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The University of Munich Lung Cancer Group Database: Design, Profile of Cohort and Outcome Analysis

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Abstract
Objective: Changes in therapeutic concepts can only be justified by a significant improvement of outcome parameters. Furthermore, detailed statistics of complications are needed to guarantee high quality of treatment. This study describes the new University of Munich Lung Cancer Group Database.
Methods: The MLCG-Database contains all patients who underwent surgery for lung cancer at the Department of Surgery, University of Munich Medical Centre since 1978. Data were database recorded on the patient's ward, or directly imported from other departments performing medical examinations on the patient. Data could be entered online at the time of surgery in the operating room. Relevant information from the Munich Tumour Registry was imported via encrypted data communication. Both epidemiological background and influence of preoperative risk factors on morbidity and mortality as well as on long-term survival were analysed.
Results: Median follow-up time was 45 months (1-295 months). Overall 5- and 10-year survival was 36% and 28% respectively. Preoperative risk factors were arterial hypertension in 43% of patients, COPD in 34%, abuse of nicotine in 26% and therapy with corticosteroids in 25%. Surgical procedure consist of lobectomy or bilobectomy in 69%, pneumonectomy in 16% and lesser resections in 15%. Intra- and postoperative complications occurred in 1.4% and 32% of patients, respectively.
Conclusions: This paper provides an overview of our MLCG-Database, which allows performing statistics for outcome analysis and quality management reports as well as medical assessment on a huge collection of patient data on a day-to-day basis. In addition, impact analysis of risk factors on postoperative morbidity and mortality as well as investigation of long-term survival underlines results reported internationally.
Key words: Lung cancer, evidence based medicine, Quality Management, database, Cancer Registry
Abbreviations: MLCG = University of Munich Lung Cancer Group

1. Background

Lung cancer is the leading cause of death from cancer in Germany among men and women, and the incidence of lung cancer has been increasing in recent years [1]. In 2004, the number of lung cancer deaths in Germany reported to the WHO was more than 40,000. Lung cancer is often resistant to treatment, therefore research programs designed to share interdisciplinary data are needed to improve patient outcome [2]. It is difficult to find out factors associated with lung cancer outcome because of the marked clinical heterogeneity of patients. Various individual characteristics like age, sex, pathologic stage, performance status, co-morbidity, molecular biological markers, marital status, psychological factors and smoking status have all been said to contribute to the survival rate in lung cancer [3]. Further clarification of the factors contributing to postoperative complications and survival from lung cancer is needed. In addition, maintenance of good quality management is not only prescribed by national law but also by professional ethics [4, 5].

Therefore, we developed a large-scale database that allows collection of detailed pre- and intraoperative information as well as postoperative complications and integration of long-term follow-up data. This database may contribute to basic research and clinical research in the future.

In this study we describe the database design, the workflow, the cohort profile, the integration structure of interdisciplinary information and the quality management of our surgical lung cancer database at the Department of Surgery, University hospital Klinikum Großhadern. Epidemiologic background and impact of preoperative risk factors on postoperative mortality, morbidity and long-term survival were analysed. By investigating these factors that influence the outcome of patients with lung cancer, we hope to illuminate several specific points related to cancer treatment in order to improve patient outcome.

2. Material und Methods

2.1 Hard- and Software

All computer workstations of our hospital are network connected and firewall protected against hacker attacks from the Internet. The database is password protected and works from a central server that is mirrored daily to a second server. Critical data were encrypted using PGP® (PGP Corporation, Offenbach am Main, Germany).

The database was created using Microsoft Access® for Windows (Microsoft Corporation, USA).

Included forms are easy and well-arranged inter-

faces between physicians and the database. Forms may combine information from several tables and query of data. Linking all information to the corresponding unique patient ID ensures correct assignment of data. Database reports, which could be updated any time, arrange all information, for example quality management data or other statistics in a concise summary.

