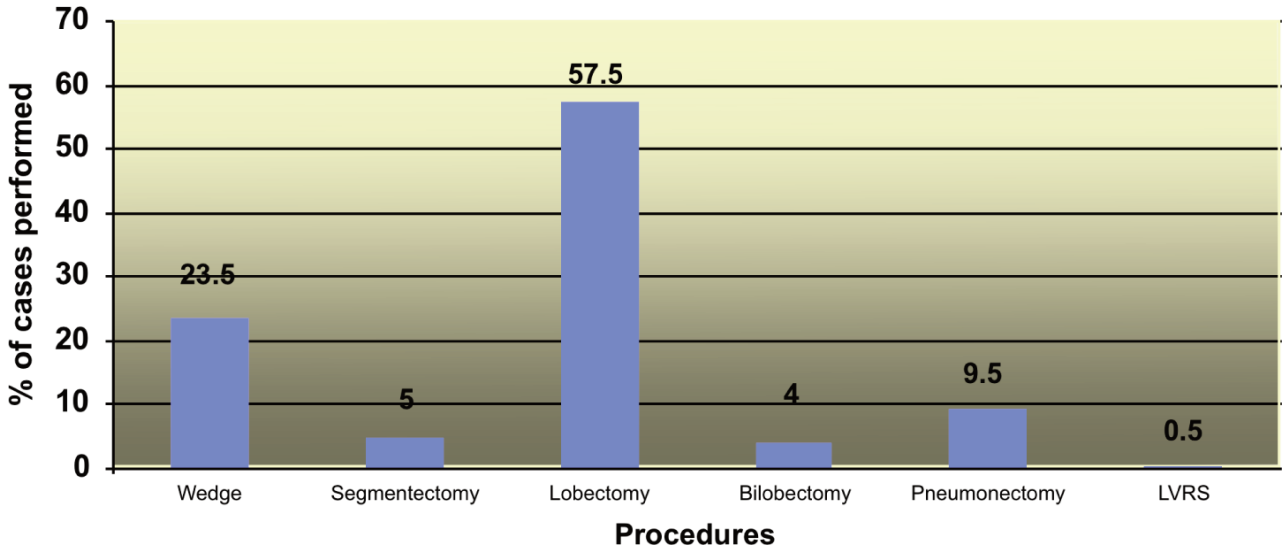
1. increase of serum creatinine to greater than 2.0, and 2-fold the preoperative creatinine level.
2. a new requirement for dialysis postoperatively.

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.

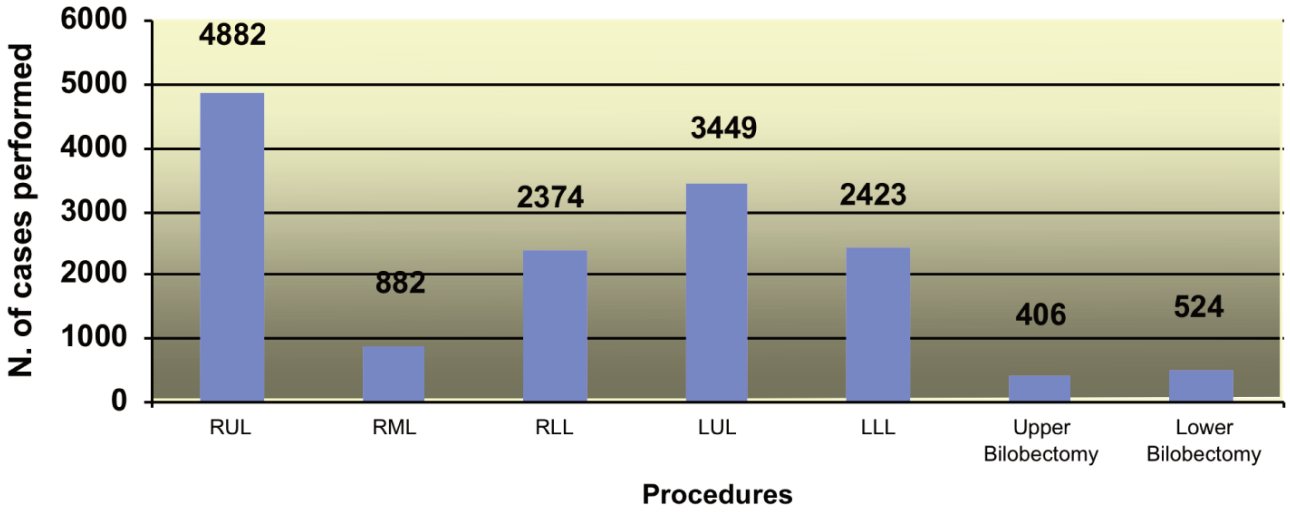
Types of lung resections performed (tot. 24574), including all diagnoses

This graph shows the breakdown of lung resections for all diagnoses. The most frequent procedure is lobectomy, which represents 57.5% of all cases (14139 cases in the database). Pneumonectomy represents 9.5% of all procedures.



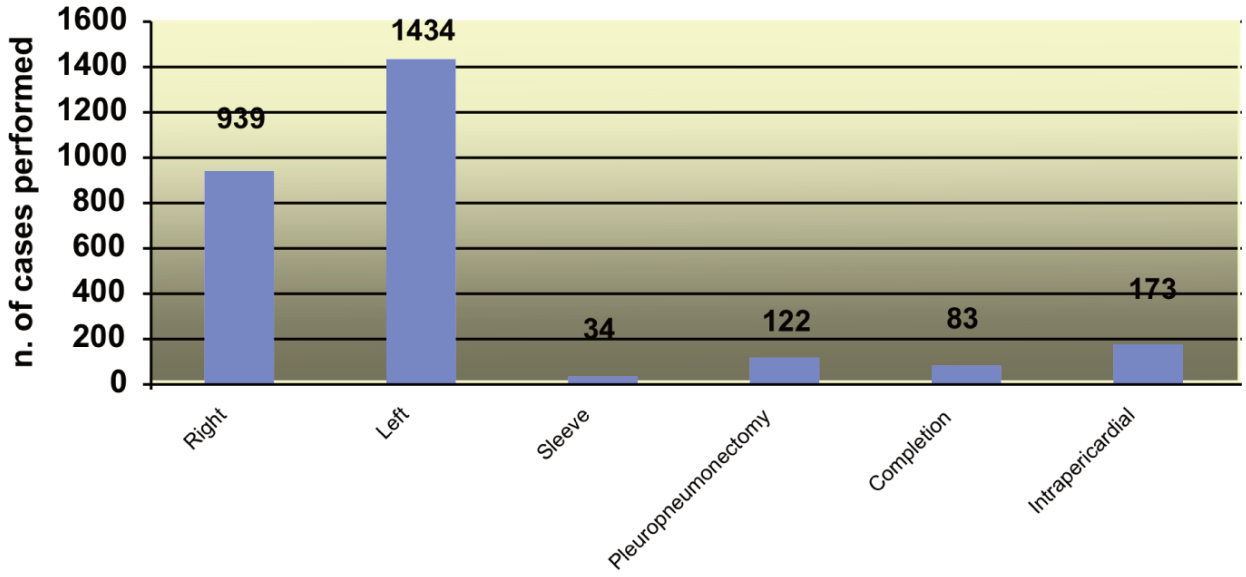
Distribution of lobectomies/bilobectomies (14940 cases) by site of resection

This graph shows the distribution by site and side of resection of all pulmonary lobectomies and bilobectomies reported in the Database. The most frequent operation is right upper lobectomy accounting for 33% of lobectomies. The less frequent lobectomy is middle lobectomy performed in only 6% of lobectomies. Lower bilobectomy was performed more frequently than upper one.



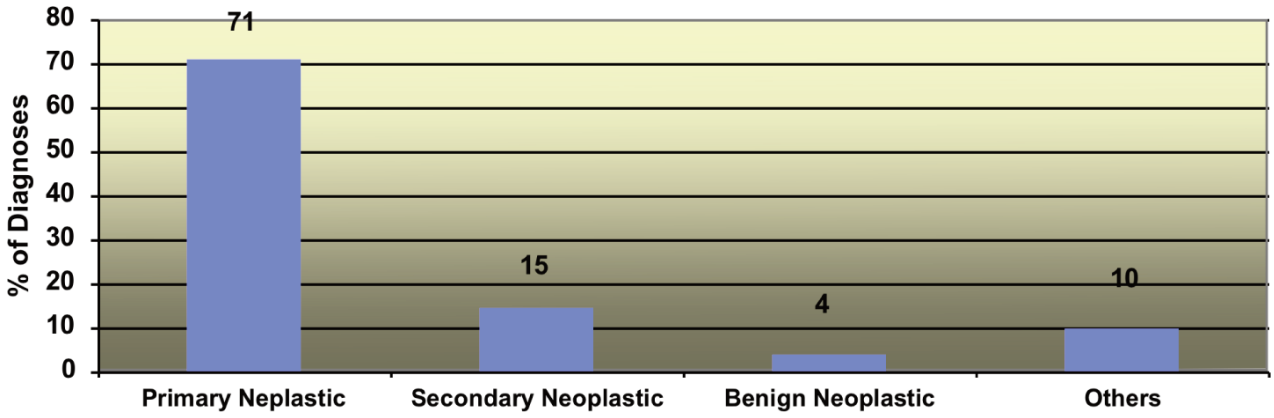
Distribution of pneumonectomies

This graph shows the distribution of pneumonectomies reported in the database. Left pneumonectomies were performed more frequently than right.



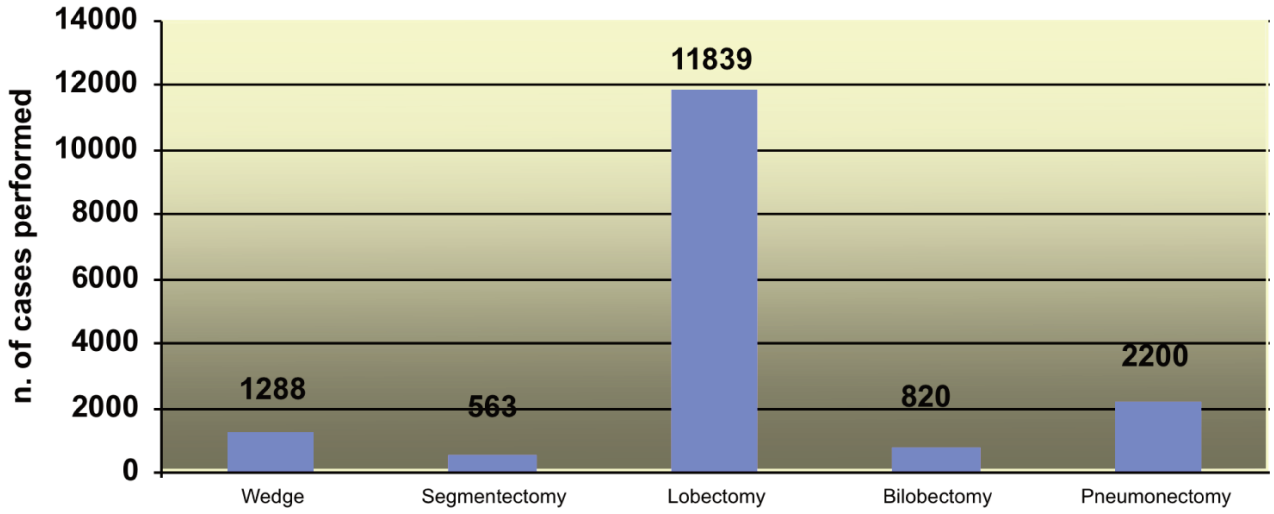
Diagnoses of all lung resections

Lung resections were performed mainly for malignant primary neoplastic disease (71%). Lung resection for metastatic disease was performed in 15% of cases.



