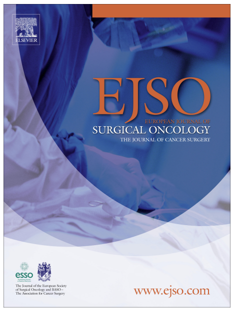
Lessons learned from the European Thoracic Surgery Database: The Composite Performance Score.

Alessandro Brunelli, Gaetano Rocco, Dirk van Raemdonck, Gonzalo Varela, Marcel Dahan



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Abstract

Background: This study reports the methods used to review the Composite Performance Score (CPS) along with a reference table, which will be used in the upcoming ESTS Quality Certification Program.

Methods: Data from 4303 patients who underwent pulmonary resection (July 2007-January 2010) were captured in the ESTS database and used for the present analysis. Only patients submitted from units contributing at least 100 consecutive lung resections were used for developing the score.

According to the best available evidence the following measures were selected for each surgical domain: preoperative care (1. % of DLCO measurement in patients submitted to major anatomic resections; 2. % of preoperative invasive mediastinal staging in patients with clinically suspicious N2 disease), operative care (% of systematic lymph node dissection), outcomes (risk-adjusted cardiopulmonary morbidity and mortality rates). Morbidity and mortality risk-models were developed by logistic regression and validated by bootstrap analyses. Individual processes and outcomes scores were rescaled according to their standard deviations and summed to generate the CPS. Units were rated accordingly and a percentile reference table was produced.

Results: Risk-adjusted survival and absence of morbidity rates varied from 91.5% to 100%, and from 50.2% to 97.5%, respectively. CPS ranged from -4.038 to 1.24. The 50% percentile of CPS corresponded to 0.404.

Conclusions: A revised Composite Performance Score was developed and a reference table presented to be used as a benchmark for the ESTS Quality Certification program.

Key words: Lung resections; Quality of care; Composite Performance Score; Process of care; Outcome; Database.

Introduction

Monitoring quality of care has become an important element in our practice. Third parties demand that our profession is scrutinized in order to provide the best care in a cost-conscious context.

For this reason, there is a growing interest in our specialty in developing and testing indicators of performance (1-3). The study of surgical quality is clearly more mature in cardiac surgery, due to imposed governmental reporting requirements (4). Organizational cardiac surgery databases are more robust due to a widespread participation of cardiothoracic surgeons, allowing for overall measurement of clinical data, analysis and benchmarking both at the regional and local levels. A similar effort to collect clinical information has been initiated in general thoracic surgery. Both the Society of Thoracic Surgeons (STS) in the USA and the European Society of Thoracic Surgeons (ESTS) in Europe have developed specific registries with the intent to monitor our practice and implement quality initiatives.

The first version of the ESTS Database was launched in 2001. It was an offline registry and data was submitted using ad-hoc software. Twenty-seven units from 14 Countries contributed a total of approximately 3 000 lung resections for lung tumors over a 3 year period (2001-2003). These patients were used to build the first European in-hospital mortality risk model (European Society Objective Score-ESOS) (5). ESOS was subsequently tested to compare the performance of three different thoracic surgery units (6), with the intention to provide a template for performance monitoring in our specialty. Although no difference was found between predicted and observed mortality rates in each unit, it appeared obvious that this lack of discrimination was in part due to the inadequacy of the indicator to assess performance when used alone. Mortality is fortunately a rare event in our specialty, which displays a lot of random noise. Large sample size and a long period of accrual are needed to achieve the sufficient number of events to perform reliable aggregate statistics. More sensitive instruments are desirable, which would be capable of providing actionable and timely information and to prevent unnecessary deaths or negative events (2).

It is now recognized that clinical outcomes are only one measure of overall health care quality (2,6).

In fact, like intelligence or musical ability, quality is an abstract construct that cannot be measured directly and it is characterized by one or more latent (unobserved) variables or traits. To quantify abstract constructs we typically rely upon some combination of measurable surrogates that are thought to be associated with or contribute to that underlying trait.

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 (7).