2.2 Acquired Interdisciplinary Data

As shown in Figure 1, results of examinations performed by non-surgical disciplines i.e. pneumology, radiology, or pathology were included in the database. For assessment of general operability and operative risk, all information concerning tumour staging and grading, history and presence of other diseases or risk factors were recorded in the database. Postoperatively all information about surgical procedures and complications can be entered in the database immediately at the operation theatre. Resected tumour or lymphatic tissue specimens were analysed by the University Institute of Pathology and results i.e. histology, TNM Staging and Grading were registered in our database. Data of postoperative examinations and interventions, as well as information concerning adjuvant chemo-radiotherapy were also entered in the database.

2.3 Quality Management

Since 1996 all intra- and postoperative complications were registered in detail in our database, as well as registration of 30 day mortality, length of intensive care including respirator time and hospital stay. Up until now, these data (Table 1) are available for 735 patients. Impact of risk factors and comorbidity on postoperative 30 day mortality and morbidity was analysed

Table 1. General (Group A) and specific (Group B) complications following lung resection for bronchial cancer with corresponding inclusion criteria listed below.

	Complication	**Minimal inclusion criteria**
Group A	Circulatory failure	Hypotension
	Arrhythmia	Indication for medical therapy
	Renal failure	Creatinine >2 mg/dl or urea >100 mg/dl
	Liver failure	Bilirubin level > 2 mg/dl or Ammoniac level >100 mg/dl or spontaneous Prothrombin time < 50%
	Cerebral failure	Symptomatic transitory psychotic syndrome
	Sepsis	Infection, systemic reaction and (multi-) organ failure [6]
	Pulmonary embolism	validated by computed tomography
	Postoperative bleeding	Significant loss of haemoglobin level
Group B	Respiratory insufficiency	Indication for oxygen therapy
	Pneumonia	Indication for antibiotic therapy
	Pleural empyema/effusion	Indication for drainage
	Bronchopleural fistula	Indication for surgical revision
	Pneumothorax/Chylothorax	Indication for surgical revision
	Prolonged air leak	Thoracic drainage > 7d
	Wound infection	Abscess, secondary wound healing
	Atelectasis	validated by X-Ray or computed tomography

Table 2. Influence of risk factors on postoperative morbidity and mortality rate.

Concomitant diseases and risk factors	Morbidity OR	95% CI	p	30day Mortality OR	95% CI	p
Cardiovascular disease	2.110	1.486-2.996	<0.001		n.s.	
Age >60 years	1.664	1.163-2.382	0.005	2.521	1.074-5.916	0.034
Sleeve-Lobectomy	2.222	1.329-3.715	0.002		n.s.	
Pneumonectomy	1.641	1.072-2.511	0.023	3.714	1.883-7.326	<0.001
Therapy with corticosteroids	1.822	1.040-3.193	0.036		n.s.	
Male gender		n.s.		4.767	1.446-15.711	0.010
Pulmonary disease		n.s.			n.s.	
Smoker or ex-smoker		n.s.			n.s.	

OR = Odds ratio, CI = Confidence interval, n.s. = non significant ($p > 0.05$)