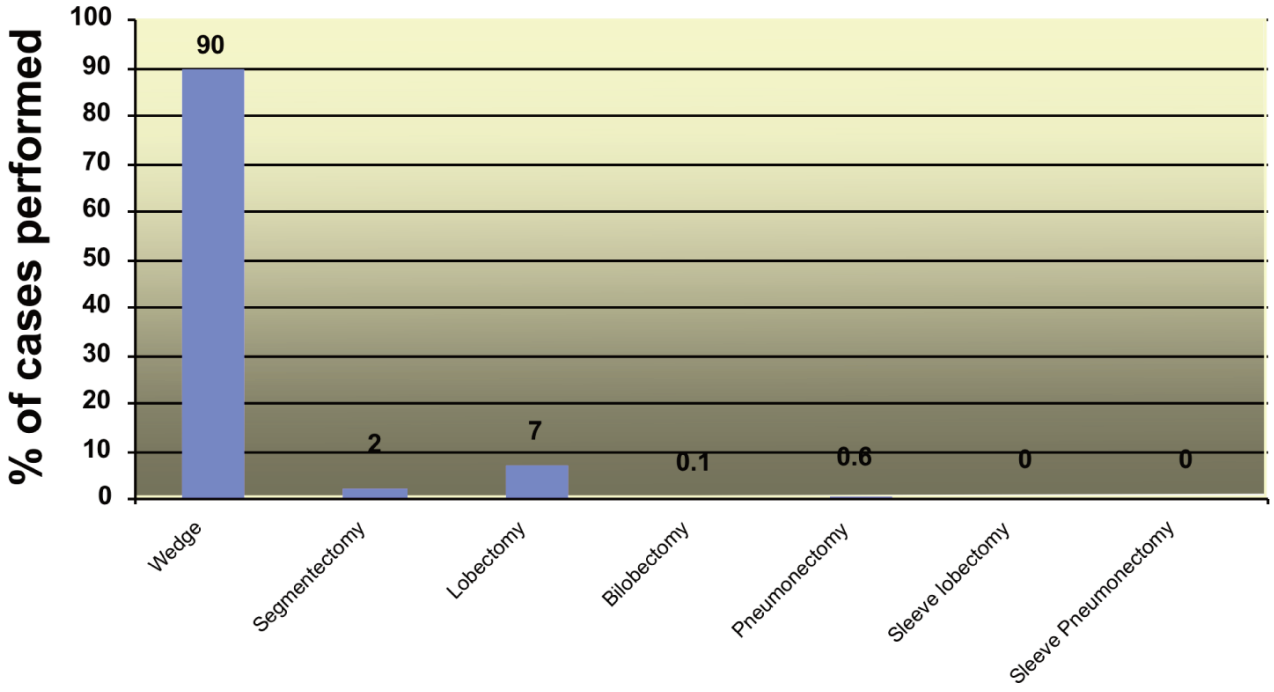
Lung resection for Primary Lung Cancer: Types of procedures (total 16710)

Pulmonary lobectomy/bilobectomy was the operation most frequently performed for lung cancer in 76% of cases. This is in accordance with current best scientific evidence stating that this type of procedure is still the best trade-off between oncological radicality and functional loss for lung cancer patients.
Minor resections (wedge/segmentectomy) were performed in only 11% of patients.
The trend of the incidence of these different types of lung resections will be followed in the next years to detect changes in therapeutic approaches in Europe and in different Countries.



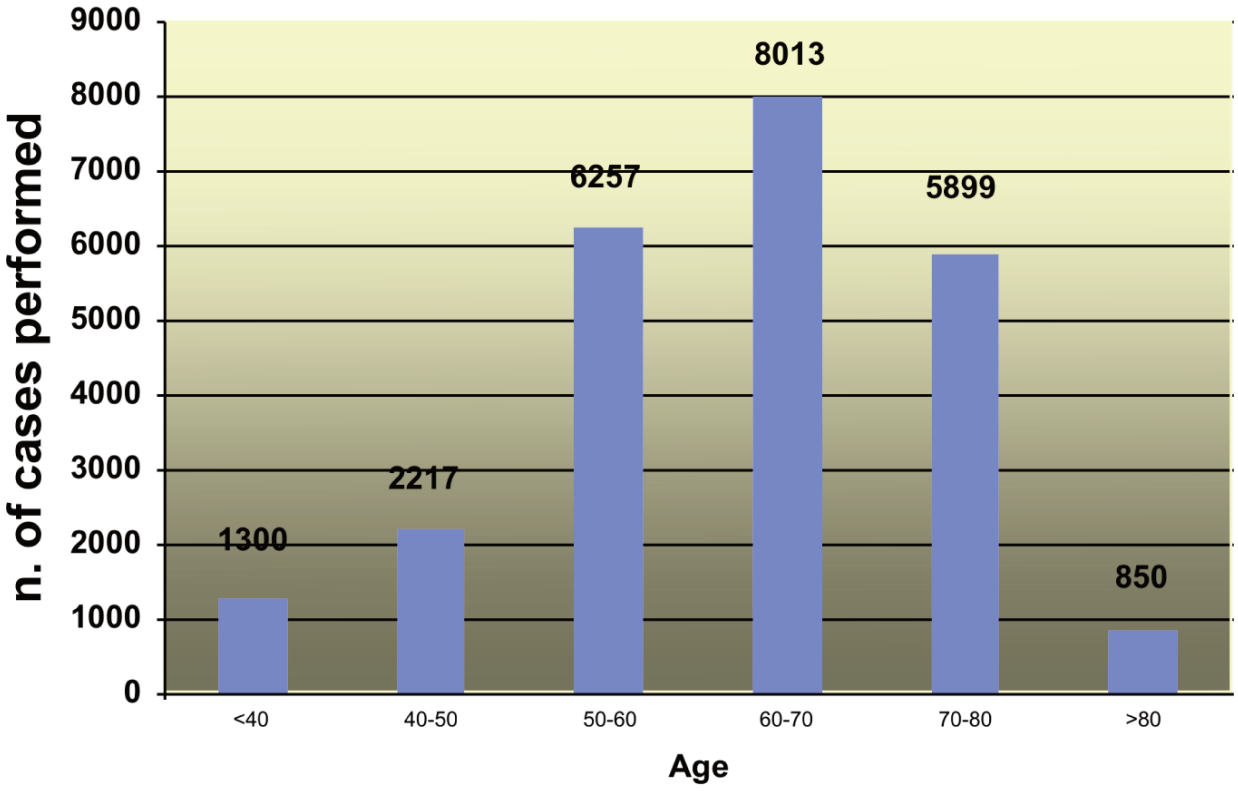
Lung resection for secondary malignant disease: Types of procedures (total 3802)

At variance with primary neoplastic disease, the most frequent operation for lung metastases was wedge resection, reported in 90% of patients.
The trend of the incidence of these different types of lung resections will be followed in the next years to detect changes in therapeutic approaches in Europe and in different Countries.



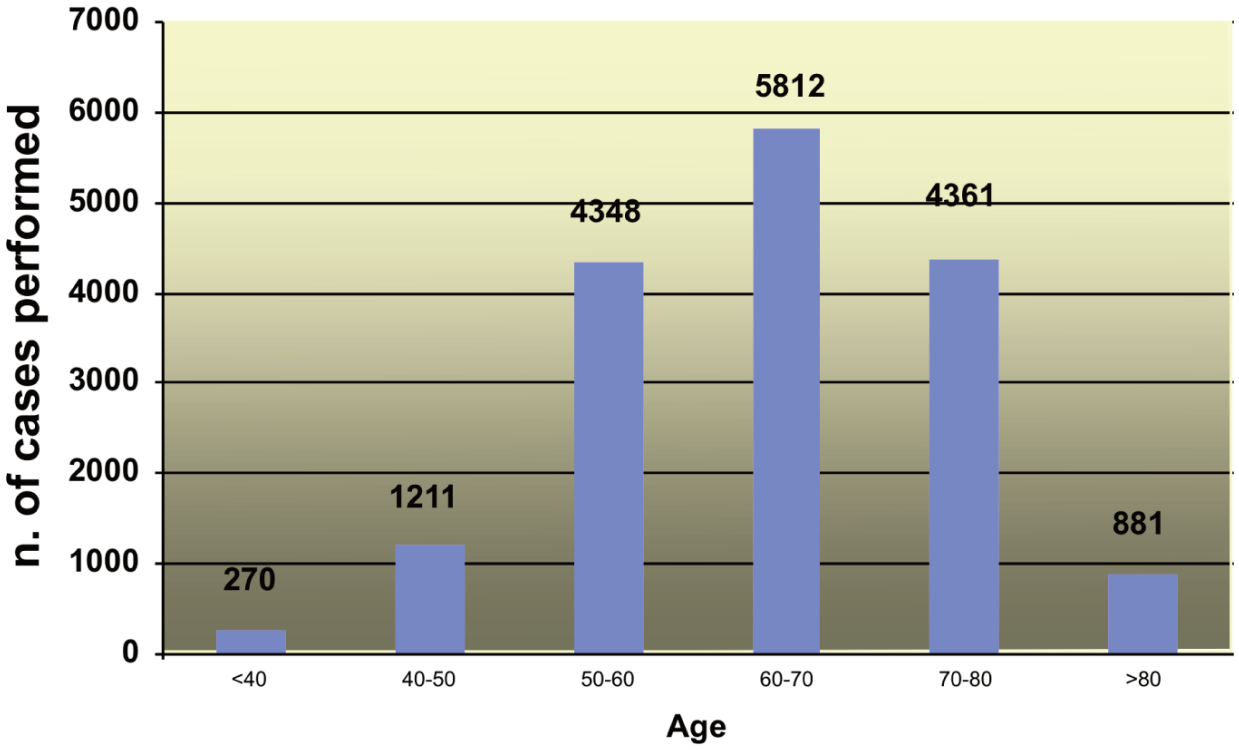
Patients age distribution in all types of lung resection

Most of the patients submitted to lung resections were older than 50 years of age (86%). Only 5% of patients were younger than 40. Elderly patients (> 70 years of age) accounted for 27% of all cases. This proportion will be followed in the next years to detect a change in epidemiology of lung resection patients in Europe and in different Countries.



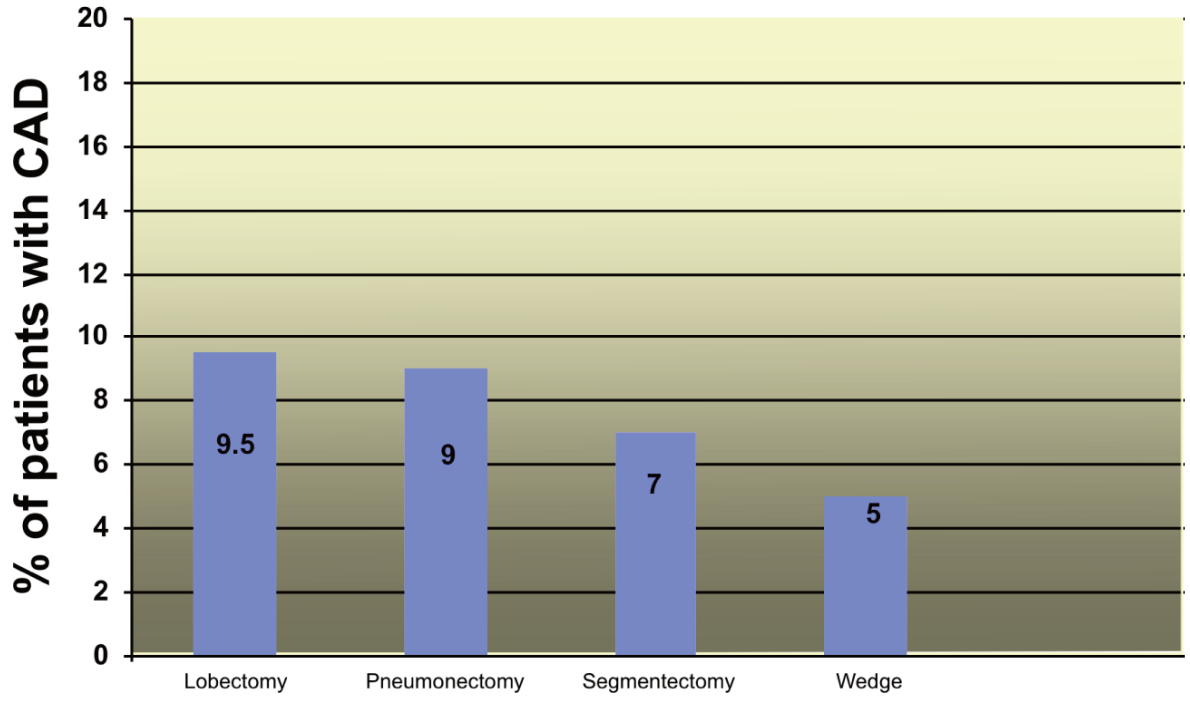
Patients age distribution in lung resection for Malignant Primary Neoplastic disease

Patients with lung cancer showed a similar distribution of presenting age. The minority of them (9%) were younger than 50 and 31% were older than 70.
This proportion will be followed in the next years to detect a change in epidemiology of lung resection patients in Europe and in different Countries.