Based on that methodology, ESTS recently developed and published a Composite Performance Score (CPS) for lung surgery (8) based on 1656 patients submitted to major lung resections for malignant primary neoplastic disease in the 10 units contributing more than 50 consecutive cases to the European Database.

CPS comprised the following indicators covering all three temporal domains of our practice (preoperative, intraoperative and postoperative):

1. The proportion of patients with ppoDLCO estimated in the eligible group with a low ppoFEV1 (ppoFEV1<40%) (9,10)
2. The proportion of patients with systematic lymph nodes dissection according to ESTS published guidelines (11)
3. Risk-adjusted in-hospital mortality

4. Risk-adjusted cardiopulmonary morbidity (pneumonia, atelectasis requiring bronchoscopy, Adult Respiratory Distress Syndrome, mechanical ventilation longer than 24 hours, pulmonary edema, pulmonary embolism, myocardial ischemia, cardiac failure, arrhythmia, stroke, acute renal insufficiency).

The final composite score combined all these four indicators (2 processes and 2 outcomes) into a single comprehensive quality score after rescaling all measures according to their standard deviations.

Interestingly, the individual 4 rescaled scores (processes and outcomes) showed only a poor or moderate correlation between each other, indicating that these measures complement each other rather than being mutually exclusive.

By using the CPS all units changed their position compared to the rank obtained by using mortality alone. One unit moved from the lower half to the upper half of the rating panel and one from the upper half to the lower half. Forty percent of units moved 2 or more positions. It was clear that the CPS provided a much more reliable and comprehensive assessment of quality of care.

This warranted further work to refine the score in order to make it possible to use it as a reliable tool in the upcoming ESTS Quality Certification Program.

We herein report the analytic steps and results of the first revision of the ESTS Composite Performance Score, presenting a table of reference values for the upcoming ESTS quality initiative programs.

Patients and Methods

Data was prospectively captured from the online web-based European Thoracic Surgery Database on thoracic surgical procedures from units across Europe. The database was designed to contain a minimum set of core variables and endpoints. Twenty-nine units from 11 European Countries consistently submitted data from July 2007 through January 2010 without external local data audit. Data was scrutinized for possible inconsistencies and missing values to improve the quality of data in the context of a voluntary database.

A total of 4303 patients who underwent lung resections (66% lobectomies/bilobectomies, 22% wedges or segment resections, 12% pneumonectomies) made up the dataset for this analysis. Only patients submitted from units contributing at least 100 consecutive lung resections (comprising 85% of the total dataset) were included and used for developing the score and rating the units to obtain a reference table.

We selected three Quality Domains assessing preoperative care (process indicator), operative care (process indicator) and postoperative care (outcome indicator). Based on the best available current evidence the following indicators were selected:

Process indicators:

Based on published guidelines,

1. The proportion of patients with DLCO estimated in the eligible group submitted to major lung resections (12)

2. The proportion of patients with primary neoplastic disease and clinically suspicious N2 disease at CT scan (nodes > 1cm) or PET submitted to preoperative invasive mediastinal staging according to ESTS published guidelines (13)

3. The proportion of patients with at least a lobe-specific or systematic lymph nodes dissection according to ESTS published guidelines (11)

Outcome indicators:

1. In-hospital mortality
2. Cardiopulmonary morbidity (pneumonia, atelectasis requiring bronchoscopy, Adult Respiratory Distress Syndrome, mechanical ventilation longer than 24 hours, pulmonary edema, pulmonary embolism, myocardial ischemia, cardiac failure, arrhythmia, stroke, acute renal insufficiency).

These two outcome indicators were risk-modeled as follows. An initial screening of preoperative and operative variables (age, gender, predicted postoperative forced expiratory volume in one second in percent of predicted normal values-ppoFEV1, type of operation-lobectomy or pneumonectomy-, presence of extended resection-lung resection associated with resection of chest wall, diaphragm, pericardium, or other mediastinal structures-) was performed by univariate analyses using the unpaired Student's t test or Mann Whitney test for numerical variables (with or without normal distribution, respectively) and the Chi-square test or the Fisher's exact test, whenever appropriate, for categorical ones. Variables with a p level <0.1 at univariate analysis were then used as independent predictors in logistic regression models. The regression models were further validated by bootstrap analyses with 1000 samples (14-16).