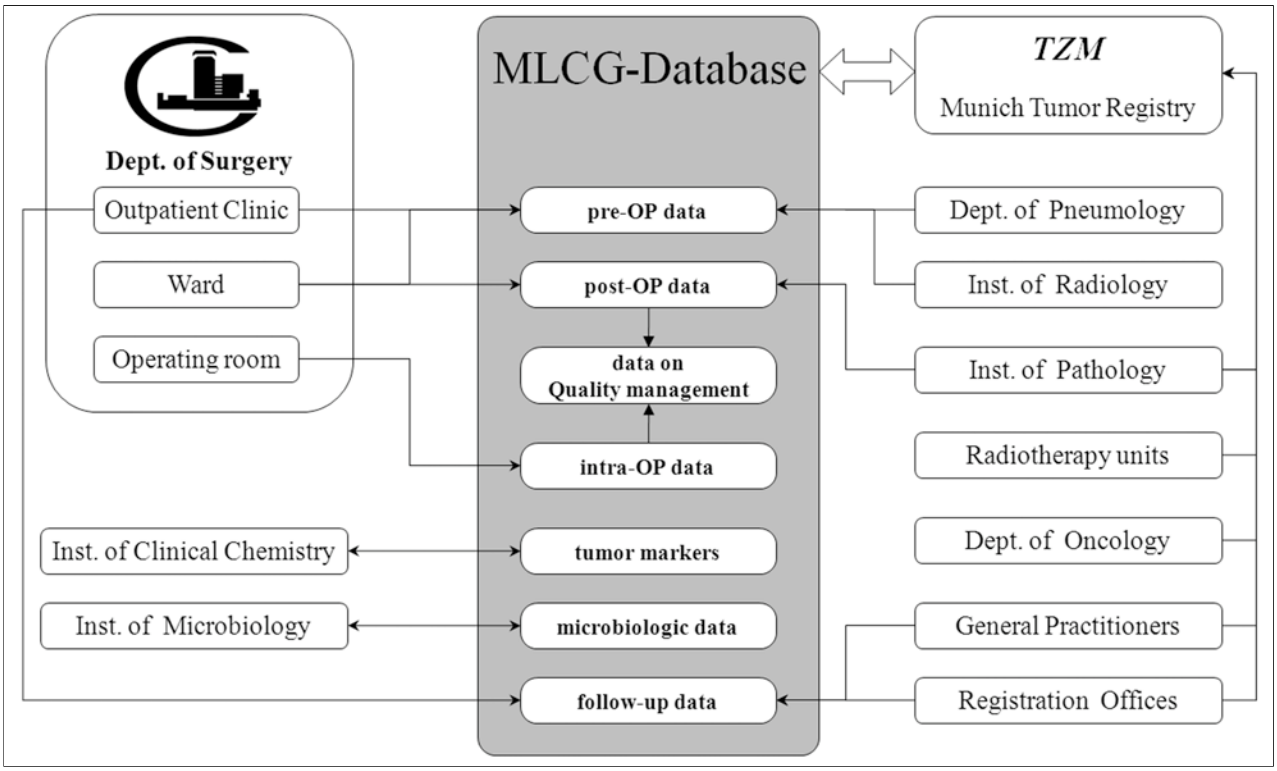

Fig. 1. Flowchart of database structure and flow of information between our database and affiliated institutions and clinics.

Table 3. Uni- und multivariate analysis of the influence of oncologic relevant factors on long-term mortality rate.

Factors	univariate analysis			multivariate analysis		
	RR	95% CI	p	RR	95% CI	p
Gender (male vs. female)	1.308	1.039-1.646	0.023	1.462	1.138-1.879	0.003
Age (>60 vs. <60 years)	1.144	0.941-1.390	0.179			
R-Status (R1/2 vs. R0)	2.598	1.990-3.391	<0.001	1.120	1.090-1.321	<0.001
pT (T3/4 vs. T1/2)	1.933	1.518-2.461	<0.001	1.656	1.273-2.155	<0.001
pN (N2/3 vs N0/1)	2.091	1.652-2.645	<0.001	1.655	1.310-2.091	<0.001
pM (M1 vs M0)	2.574	1.933-3.429	<0.001	2.473	1.815-3.368	<0.001
Grading (G3/4 vs. G1/2)	1.389	1.106-1.744	0.005	1.306	1.041-1.639	0.022

RR = relative risk, CI = Confidence interval

(Table 2).

2.4 Follow-up

Follow-up data were collected by the Munich Tumor Registry, which receives patient and survival information from all surgical, oncological and pathological departments in Munich as well as from over 4500 General Practitioners and Munich's Public Health Departments and Registration Offices (Fig. 1). Impact of tumour specific factors on overall survival was analysed as shown in Table 3. Variables significantly related to the morbidity, mortality and survival in univariate analyses were considered in a multivariate analysis.

2.5 Statistics

Data were analyzed using MedCalc® for Windows, Version 9.2.0.1 (MedCalc Software, Mariakerke, Belgium). A p value of less than 0.05 was considered statistically significant. Categorical variables like preoperative risk factors and comorbidities were entered into a multivariate stepwise logistic regression model. Continuous data are presented as means ± standard deviation and categorical variables as percentages. The prediction of survival with 95% confidence interval limits was estimated with the Kaplan-Meier product limit method and the resulting curves were compared with the log-rank test. To identify independent predictors of survival, the variables attaining a p value of less than 0.05 on univariate analysis were entered into the Cox proportional hazards regression model for multivariate analysis.