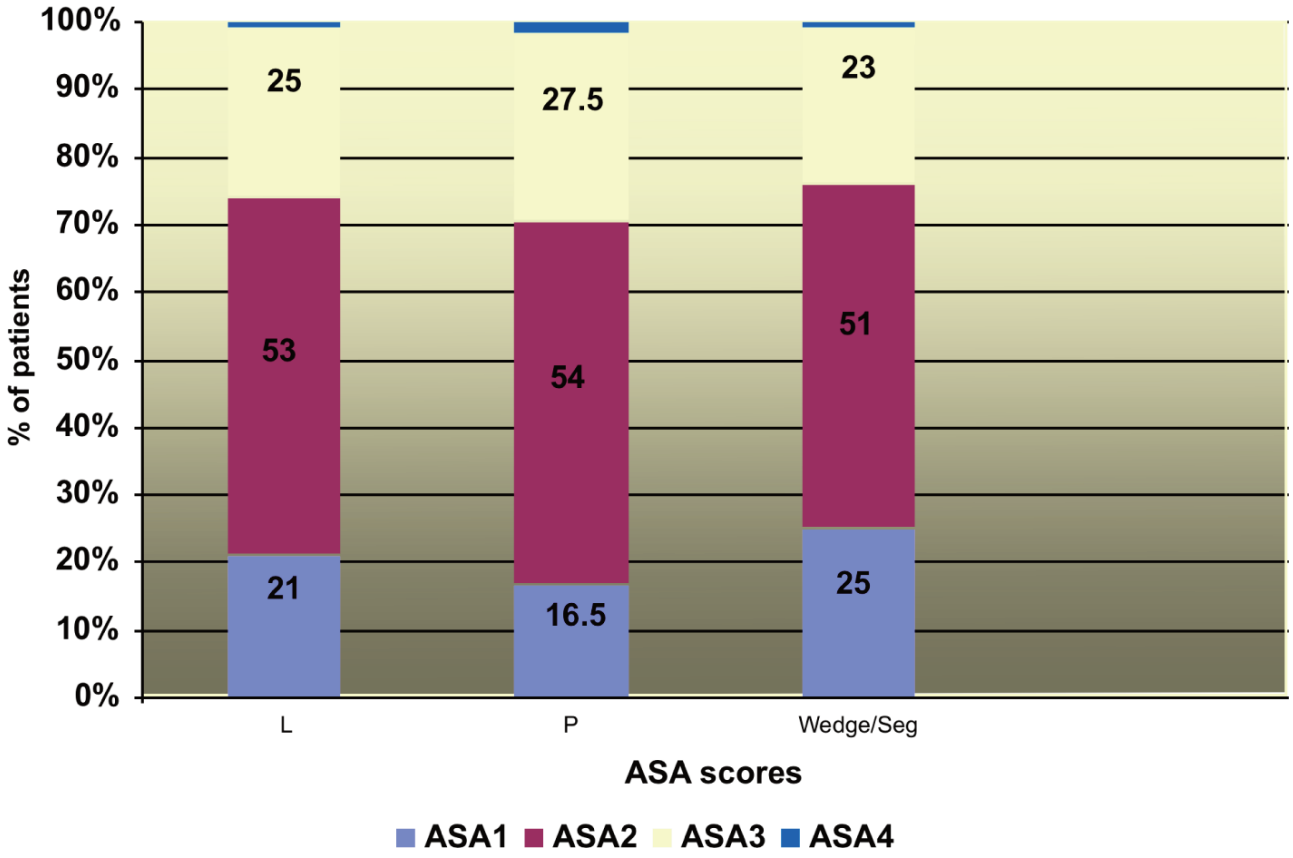
Incidence of Coronary Artery Disease by operation

Coronary artery disease is a frequent occurrence in patients submitted to lung resection since it recognized the same risk factors of lung cancer. CAD is also known as a potential risk factor for morbidity and mortality following lung surgery and increase complexity of preoperative work-up and perioperative treatment. It is reported in approximately 5-10% of patients submitted to lung resection irrespective of the type of procedure.



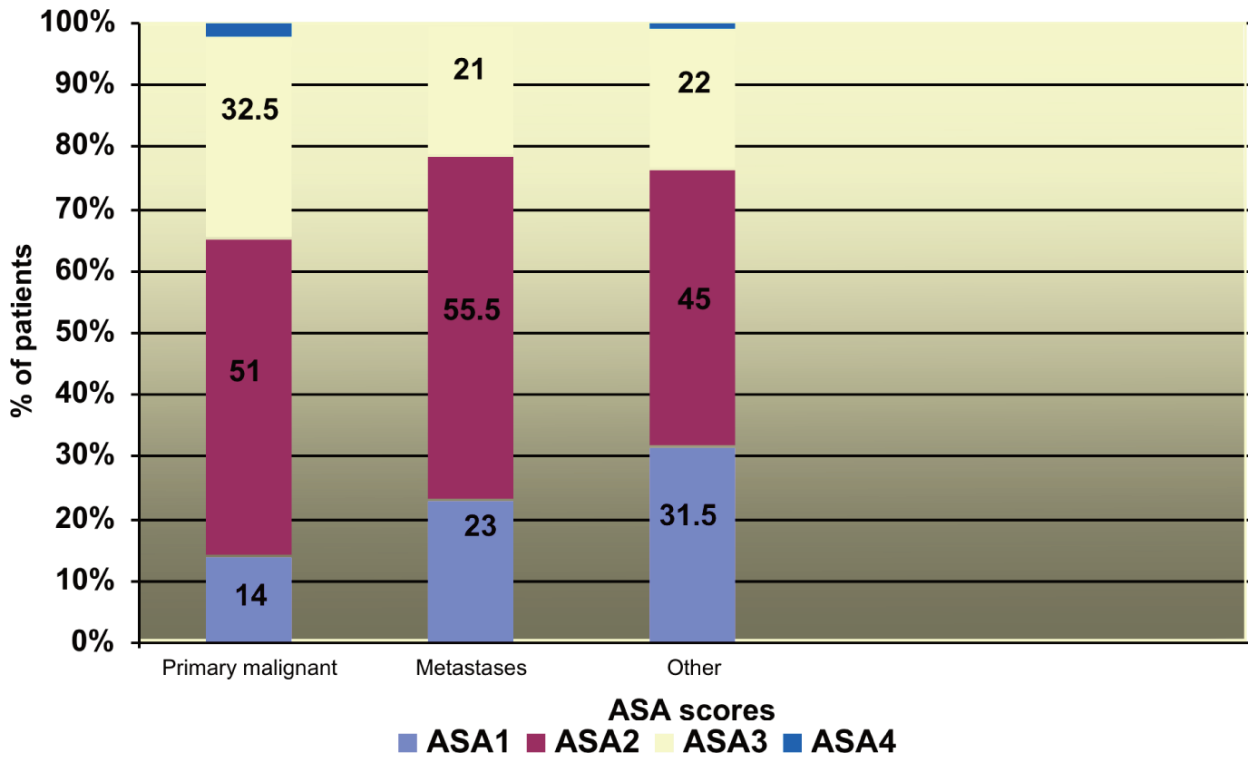
Distribution of ASA score by type of operation

This graph displays the incidence of different ASA score classes in different operations. Most of the patients submitted to lung surgery were in ASA 2 class, reflecting some form of mild systemic disease at presentation. Of notice, 27.5% of patients submitted to pneumonectomy were ASA 3, with a severe but not incapacitating systemic disease.



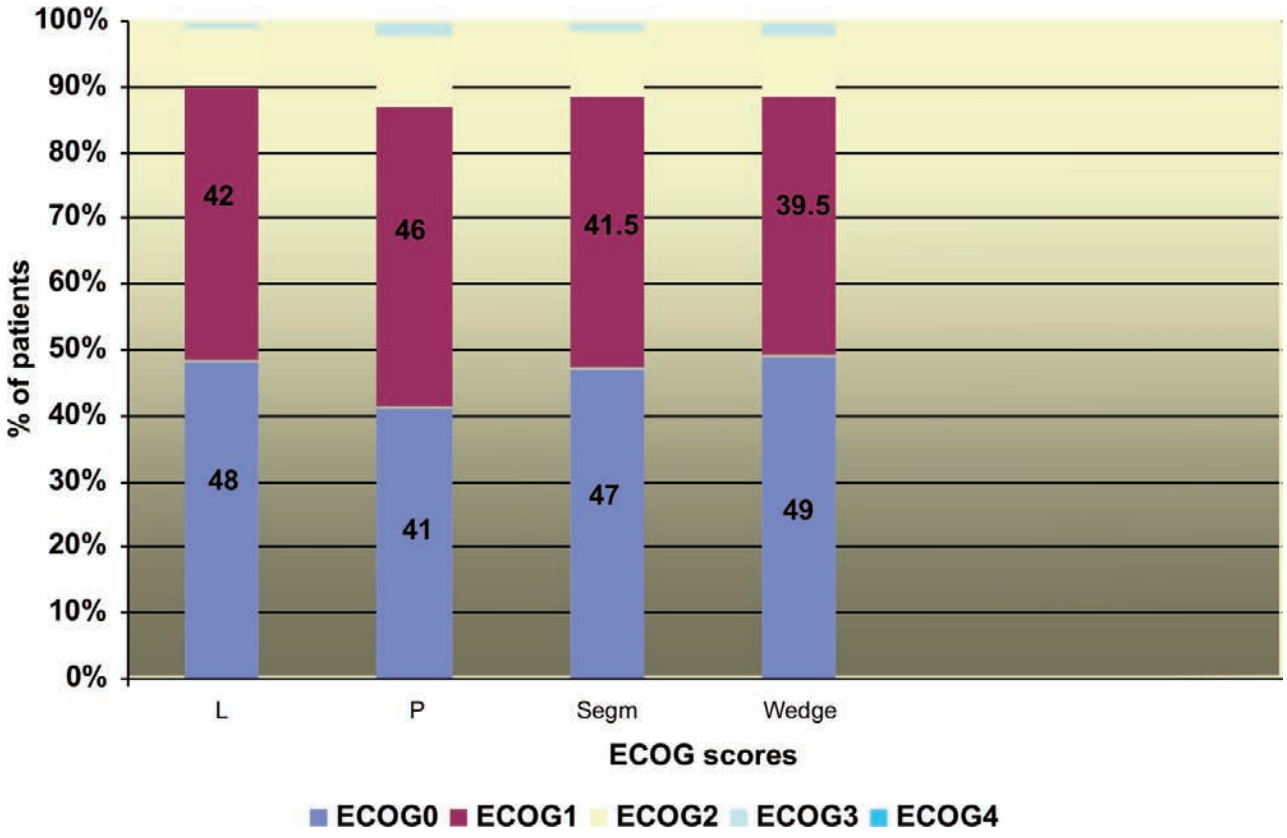
Distribution of ASA score in wedge resections grouped by diagnosis

This graph shows the distribution of ASA classes according to the pathological diagnosis in patients submitted to wedge resections. Only 14% of the patients with lung cancer were in ASA class 1. Most of them were in class 2 (mild systemic disease) or 3 (severe systemic disease, not incapacitating), indicating that this limited procedure was selected owing to underlying co-morbidities. In patients operated on for lung metastases, there was a balanced distribution of ASA scores. Most of the patients operated on for other diagnoses were in class 1 (normal healthy individual) or 2.