Finally, risk-adjusted morbidity and mortality rates were calculated for each unit by dividing the observed by the predicted outcome and multiplying this by the mean observed outcome rate in the total population. Risk-adjusted outcome rates (morbidity or mortality) are regarded as the outcome rates a unit would have if its case-mix were similar to the average case-mix in the entire population.

Determination of Final Composite Score: Final composite score combined the three process measures with the two risk-adjusted outcome measures into a single comprehensive quality score.

To assure consistent directionality, (increasingly positive values reflecting better performance), mortality rates were converted to survival rates (risk-standardized survival rate = 100 – risk-standardized mortality rate), and morbidity rates were converted to "absence of morbidity" rates (risk-standardized absence of morbidity rate = 100 – risk-standardized morbidity rate).

To account for any differences in the measurement scales of the domain-specific scores, the scales of measurement were standardized by the reciprocal of their standard deviations (Rescaled score = Original score-Average score of the entire population/ Standard deviation of the entire population). This rescaling method was applied to all the outcome and process indicators before summarizing in the final composite score of each unit.

All data was at least 95% complete. Missing data was imputed by averaging the non-missing values for numerical variables and by taking the most frequent category for categorical variables. All the statistical tests were two-tailed and a significance level of 0.05 was accepted. The analysis was performed by using the STATA 9.0 (Stata Corp., College Station, TX) statistical software

Results

Table 1 and 2 show the results of the stepwise logistic regression analyses for in-hospital morbidity and mortality, respectively. Factors reliably associated with cardiopulmonary complications were age ($p<0.0001$), ppoFEV1 ($p=0.001$), presence of an extended resection ($p=0.02$), pneumonectomy ($p<0.0001$) and cardiac co-morbidity ($p=0.004$). The resulting model for morbidity was:

Logit: -3.52 + 0.659Xpneumonectomy + 0.403Xextended resection (coded as 1 and including chest wall resection, pleuropneumonectomy, completion operation, intrapericardial operation) + 0.322Xcardiac comorbidity (coded as 1 and including CAD, any previous cardiac surgery, history and treatment for arrhythmia, congestive heart failure, hypertension) -0.0065XppoFEV1% + 0.0315Xage.

Factors reliably associated with mortality were ppoFEV1 ($p<0.0001$), presence of cardiac co-morbidity ($p<0.0001$) and pneumonectomy ($p<0.0001$). The resulting model for mortality was:

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%

Table 3 summarizes the average rates of processes and outcomes in the entire population.

Risk-adjusted survival rates varied from 91.5% to 100%. Risk-adjused absence of morbidity rates varied from 50.2% to 97.5%.

Figures 1 to 3 show the proportion of patients in each unit submitted to the processes of interest. Both the DLCO measurement and the preoperative mediastinal staging compliance varied from 0 to 100%, whereas the range varied from 14% to 100% for the intraoperative lymph node dissection.

Composite scores were generated by adding the rescaled individual process and outcome scores of each unit, and they ranged from -4.038 to 1.24.

Table 4 shows the percentile distribution of CPS. The 50% percentile CPS corresponds to 0.404. This reference table has been derived rating all units with more than 100 lung resections as of January 2010 according to their individual CPS.

Discussion

Data collection is arguably the most important part of quality assessment.

The ESTS database was launched online in July 2007. It is a web-based registry, designed to capture all thoracic procedures but with a particular focus on lung procedures, for which a series of additional standardized variables have been included. The purpose of the ESTS Database is to monitor quality of care across Europe and to develop measures to help participating units to improve their performance.

As of February 2010, 45 European units contributed at least 20 cases, for a total of 4303 lung resections captured over a period of 2.5 years. Eighty percent of data come from the 29 units, which contributed more than 100 cases. It is clear that although the participation is ever increasing and recent implementations will improve recruitment, the current data must be interpreted cautiously as they cannot yet provide a complete representation of the European thoracic surgery practice.