3. Results

Between January 1978 and January 2006, pulmonary

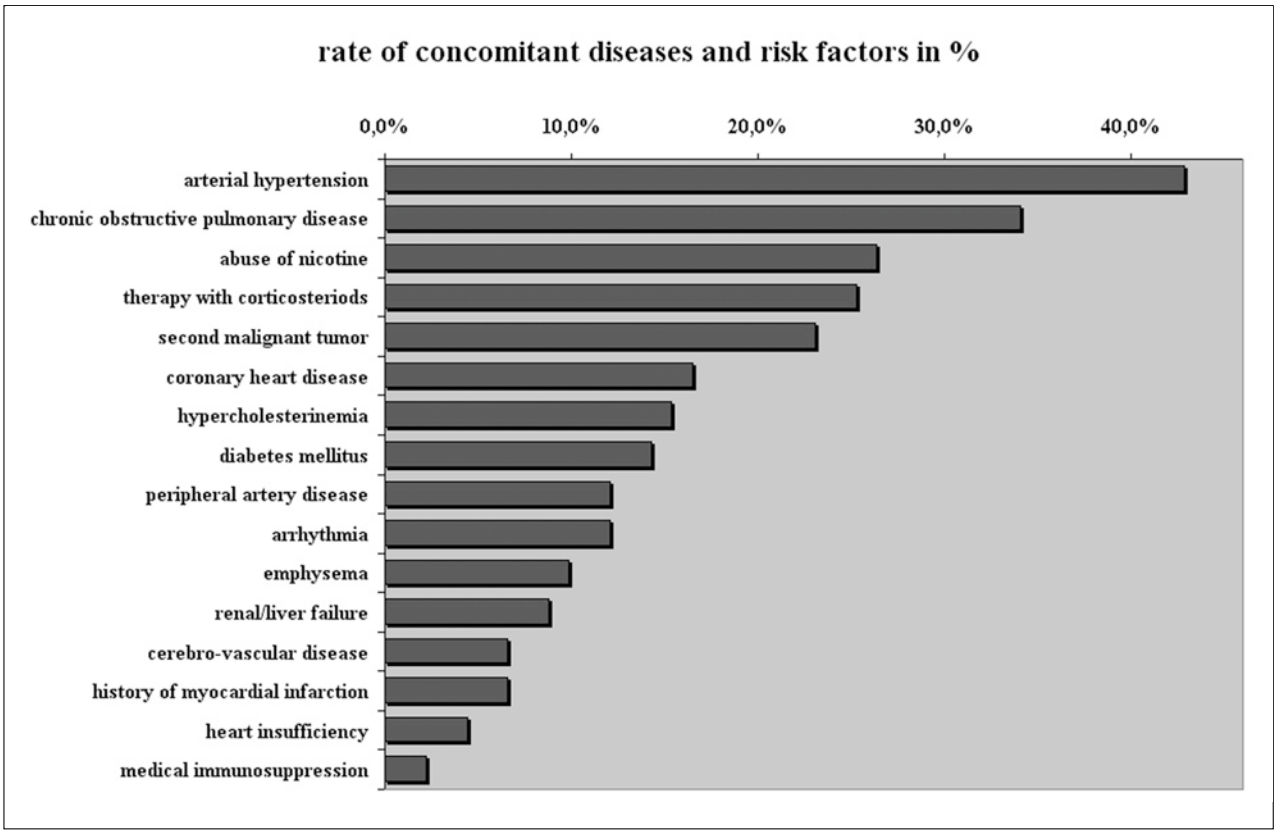

Fig. 2. Incidence of risk factors and concomitant diseases in our collective of patients since 1996 (in %, n = 735).