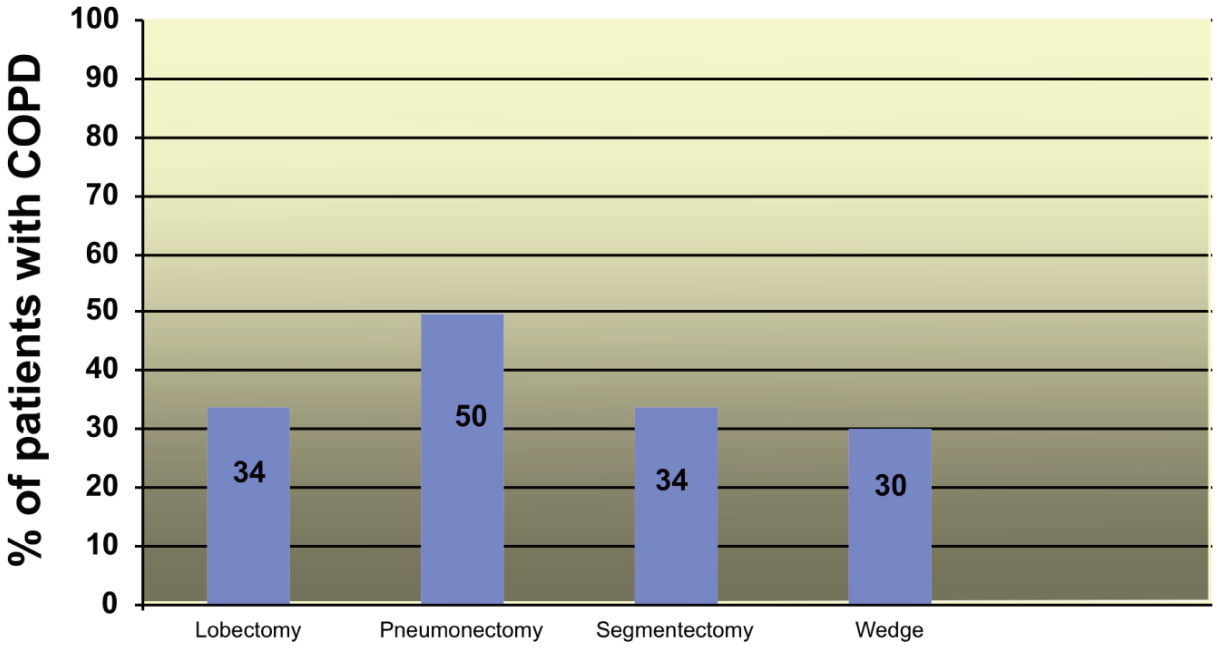
Distribution of ECOG score by type of operation

The graph shows the distribution of ECOG (Zubrod) score in patients submitted to different types of operation. In all procedures the most frequent classes of ECOG score were 0 (fully active patients) and 1 (symptomatic but completely ambulatory). Only approximately 10% of patients had an ECOG score >1.



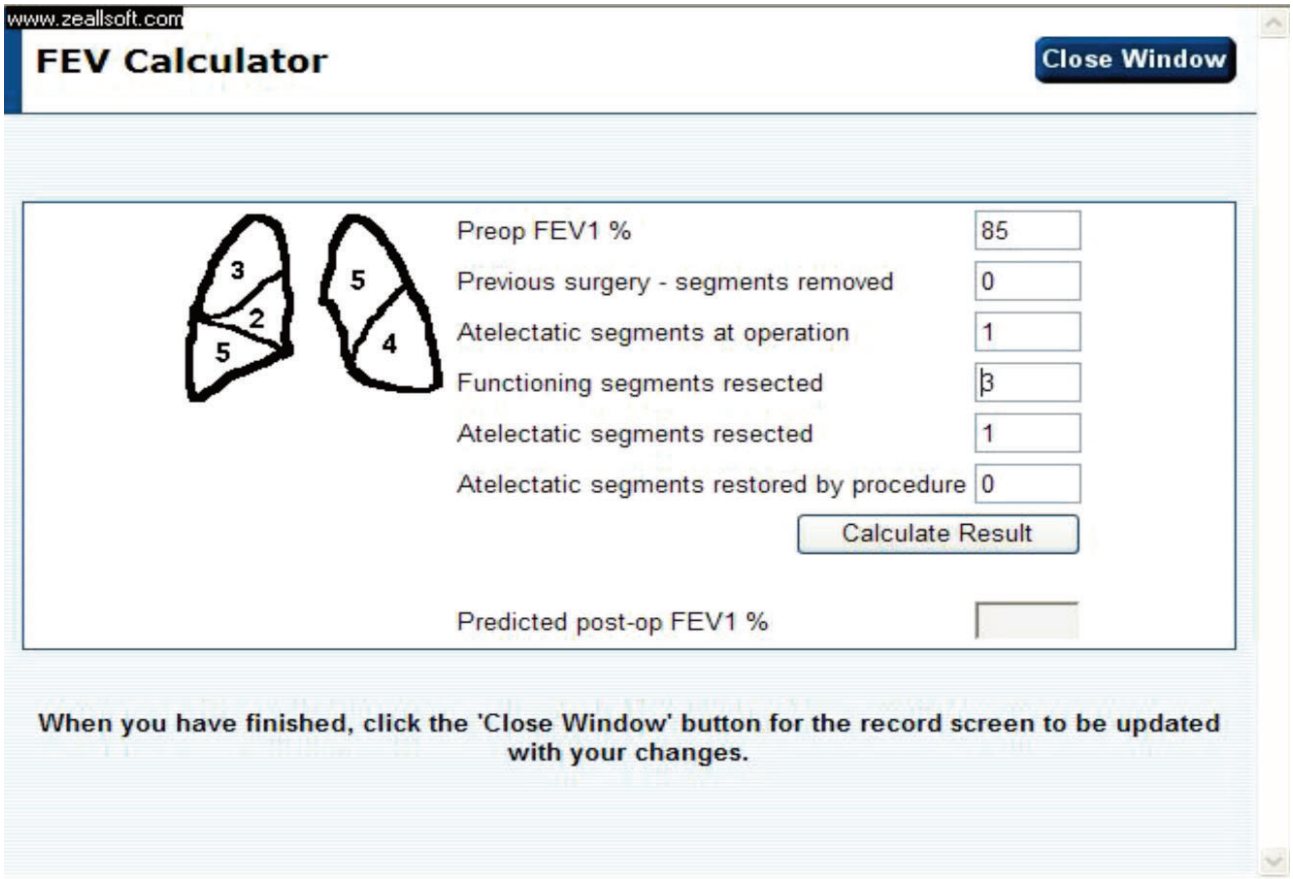
Incidence of COPD (FEV1 <80% and FEV1/FVC ratio < 0.7) in different types of lung resections.

The incidence of moderate to severe Chronic Obstructive Pulmonary Disease according to the GOLD criteria appears stable across different types of procedures and ranges from 34 to 50% of patients. COPD has been associated with an increased rate of postoperative complications and prolonged air leak although selected patients with lung cancer and COPD may experience a reduced functional loss after resection compared to patients with better respiratory function.

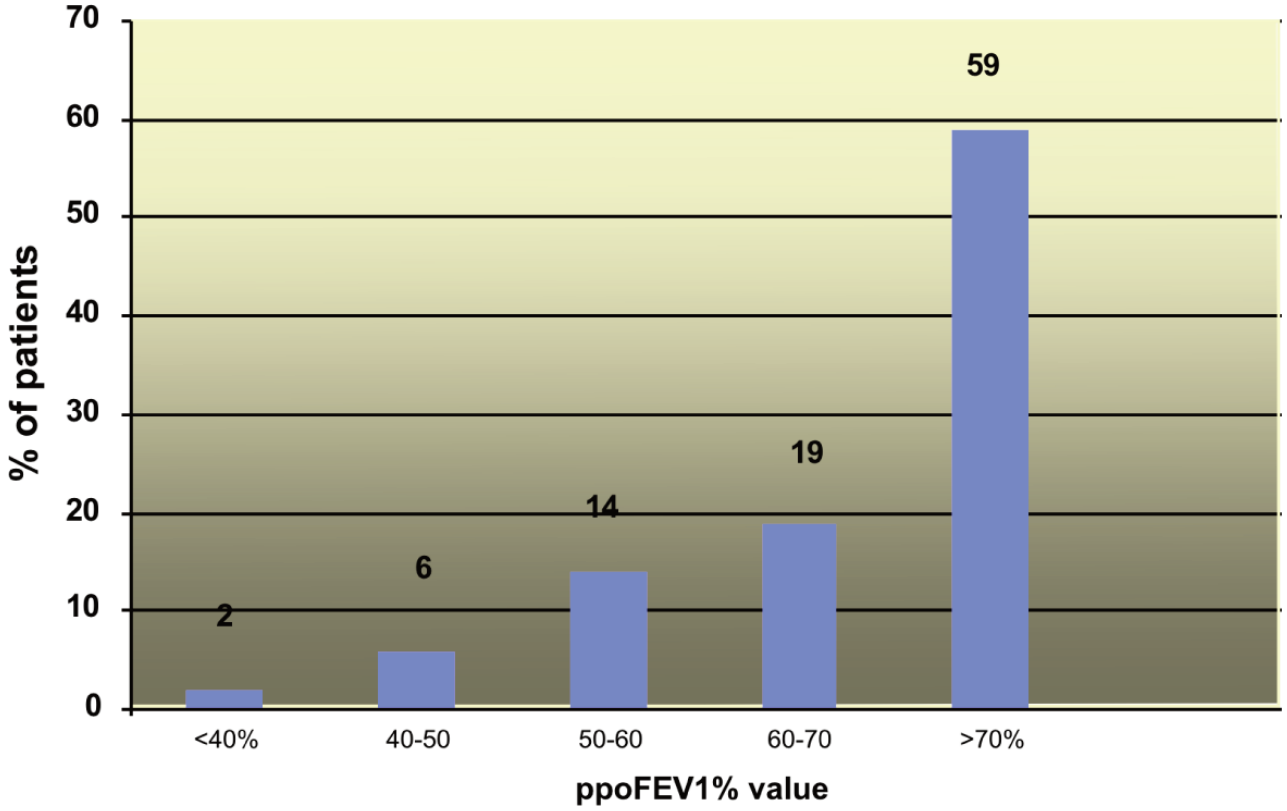


Distribution of ppoFEV1% in lobectomy patients

The calculation of Predicted Postoperative Forced Expiratory Volume in one second (ppoFEV1) 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.