The last version of the ESTS Database Annual Report still shows a great variation in practice and case-mix is evident.

For instance, the proportion of elderly patients (>70 years) operated on in different units may vary from 9% to 45%. Social, geographical, cultural and referral patterns may have influenced this data.

Similarly, the rate of pneumonectomy for malignant primary neoplastic disease, which in some National Registries is regarded as a quality indicator, may vary from as low as 5% to as high as 35%.

Even more striking are the differences in risk-adjusted (according to ESOS-5) mortality rates, which can vary from 0 to 13.5%.

It is clear that, particularly in Europe, where social, cultural, geographical differences couple with different thoracic surgery educational backgrounds and national regulations, reliable instruments to monitor and standardize practice are most needed. These instruments should be provided at an international societal level through collaborative efforts. ESTS is the ideal organization devoted to improve the quality of European thoracic surgical practice through its multifaceted educational activities. Its role is to “enlighten the path, provide the tools, and set the standards for basic quality inspired practice in order to serve and to protect anyone, from trainee to established consultant (17)”.

Inspired by these principles, we developed an instrument to monitor the institutional performance based on multiple indicators (either processes and risk-adjusted outcomes) incorporated into a single Composite score.

The score is based on the following principles:

1. Quality assessment should be at the level of the program or hospital rather than the individual surgeon.

2. Quality scores should consider structure, process, and outcomes (18).

3. Quality scores should assess three temporal domains: preoperative, operative, and postoperative (7).

4. Quality scores should be interpretable and actionable by providers.

5. Initial quality reports should focus on lung resection as the most representative operation in our specialty

6. All Quality measures should be available as data elements within The European Thoracic Surgery Database

Although quality improvement requires attention to each individual aspect of quality, there are many settings in which the users of quality measures are most interested in the bottom line. Thus, composite indicators seem particularly useful for summarizing and comparing the quality of care delivered by healthcare providers. This is particularly true in many surgical areas where the small sample size and the low rate of adverse events diminish the statistical utility of outcomes comparisons (19). Thus, composite indicators may provide a quantitative basis for clinicians, organizations, and planners aiming to improve care and the process by which patient care is provided.

We recognize that some important areas of performance may not be addressed or may be relatively undervalued, and aggregation may also obscure individual areas of strength or weakness. The ability to decompose the composite into its individual components is critical. This allows providers to analyze their performance in specific areas and to formulate improvement strategies (20). The CPS developed in this analysis can be easily decomposed and the units may be evaluated according to their individual scores related to preoperative, operative and postoperative domains.

Limitations:

- Data submitted to the ESTS database are not yet audited. A central and independent audit system is to be implemented to assess quality of data for the participating units.

- Determining a set of valid exclusion criteria for process measures has proven challenging in many areas of medicine, and information on contraindications to various process measures is absent in the European Database. As a result, some patients who are appropriately denied a practice owing to a contraindication will be misclassified as representing a process failure. The true overall percentage compliance with process measures will therefore be underestimated because some ineligible patients are included.

- Because certain outcomes (morbidity) are difficult to define precisely, it is possible that variation in coding practices could account for some of the observed differences between providers.

ESTS Quality certification Program:

It is the natural complement of all the other ESTS educational activities (ESTS School, Annual Congress, Itinerant Courses, Scholarships, Traveling Fellowships) and has been developed with the intent to generally improve and standardize practice of care across Europe. The concept is to provide the participating units with an instrument to monitor their performance and possibly identify areas of potential improvement through reliable, peer-driven, evidence-based recommended practices.

In order to be eligible for the Quality Certification, units must meet some structural, procedural and professional criteria as long. A minimum 2-year period of consecutive submission of high-quality data to the ESTS Database is a pre-requisite for application. The data submitted to the ESTS database is essential for calculating the Composite Score as all the standardized outcomes and process indicators are elements of the database. The units must also demonstrate the presence of a quality surveillance activity performed on a regular basis.