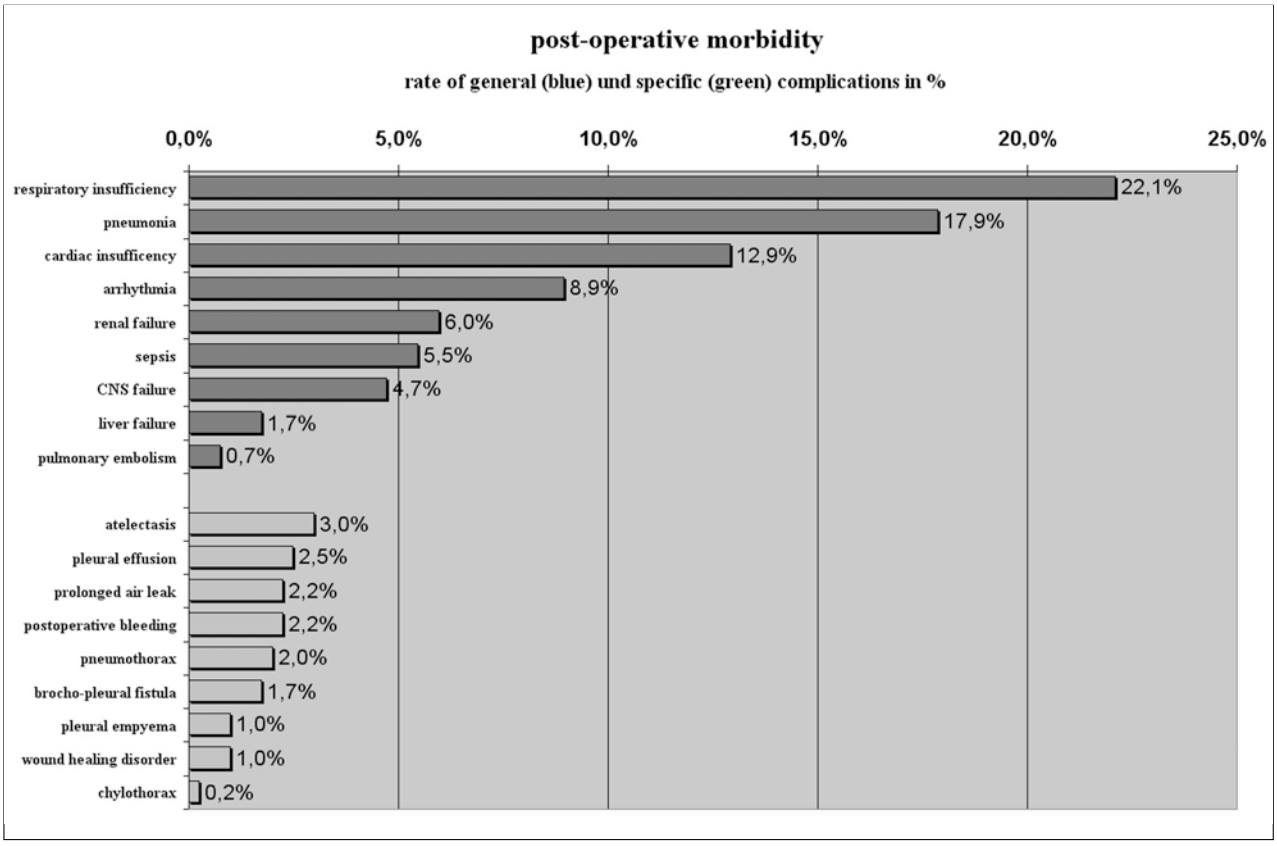

Fig. 3. Postoperative complications (in %, n = 735).

resection for lung cancer was performed on 2258 consecutive patients (1740 men, 518 women, m:w = 3.4:1) and database recorded. The mean age was 62 years for men and 60 years for women. Preoperative risk factors and postoperative morbidity and mortality were available from 735 patients operated since 1996.

Risk factors or other concomitant diseases were present in 94.5% of these patients. As shown in Figure 2, 42.9% of patients had arterial hypertension, 34.1% COPD, 26.4% were smokers at the time of surgery and 25.3% were treated with inhalative or systemic corticosteroids. In addition, 23.1% of patients had a history of other malignant diseases.