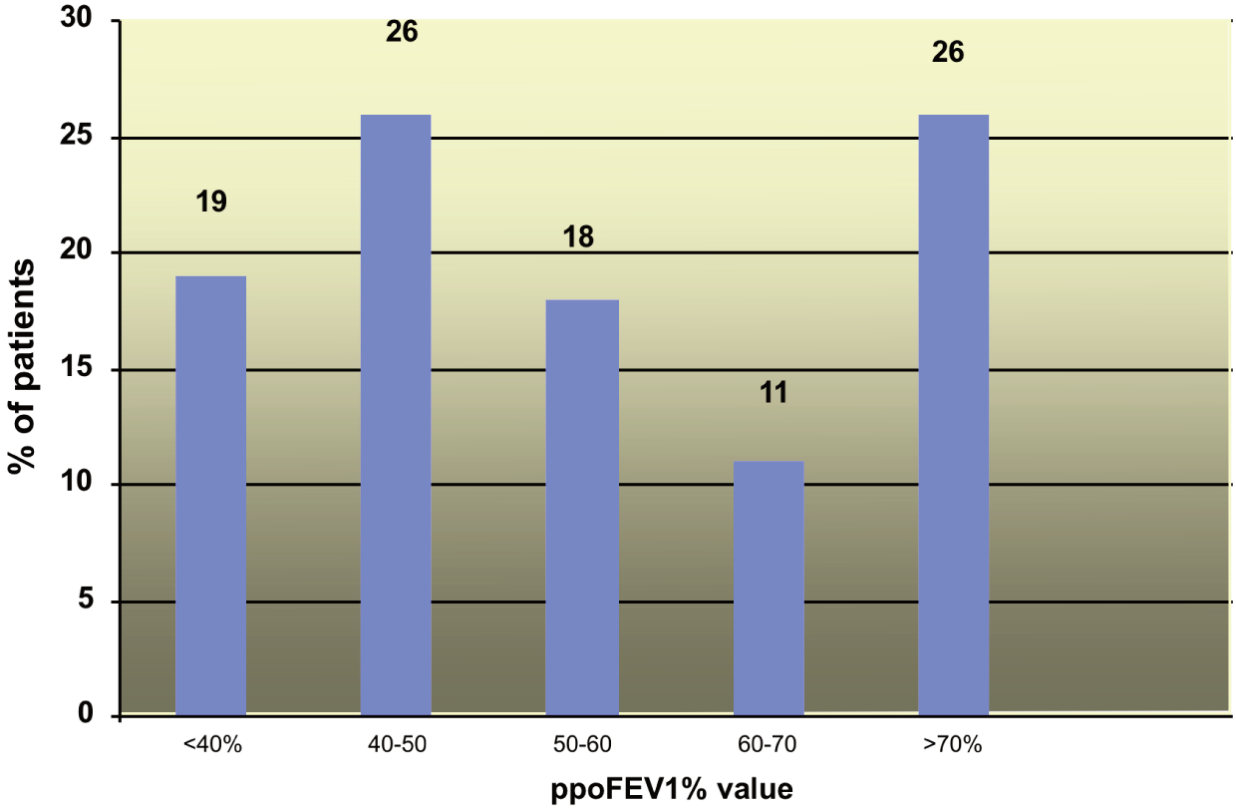


Most of the patients had a ppoFEV1 value greater than 70% (59%) and only 2% of lobectomy patients had a value below 40%. This data is important as highlight the critical role of this threshold in selecting patients for major lung resection and in light of most recent scientific evidence suggesting that this parameter should not be used alone to select patients for operation even in case of prohibitive values.



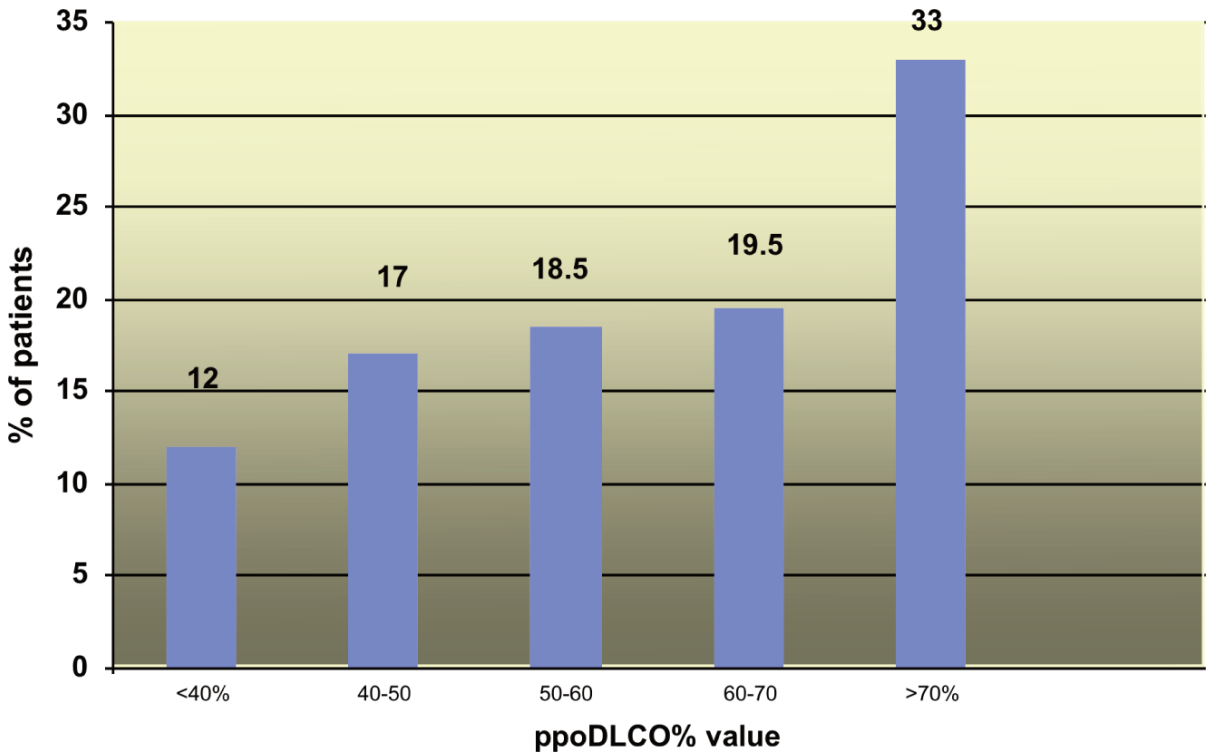
Distribution of ppoFEV1% in pneumonectomy patients

In pneumonectomy patients, given the extent of lung tissue removed at operation, the average value of ppoFEV1 is considerably lower than the one in lobectomy patients (57% vs. 74%, $p<0.0001$). Compared to lobectomy, a higher proportion of patients had a ppoFEV1 lower than 40% (19% vs. 2%) and a much lower proportion had a ppoFEV1 > 70% (26% vs. 59%).



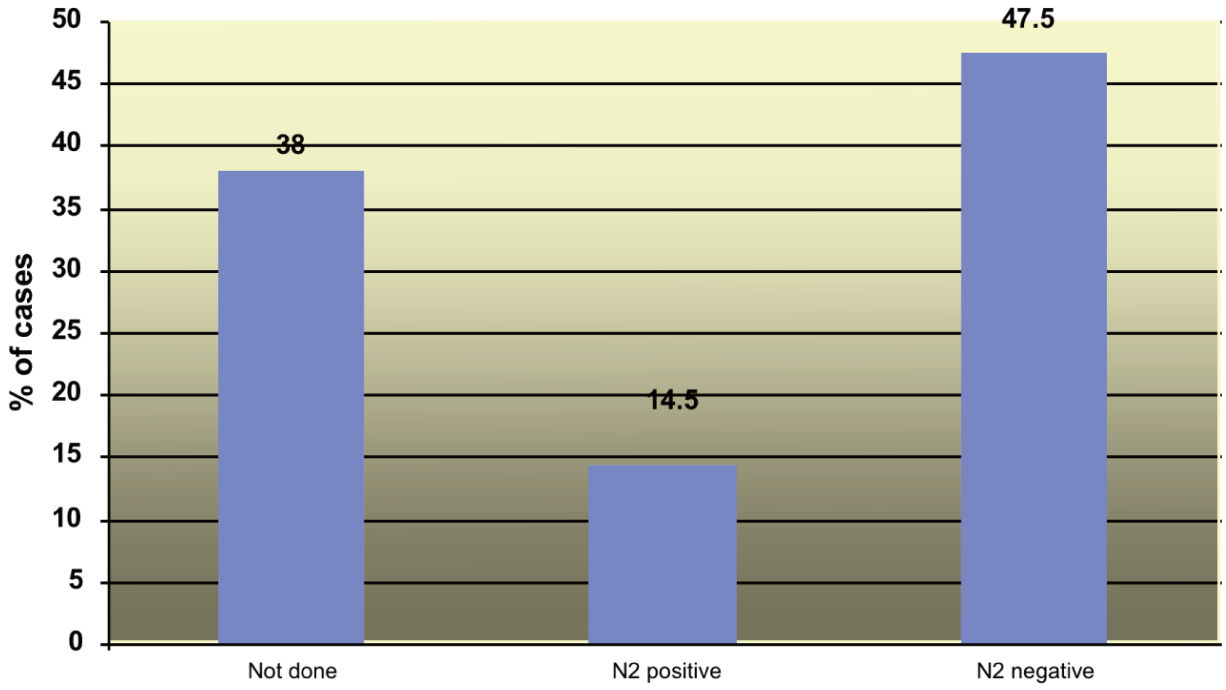
Distribution of ppoDLCO% in major lung resections (lobectomy and pneumonectomy)

Using the same calculator and the same settings as of the ppoFEV1, the estimation of ppoDLCO is standardized in this version of the Database. The total proportion of major lung resection patients with DLCO measured before operation was 20%. The distribution of values in the entire cohort of major lung resection shows that a considerable proportion of cases had a value below 40% (12%).



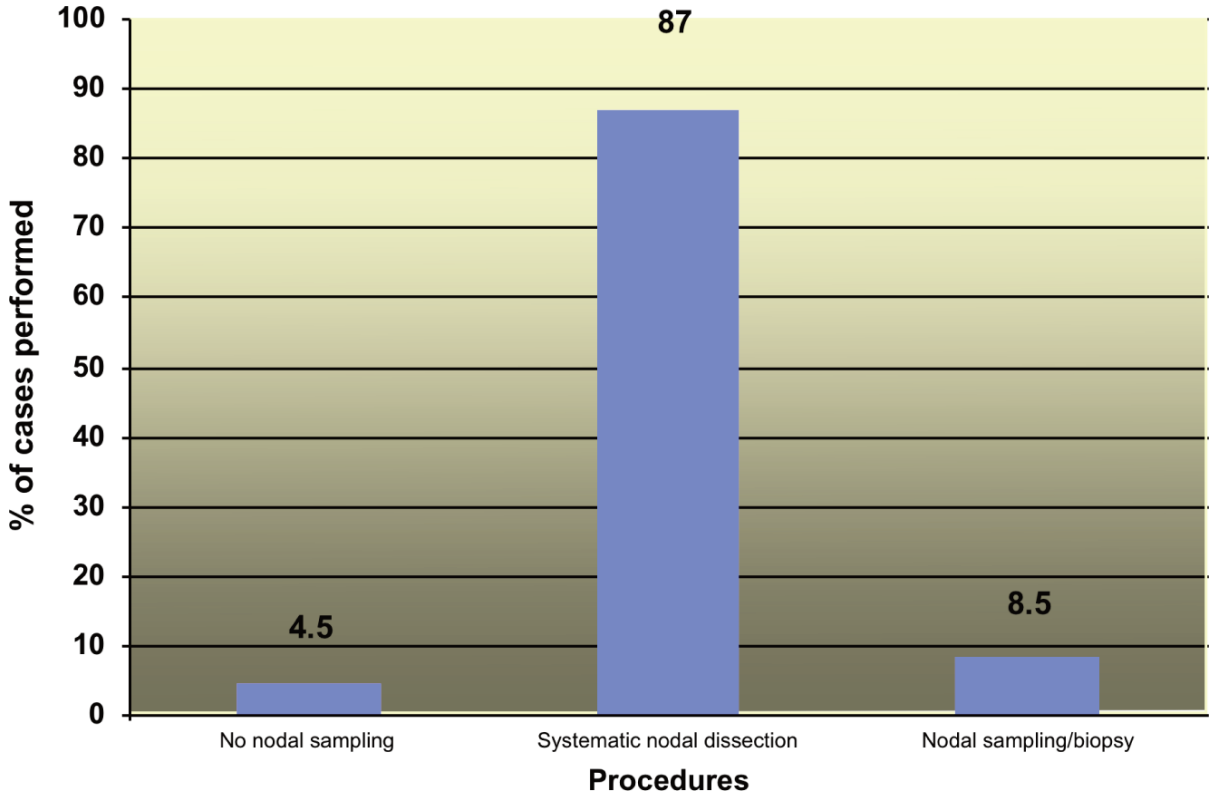
Incidence of invasive mediastinal staging performed in all types of lung resections in patients with enlarged mediastinal nodes at CT scan or PET positive mediastinal nodes

The graph shows the incidence of invasive mediastinal staging (including mediastinoscopy, mediastinotomy, VATS, EBUS-NA, EUS-NA) performed in patients with primary malignant disease of the lung and with enlarged (>1 cm) mediastinal lymph nodes detected at CT scan or PET positive mediastinal nodes. Only 62% of clinically suspicious N2 diseases were submitted to one or more of these procedures before lung resection. It must be noted that in addition to mediastinoscopy the other preoperative mediastinal staging procedures were included in this record from October 2008. This should be taken into consideration in the interpretation of these data.