The ESTS Database Committee and the ESTS Audit and Clinical Excellence ad hoc Committee developed and the ESTS Council approved the following eligibility criteria for the certification (modified in part from the EACTS/ESTS Working Group on Structures in Thoracic Surgery Structure of General Thoracic Surgery in Europe-21)

- **Structural characteristics:**
  - o 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 unit 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 CT scan and PET, cytology, histopathology and frozen section analysis.
- In-house facilities for research and education (meeting room, medical libraries, email and internet)

- **Procedural 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**

- o All surgeons must be qualified to perform thoracic surgery according to individual national or European legislation.
- o The Head of the unit must have a minimum experience of 5 years of clinical practice as qualified thoracic surgeon.
- o The Head of the unit or the Clinical Audit Lead, responsible for data collection and quality of care audit, must be an ESTS member.

The above-mentioned criteria and random samples of data submitted to the ESTS Database will be subjected to external audit.

The units meeting the recommended criteria will be eligible and rated centrally by using the CPS. Those with a CPS above the 50^{th} percentile according to the updated reference table (table 4) will be certified.

To this purpose the CPS reference table will be reviewed and published for transparency in the ESTS Database Annual report.

FINAL COMMENT

Among all stakeholders in health care activities, clinicians are the most interested in quality management programs to ensure that effective practices are implemented in an efficient way in a social environment highly concerned with cost-containment policies.

Professional organizations such scientific societies have a prominent role in promoting evidence based clinical practices and encouraging their members to adopt them and to be involved in programs of continuous improvement of quality of care. The methods depicted in this paper to develop a CPS have been developed under the auspices of the European Society of Thoracic Surgeons and can be adapted to different medical domains. In the future, the CPS will be one of the parameters to be evaluated in the ESTS quality certification program.

CONFLICTS OF INTEREST

None of the Authors of the manuscript entitled “Lessons learned from the European Thoracic Surgery Database: The Composite Performance Score” have potential conflicts of interest to declare with the exception to be members of the European Society of Thoracic Surgeons Database Committee.

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Table 1: results of the stepwise logistic regression analysis (dependent variable: cardiopulmonary morbidity). Parsimonious model shown.

Variables	Coefficients	SE	P-value	Bootstrap%
Intercept	-3.52	0.35		
Age	0.0315	0.005	<0.0001	100
PpoFEV1	-0.0065	0.002	0.001	92
Extended resections	0.403	0.18	0.02	65
Pneumonectomy	0.659	0.16	<0.0001	98
Cardiac comorbidity	0.322	0.1	0.004	83

Bootstrap%: percentage of significancy (p<0.05) in 1000 bootstrap samples; c-index:0.66; Hosmer-Lemeshow statistics, p=0.4

Table 2: results of the stepwise logistic regression analysis (dependent variable: mortality). Parsimonious model shown.

Variables	Coefficients	SE	P-value	Bootstrap%
Intercept	-3.22	0.29		
PpoFEV1	-0.0175	0.004	<0.0001	99
Pneumonectomy	1.049	0.26	<0.0001	97
Cardiac comorbidity	0.928	0.25	<0.0001	96

Bootstrap%: percentage of significancy ($p<0.05$) in 1000 bootstrap samples; c-index: 0.74; Hosmer-Lemeshow statistics, $p=0.9$

Table 3: Mean observed process and outcome rates in the total population.

Indicator	Rate	SD
Preop DLCO measurement	41%	49
Preop invasive mediastinal staging	62.6%	48
Intraop systematic lymph node dissection	82.6%	38
Absence of cardiopulmonary complications	82.5%	38
Intra-hospital or 30-days survival	96.5%	18

Preop DLCO measurement in patients submitted to major lung resections; Preop invasive mediastinal staging (EBUS, EUS, mediastinoscopy, mediastinotomy, VATS, TEMLA, VAMLA) in patients with clinically suspicious N2 disease (CT scan nodes>1 cm or PET positive nodes); Intraop systematic lymph node dissection in patients submitted to major anatomic lung resections for NSCLC.