ASA-Stage was 1 in 2.2% of patients, 2 in 47.3%, 3 in 49.5% and 4 in 1.1% of patients. In the last 10 years, lobectomy was performed in 68.7% of cases, pneumonectomy in 16.2% and lesser resections in 15.1%. The rate of bronchoplastic reconstructions was 9.7%.

For men and women, the pathohistological distribution was squamous cell carcinoma in 51.3% and 20.2%, adenocarcinoma in 26.0% and 52.8%, large cell carcinoma in 11.4% and 10.6%, small cell carcinoma in 4.8% and 4.2%, and others in 6.5% and 12.2%, respectively.

UICC [7] stage distribution was 40.9% for stage I, 21.0% for stage II, 20.7% for stage IIIa, 6.3% for stage IIIb and 11.1% for stage IV.

An intraoperative complication occured in 10 of 735 patients operated within the last 10 years (1.4%). These were four bronchial complications, three major bleedings, two cardiogenic shocks and one oesophageal injury.

40.2% of patients were postoperatively admitted to the ICU with a median stay of three days. Median respirator time was nine days in 12.1% of patients who needed prolonged mechanical ventilation. Median hospital stay for patients with and without postoperative complications was 14 and 10 days, respectively.

Overall 30 day mortality and morbidity rate were 3.5% and 32.2%, respectively. Cause of death was cardio-circulatory failure in 46% of cases, septic multiorgan failure in 32% and respiratory failure in 22%.

As shown in Figure 3, the most common postoperative complications were respiratory insufficiency in 22.1% of patients, pneumonia in 17.9%, circulatory failure in 12.9% and arrhythmia in 8.9%. Rate of bronchopleural fistulas was 1.6%.

Statistical significant risk factors for postoperative morbidity were age, history of cardiovascular disease or treatment with corticosteroids, brochoplastic procedures and pneumonectomy (Table 2).

The 30day mortality rate was significantly higher in male patients older than 60 years or patients who underwent pneumonectomy. Other risk factors failed to reach level of statistical significance (Table 2).

For the whole collective of 2258 patients, documented since 1978, mean follow-up time was 45 months (1-295 month). A Kaplan-Meier calculation revealed an overall 5- and 10-year survival of 36% and 28%, respectively. The survival rate for UICC stage I to IV was 59%, 38%, 16% and 9%, respectively. Age had no significant influence on long-term survival. Male gender, positive resection margins (R1/2), T3/4 stage, N2/3 lymphatic node status, distant metastasis and dedifferentiated tumour (G3/4) are statistically significant for shorter survival (Table 3).

4. Discussion

The MLCG Database was created with a commercial licensed standard version of Microsoft Access 2003®. Thus, expensive de novo programming by third party software companies was not necessary. Furthermore, the database enables quick and easy adjustment of its design to new issues and individual requirements in the future.

Surgical therapy of lung cancer is mainly enclosed in a multidisciplinary concept of treatment regimens. Complete long-term follow-up is not practicable by our surgery department alone and is therefore supplemented by other disciplines and particularly by information from the Munich Tumour Registry.

Since 2005 all hospitals in Germany are legally obliged to publish a yearly certificate of their quality management structure (§137 SGB V) [5]. These reports should help GPs and patients to get a clarified image of internal performance status.

In contrast to other databases reported in the literature [8-10], this is the first to combine epidemiologic, pre-, intra- and postoperative data, morbidity and mortality as well as integration of long-term follow-up information supported by the Munich tumour registry.

4.1 Profile

Up until now, the cohort of the MLCG-Database contains 2258 patients and is, compared to other reports [11-14] one of the largest single-centre databases on lung cancer surgery. Mean age at surgery of 62 years and gender distribution of 3.4:1 (m:w) is nationally and internationally comparable [14].

Preoperative morbidity analysis showed that nearly 50% of patients had arterial hypertension and one third suffers from chronic obstructive pulmonary disease. Due to the latter case every fourth patient is treated with inhalative or systemic cortico-steroids.