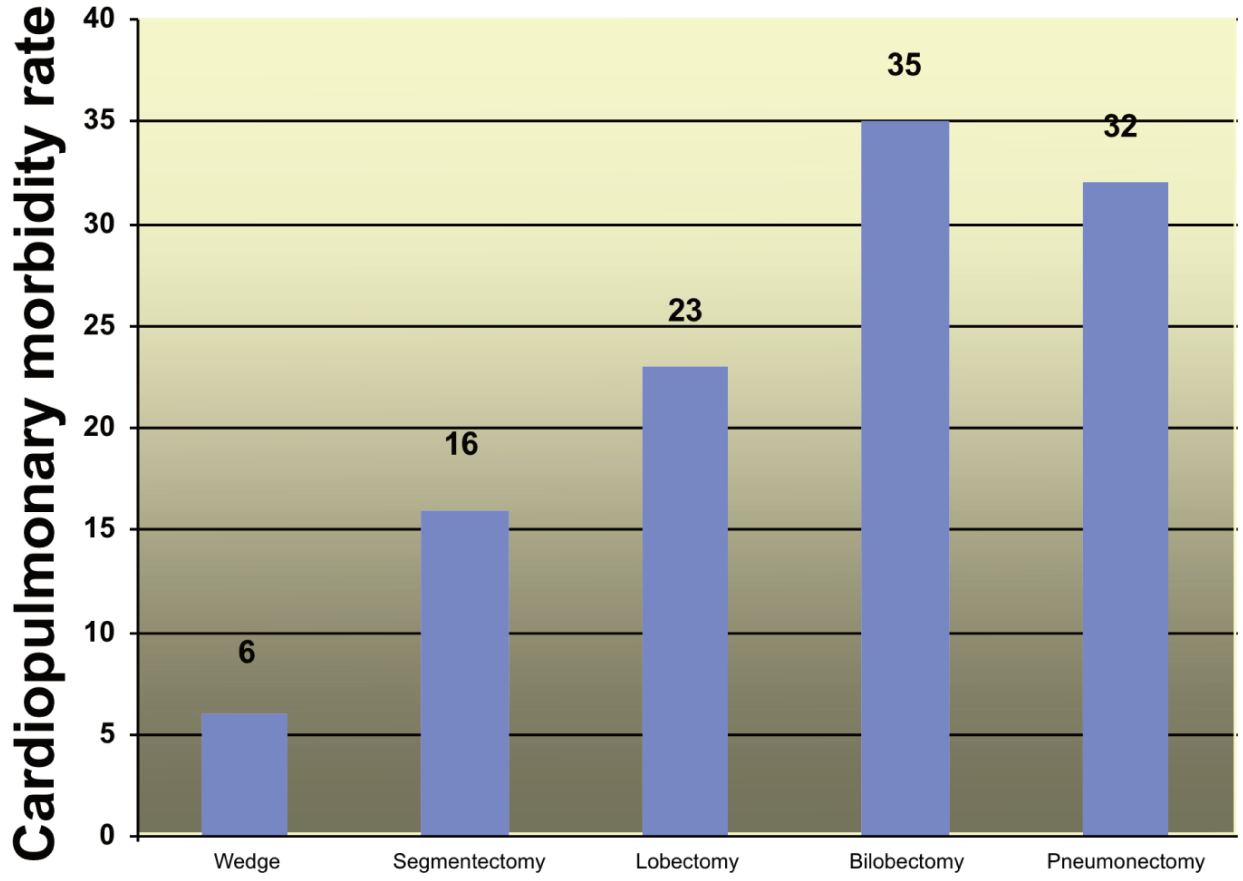
Type of intraoperative mediastinal nodal staging in lung resection for malignant primary neoplastic disease

This intraoperative staging variable was implemented with the purpose to create a process indicator of performance, assuming as a recommended evidence-based practice the systematic lymph node dissection in patients with primary malignant lung disease (as recommended by 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). Indeed the results are gratifying since 87% of patients with lung cancer had lymph node dissection. Only 4.5% were not submitted to any nodal sampling. One limitation of this indicator (like most of the other process indicators collected in multicenter registries) is the absence of pre-specified legitimate exclusion criteria within the eligible population (primary malignant disease). For example, certain selected patients may be not submitted to a systematic lymph node dissection in case of a reoperation or minor resection and major co-morbidities to shorten the operating time, or when for medical reason they are contraindicated any additional treatment (chemotherapy). However, these legitimate exclusion criteria are usually considered balanced in a homogeneous population and with an incidence not affecting the audit analysis.



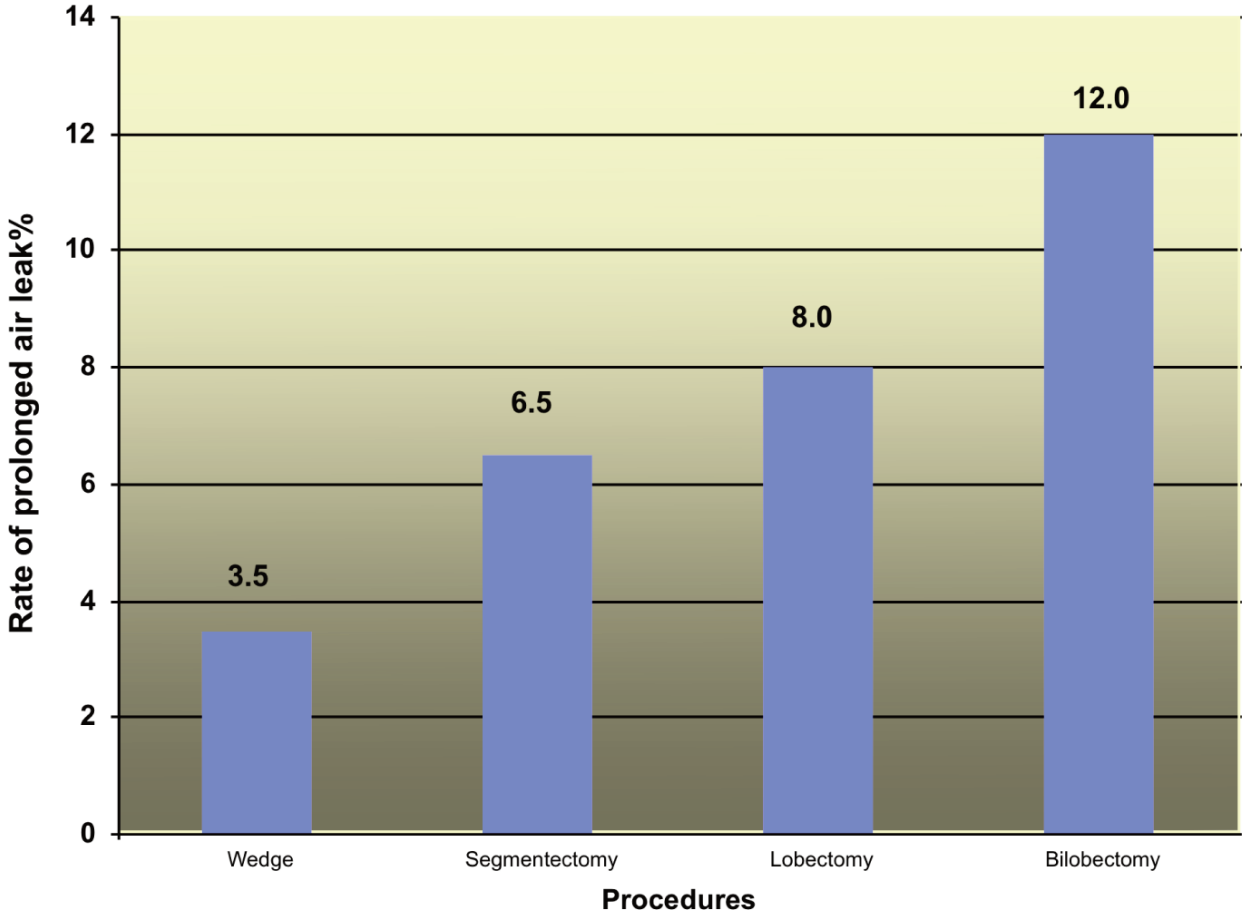
Unadjusted Cardiopulmonary Morbidity rate in different types of lung resections

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.
The graph shows that lobectomy and bilobectomy have an incidence of complications of 23% and 35%, respectively. Wedge resections have the lowest incidence of major cardiopulmonary complications (6%).



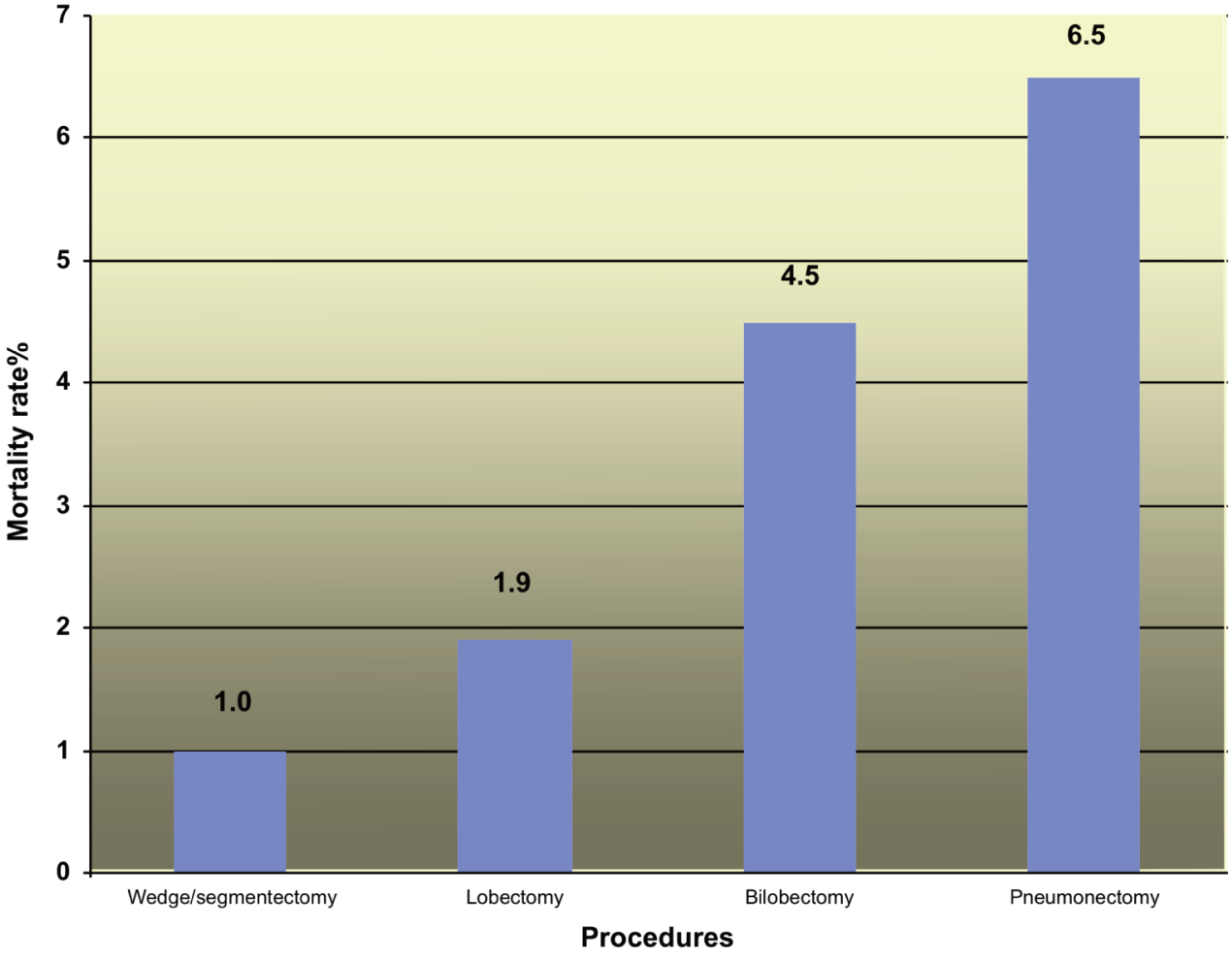
Incidence of prolonged air leak (> 5days) in different types of lung resections

Prolonged air leak remains a frequent complication after lung resection that prolongs the hospital stay and increases costs. From the graph below it is apparent that certain procedures are at higher risk of developing a prolonged air leak, such as lobectomy (8%) and most of all bilobectomy (12%), whereas minor resections have a limited risk around 4-7%. This finding is in line with reported scientific evidences and it is of interest for researcher and companies willing to investigate new technologies or products aimed at preventing this complication.