Table 4: Reference table for ESTS Composite Performance Score percentiles (updated as of January 2010)

Percentiles	**CPS score**
25%	-1.004
50%	0.404
75%	1.019
95%	1.24

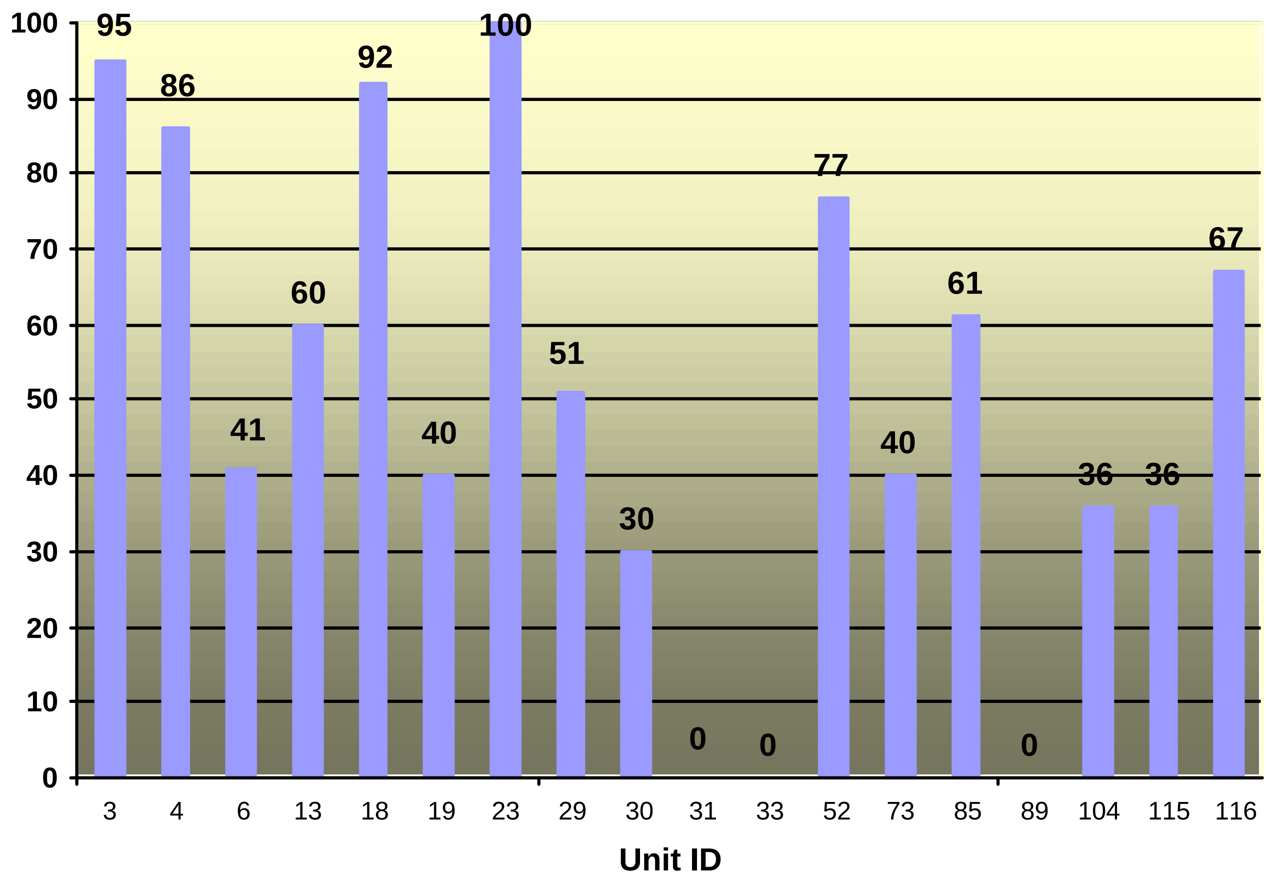
The following reference table has been derived rating all units with more than 100 lung resections as of January 2010 according to their individual CPS

Figure Legend:

Figure 1: Proportion of patients with DLCO measured before major lung resection in different European units (from ESTS Database Annual Report 2010)