Except of lung cancer and undetected diseases, only 5.5% of patients are completely healthy at the time of surgery. Compared to the normal population, prevalence of concomitant diseases is elevated in our patient collective. This is also reflected in the distribution of ASA stages, where more than the half of patients are ASA III/IV. This must be mentioned when interpreting postoperative morbidity and mortality.

Surprisingly, quite one quarter of patients suffered allmost from at least one additional malignant tumour other than lung cancer. Distribution of histology, containing 45% squamous cell carcinoma, 32% adenocarcinoma and 11% large-cell carcinoma, is equal to data reported from south Germany [14-16].

Two-thirds of the patients underwent lobectomy or bilobectomy, 15% of patients received lesser resection, the rate of pneumonectomy was 16% and the rate of bronchoplastic procedures was 10%, which is within the range of internationally published data [11, 17-19].

As reported in other studies [18], the high rate of atypical and segment resection in our cohort is due to

the large part of patients, who are in fact anatomically and oncologically eligible for lob- or bilobectomy, but poor pulmonary function prohibit extended resection.

4.2. Complications, Postoperative Morbidity and Mortality

Intraoperatively, there were four bronchus complications, three major bleedings, two cardiac shocks and one oesophageal injury, which results in a rate of intraoperative complications of 1.4%. Thus there are no comparable internationally reported data, this rate seems to be low with respect to preoperative risk profiles.

Equally, comparison of complication rates is not easy, because there are only a few studies with clear definitions or inclusion criteria for morbidity. Albeit an overall postoperative morbidity rate of 32.2% is comparable to other studies [20] or even slightly lower [19].

Detailed complication rates of respiratory insufficiency (22.1%) and pneumonia (17.9%) are higher than internationally reported [18, 20]. We think this is due to our inclusion criteria (Table 1), which comprise all patients to have these complications if they only need oxygen therapy or have clinical symptoms of mild pneumonia. We also attribute the high rate of cardiocirculatory insufficiency to our strict inclusion criteria.

In contrast, rates of arrhythmia, broncho-pleural fistula, postoperative bleedings, atelectasis and wound infections are fortunately low compared to other studies [21].

The 30 day mortality rate of our collective was 3.5% and is within the internationally reported range of 1.7-6.6% [14, 19].

Interestingly, presence or history of pulmonary diseases and risk factors like smoking, chronic obstructive pulmonary disease, retention pneumonia or emphysema had no significant impact on postoperative morbidity.

However, operative procedures like pneumonectomy or broncho-plastic reconstruction had a significant influence on morbidity, but only patients who underwent pneumonectomy had a higher 30 day mortality rate.

In contrast to its absent impact on long-term survival, age revealed to be an independent risk factor for postoperative mortality and morbidity, as described in other studies [14, 22].

Cardio-vascular diseases are highly significant associated with increased postoperative morbidity, but there was no significance for a higher surgical related death rate.

4.3 Follow-up

Compared with internationally reported survival rates of 25-30% [12, 14, 23, 24], the overall 5-year survival rate of 36% of patients reported in this study is slightly higher. This may be due to the high rate (>60%) of patients with early cancer stages UICC I and II in our collective. Furthermore, UICC stage differentiated analysis of Kaplan-Meier survival calculation revealed national and international comparable survival rates [12, 23, 24]. In accordance with Williams et. al. [25] and other studies [14, 26, 27], multivariate analysis revealed male gender, margin positive resection (R1/2), T3/4 stage, N2/3 lymphatic node status, distant metastasis and dedifferentiated tumour (G3/4) to be independent factors limiting long-term survival (Table 3). As controversially discussed in several studies [14, 25, 27, 28], age had no significant influence on long-term survival of our cohort.

5. Conclusion

In summary, this study describes construction, workflow and cohort profile of a large-scale lung cancer database containing data on epidemiology, preoperative risk factors, concomitant diseases, details of operative procedure, postoperative complications and long-term follow-up on patients operated on for lung cancer at University of Munich Medical Centre, Klinikum Großhadern. In addition, impact analysis of risk factors on postoperative morbidity and mortality as well as investigation of long-term survival underlines internationally reported results.

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