Unadjusted Mortality rates in different types of lung resections

Cumulative mortality rates in lobectomy and pneumonectomy were 1.9% and 6.5%, respectively. At variance with previous international reports, minor resections had a very low mortality rate, suggesting that even in compromised patients these procedures are relatively safe.

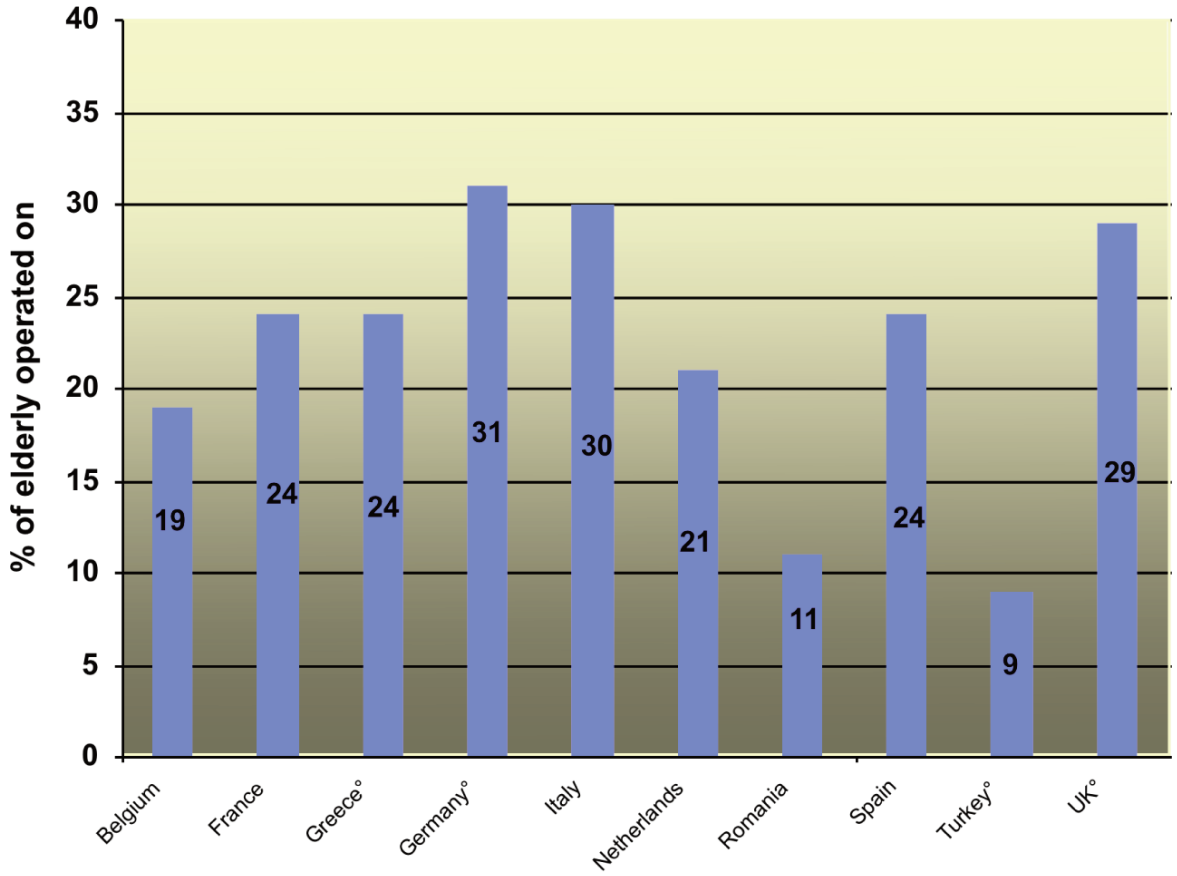


PART 2
COMPARATIVE ANALYSIS BETWEEN DIFFERENT COUNTRIES

Only Countries contributing more than 100 lung resections were included

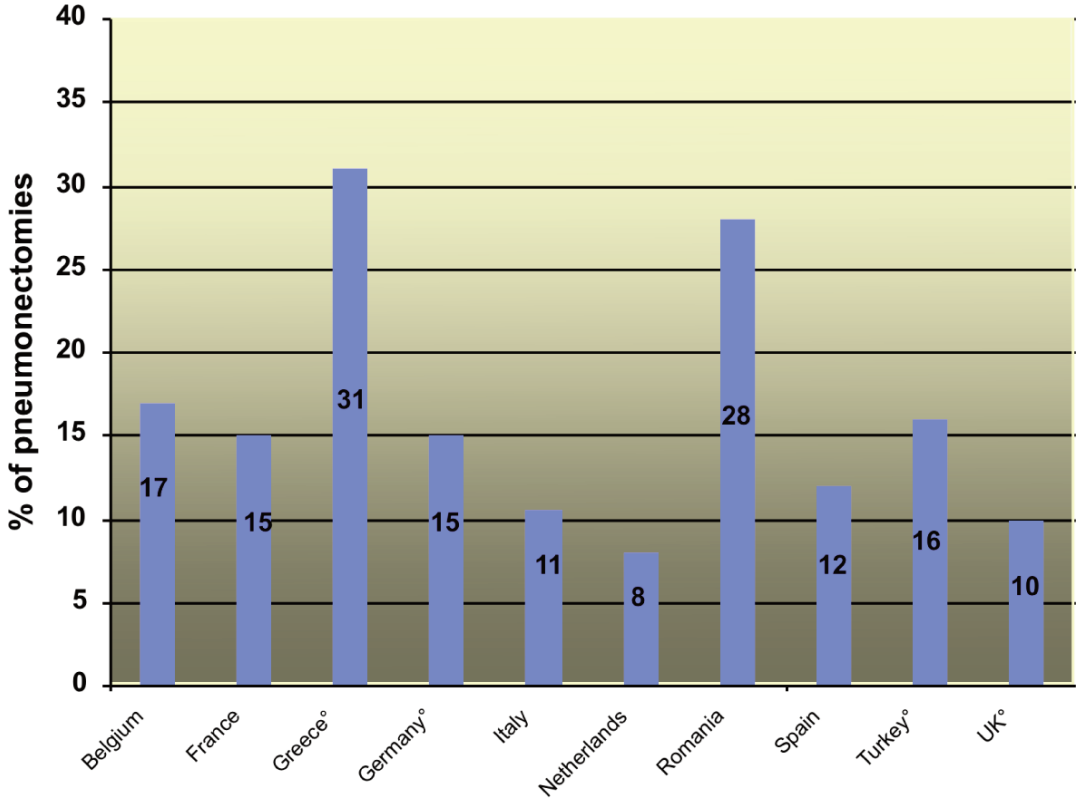
Proportion of elderly patients (older than 70 years of age) operated on in different European Countries

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 31% 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.



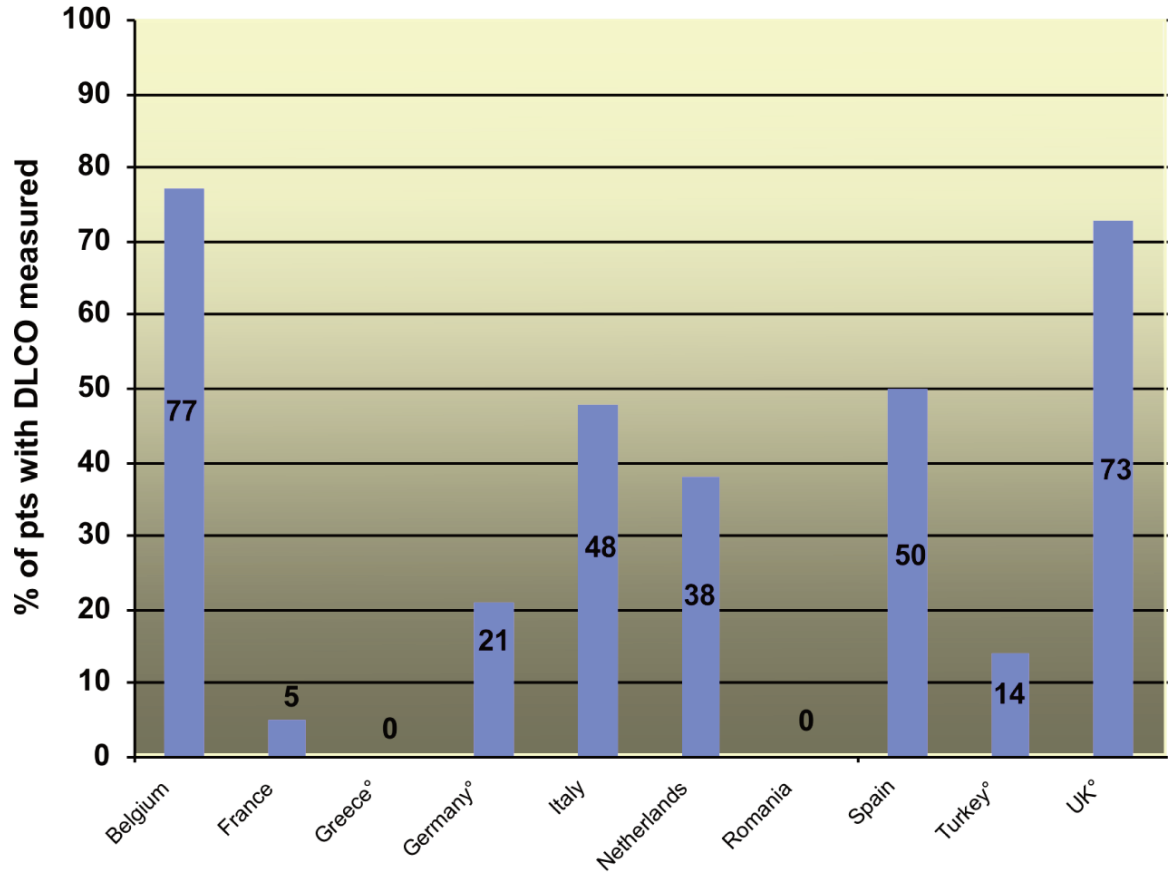
Percentage of pneumonectomies (out of major anatomic resections) for malignant primary neoplastic disease in different European Countries

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 31%.
(°): Country with less than 500 patients included, results must be interpreted with caution.