Figure 2: 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.) in different European units (from ESTS Database Annual Report 2010)

Figure 3: Percentage of patients submitted to at least lobe-specific lymph node dissection or systematic lymph node dissection during major lung resection for malignant primary neoplastic disease grouped by units (from ESTS Database Annual Report 2010)



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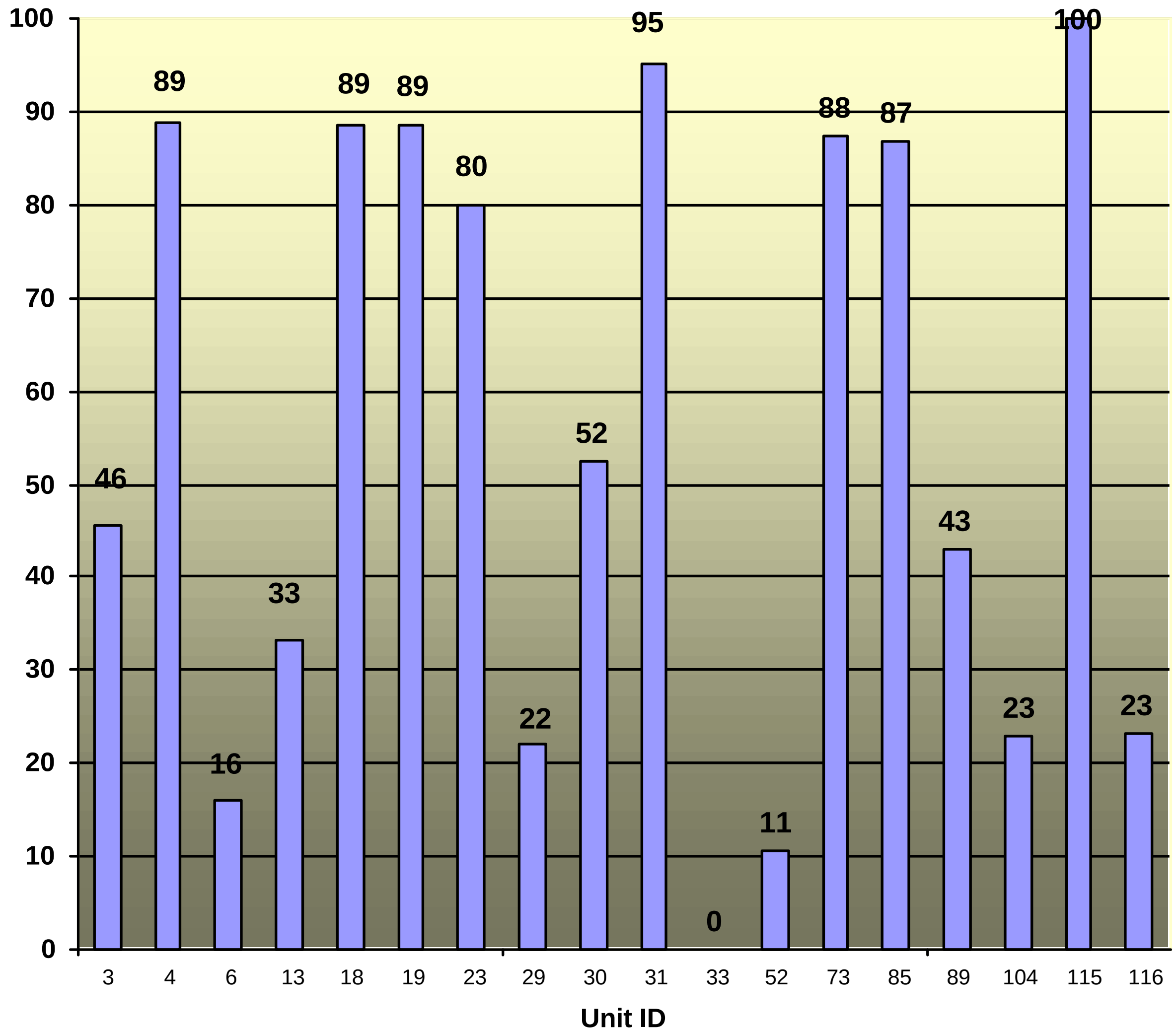
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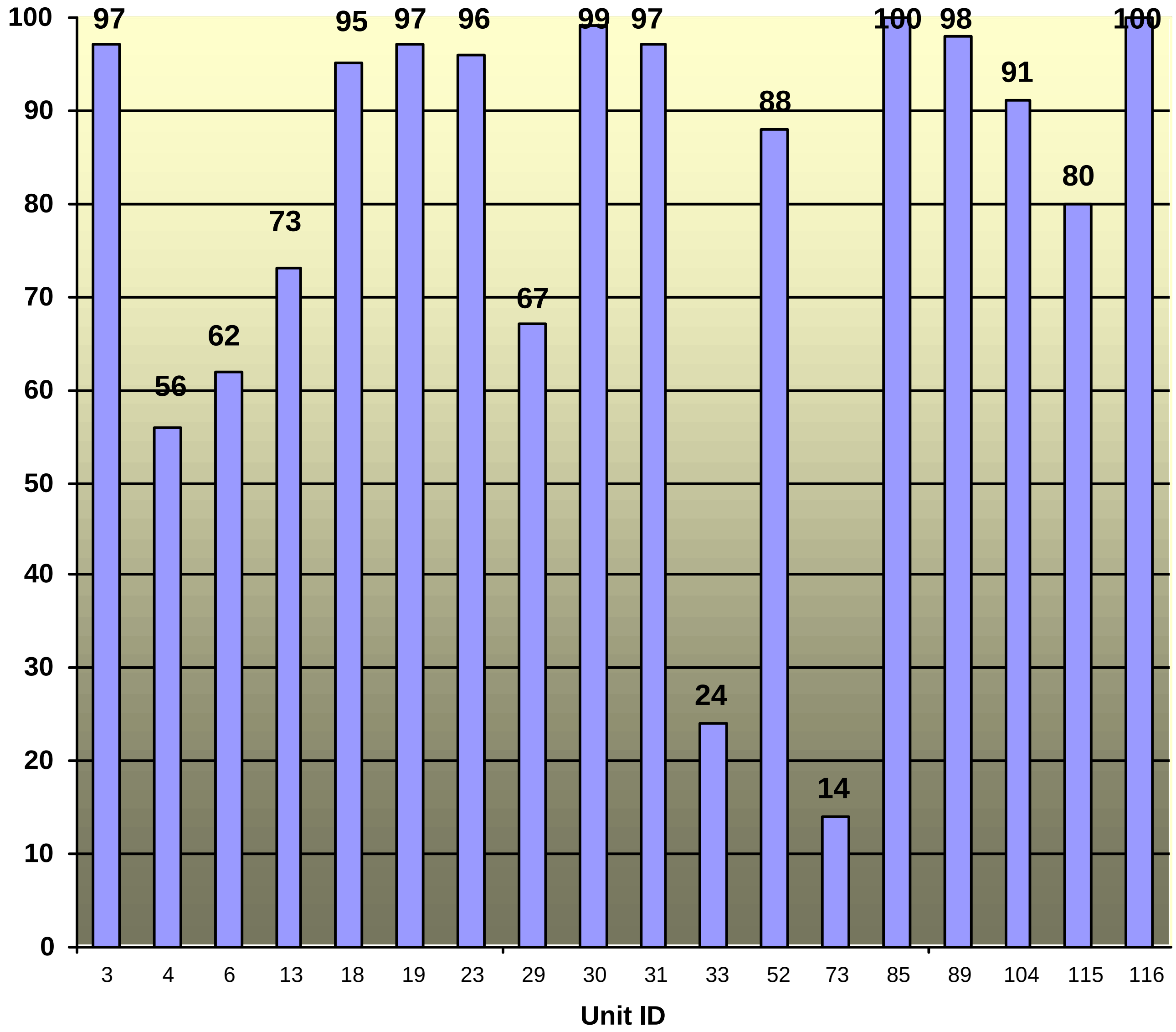

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