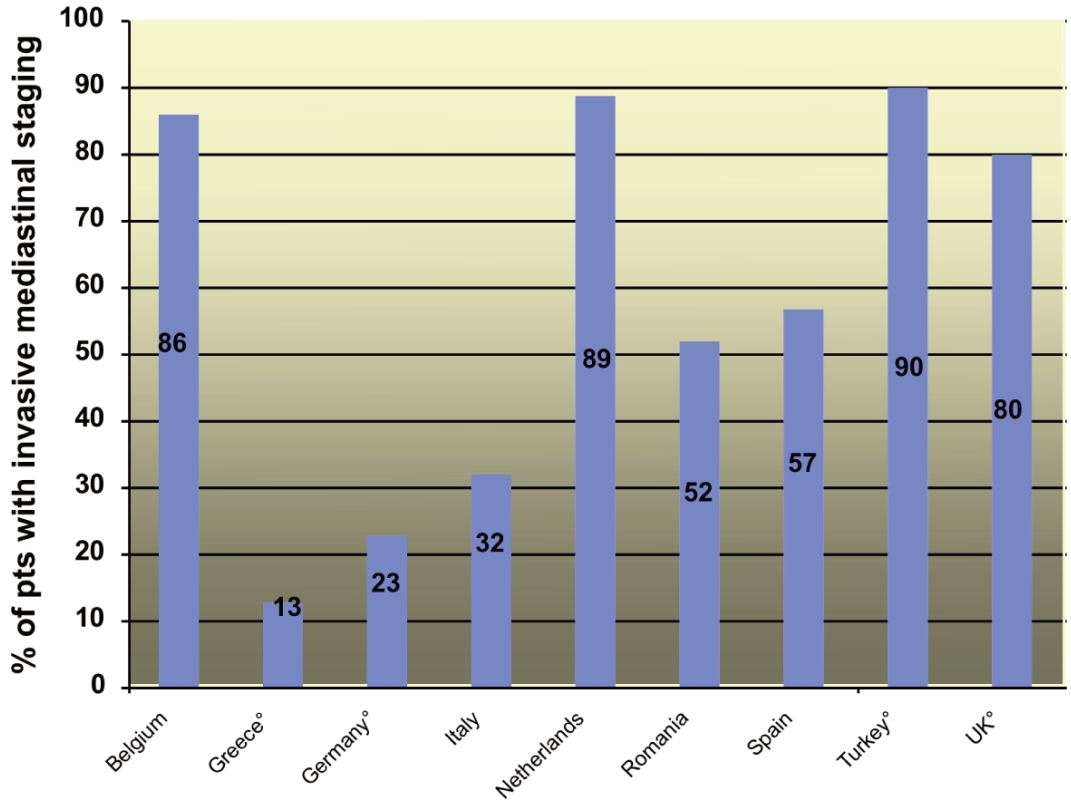
Percentage of patients submitted to major anatomic lung resections with preoperative measurement of DLCO in different European Countries

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.



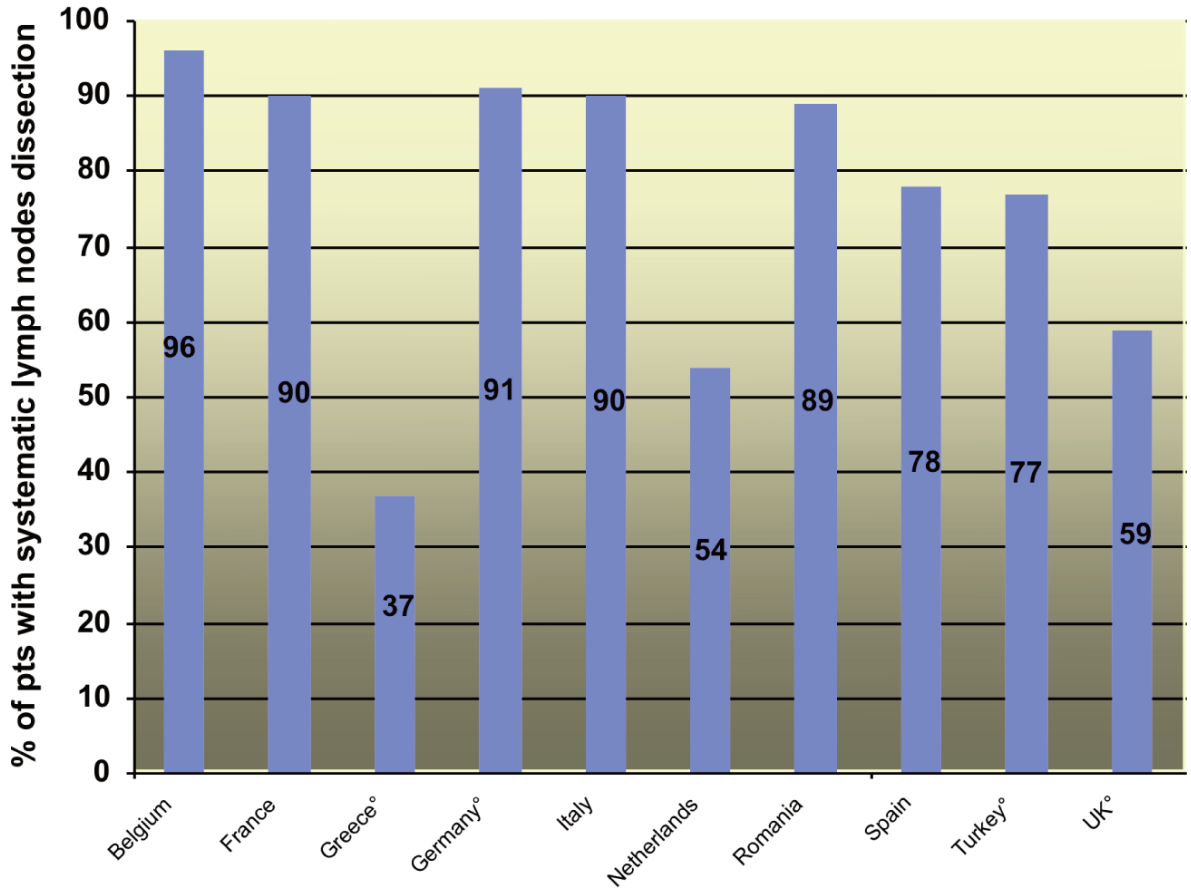
Percentage of patients with primary neoplastic disease and suspicious clinical N2 stage (enlarged >1cm mediastinal nodes at CT scan or PET positive mediastinal nodes) who underwent at least one preoperative invasive mediastinal staging procedure (EBUS, EUS, mediastinoscopy, mediastinotomy, VATS, TEMLA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



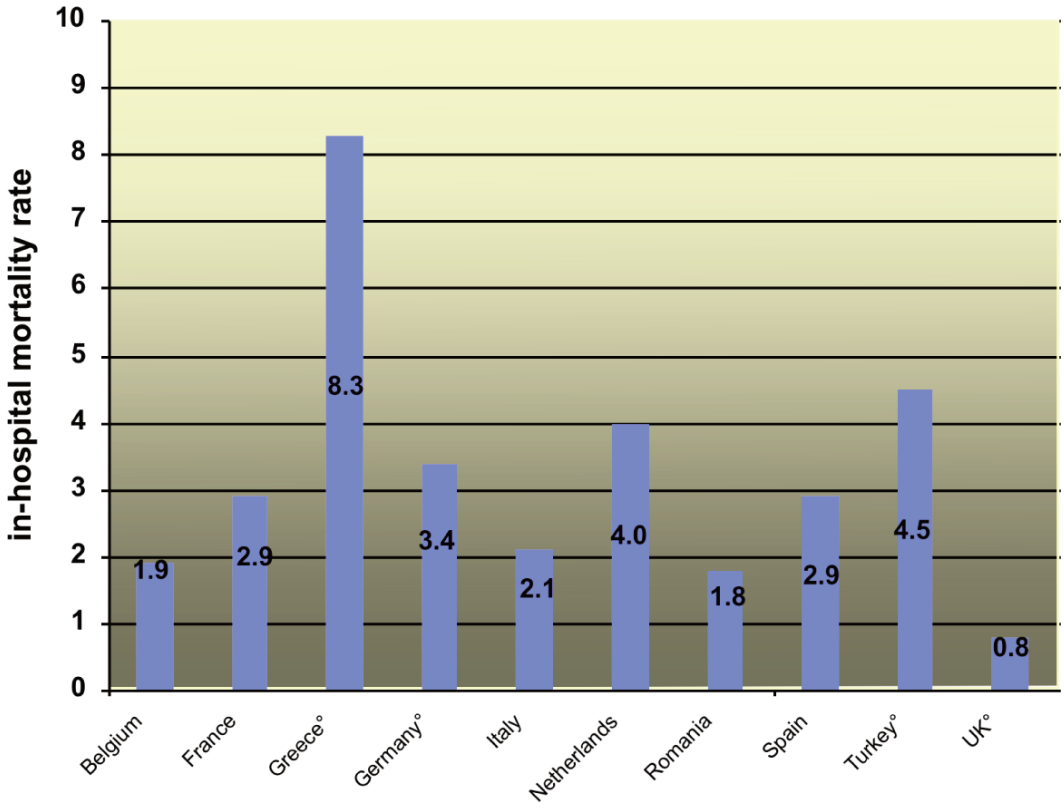
Percentage of patients submitted to lymph node dissection during major lung resection for malignant primary neoplastic disease grouped by Countries

Lymph node dissection more extended than sampling alone or selected biopsy (as defined and recommended by the ESTS guidelines for intraoperative medistinal 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

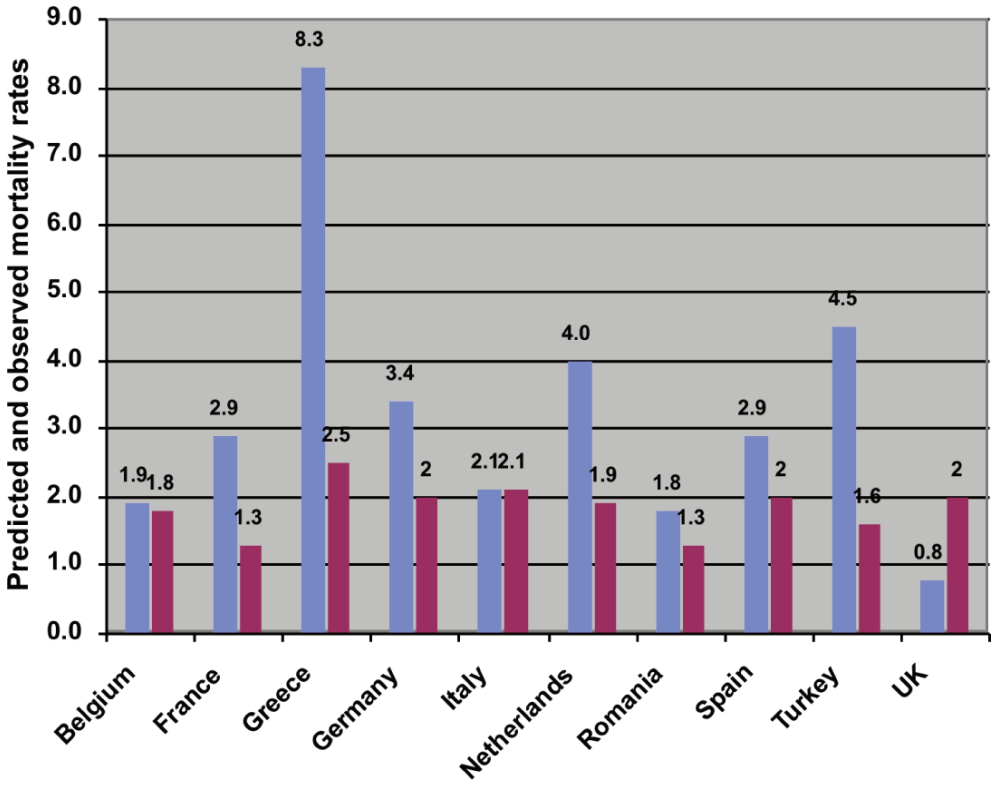
The analysis of raw mortality rates does not take into consideration the characteristics of the patients operated on and the extent of procedures. Most of the Countries display mortality rates between 1% and 4%.



Observed versus ESOS-predicted mortality rates of major lung resections in different European Countries. Risk adjustment performed by using ESOS.1 model

(Berrisford R, Brunelli A, Rocco G, Treasure T, Utley M. The European Thoracic Surgery Database project: modelling the risk of in-hospital death following lung resection. Eur J Cardiothorac Surg 2005; 28: 306-11)

Expected mortality is represented by the purple bars whereas the observed mortality by the blue bars.



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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