European Journal of Cardio-thoracic Surgery 29 (2006) 20—25

EUROPEAN JOURNAL OF CARDIO-THORACIC SURGERY

www.elsevier.com/locate/ejcts

Hospital volume: operative morbidity, mortality and survival in thoracotomy for lung cancer. A Spanish multicenter study of 2994 cases

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Received 17 August 2005; received in revised form 7 October 2005; accepted 10 October 2005

Abstract

Introduction: It has been hypothesized that medical procedures performed in high-volume units carry less risk and achieve a better outcome. **Objective**: To determine the relationship between the number of interventions and the operative morbidity, mortality and long-term survival in the surgery of bronchogenic carcinoma (BC). **Patients and method**: Prospective, multicenter Spanish study was conducted in 19 departments of thoracic surgery on 2994 patients operated on consecutively with the aim of curing BC. The thoracic surgery departments have been classified into three groups, according to the number of interventions performed per year: I (1—43 cases/year; centers = 7; *n* = 565; 18.9%), II (44—54 cases/year; centers = 6; *n* = 1044; 34.9%) and III (55 or more cases/year; centers = 6; *n* = 1385; 46.3%). **Results**: When the three groups were compared, the frequency of complete surgery was found to be 84% for group I, 76% for group II and 83% for group III ($p = 0.001$, for comparisons between groups I/II and II/III). The pathological stages were identical in the three groups. The overall morbidity and the mortality in all patients or above the age of 75 or in pneumonectomies were not different among the groups. When considering all the patients with prognostic information ($n = 2758$), no differences were found regarding the 5-year survival among the groups. When only patients in postoperative stage I—II and complete resection were evaluated, excluding operative mortality ($n = 1128$), 5-year survival was 0.58 for group I, 0.57 for group II and 0.50 for group III ($p = 0.06$ between groups II and III; $p = 0.08$ between groups I and III). **Conclusions**: No significant differences that do not favor the hypothesis that there is increased surgical risk and worse survival in centers having a lower volume were found in this Spanish multicenter study.

Keywords: Lung cancer; Surgical treatment; Morbidity; Mortality

1. Introduction

The relationship between the experience acquired in a given technique and the better or worse outcome achieved when such technique is employed is well known. However, on certain occasions, it is difficult to demonstrate this relationship. There are some studies that make reference to this problem with regard to complex or high-risk surgical procedures such as those performed for different types of neoplasia. Studies on esophageal neoplasia [1], gastric neoplasia [2], cancer of the pancreas [3], breast cancer [4], rectal cancer [5], colon cancer [6] and prostate cancer [7] have been published. This relationship has also been subject of study in the surgery of intracranial aneurysms [8] and in cardiac surgery [9].

Several more extensive studies have also been conducted comparing the various types of surgery in large population groups [10—12]. These studies analyze the relationship between surgical volume and operative mortality in several types of cardiovascular surgery and in cancer resections. In general terms, the conclusions reached are that it is advisable to perform complex surgical procedures in large-volume hospitals. A recent article sought to carry out a more detailed analysis by studying surgeon volume on an individual basis [13].

Bronchogenic carcinoma (BC) is the main cause of death of neoplastic origin in our setting in the male population and an important one in women. Surgical resection continues to be the best therapeutic option to treat this disease. Nevertheless, only a limited number of patients can benefit from this option, be it because the disease is in a very advanced

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[1] A complete list of GCCB-S members is given in Appendix A.

1010-7940/$ — see front matter
doi:10.1016/j.ejcts.2005.10.014

stage at the time of diagnosis or because there are other causes of functional or oncological inoperability [14]. In lung resections for BC, the number of procedures per year with regard to a particular hospital varies greatly. This consideration has also been the subject of previous studies, although very few have made specific reference to BC [15,16]. No study of this nature has been conducted in our country to date.

Based on the experience gained by the Bronchogenic Carcinoma Cooperative Group of the Spanish Society of Pneumology and Thoracic Surgery (GCCB-S), the aim of this paper is to analyze the impact that hospital volume has on the operative morbidity and mortality risk and on the prognosis of patients with thoracotomy due to BC.

2. Materials and methods

2.1. Study subjects

All the patients included in the study had BC in initial stages and had undergone thoracotomy with the intent to cure in hospitals pertaining to the GCCB-S (Appendix A). All the departments participating in the study were exclusively thoracic surgery departments (general non-cardiac thoracic surgery). In Spain, the registrar training in this specialty is undertaken after a 5-year training period in departments approved to teach post-graduate education courses.

We included prospectively all patients treated surgically from October 1993 to September 1997 in hospitals participating in the GCCB-S. The annual cumulative number of cases was close to 50% of the surgical cases occurring in Spain. The participating GCCB-S hospitals had a wide variety of activities, including a representative range of number of beds, teaching or research activities (university and non-university hospitals), public and private ownership, and number of interventions per year (from 8 to 100 interventions were performed in participating hospitals for this disease). All cases were collected and followed up prospectively by the thoracic surgeon responsible for each of the centers participating in the study. The sample was complete, as verified by the inclusion in the registry of all patients undergoing surgery, including incomplete resections and exploratory thoracotomy.

Operative mortality was understood to include all deaths directly related with the surgical act, regardless of time of occurrence. We have used this concept in order to consider broad clinical criteria, trying to include late mortality though related with surgery [17]. However, 30-day mortality rate is also considered. The final number of cases included in the study was 2994.

2.2. Methods and analysis

The 1997 TNM staging classification currently in effect was used in this study. The degree of certainty of the TNM stages classification depends on the diagnostic methods used; according to some international organizations post-mortem study yields the maximum certainty factors, and the clinical findings yield the minimum certainty. By ensuring consensus among the members of the GCCB-S coordinating group (two thoracic surgeons and one pneumologist), we established the methods for affirming maximum classificatory certainty for each component (maximum possible clinical certainty adjusted for each problem). Lymph node categories (N) were evaluated using different diagnostic criteria of classificatory certainty. In order to confirm a clinical N0 classification, the absence of lymph node enlargement or lymph node enlargement of less than 1 cm in diameter had to be confirmed by CT in lymph node areas 4, 7 and 10. Moreover, no lymph node enlargement should be present in the aorto-pulmonary window or in the anterior mediastinal area (areas 5 and 6), if the BC is left-sided (upper lobule or main left bronchi). If these criteria were not met, negative mediastinoscopy—mediastinotomy or negative fine-needle aspiration biopsy (transbronchial, transthoracic, or transesophageal) of these areas was required. The clinical N1 classification was confirmed by cytohistological evidence (transbronchial fine-needle biopsy and hilioscopy). To confirm a clinical N2 classification, cytohistological evidence was required (mediastinoscopy, mediastinotomy, and fine-needle aspiration biopsy using any approach).

Surgical pathological N0 was classified by radical mediastinal lymph node dissection or sampling of at least four lymph node areas (2 [only in right BC], 4, 7, and 10 on the same side as the tumor), especially in postoperative T3.

Internal and external audits were made to survey the ratio between the number of patients undergoing surgery and the cases included in the registry (standard over 95%), the presence and validity of the data recorded for each case (standard over 70%), including the consistency of tumoral staging. The criterion for the validity of the survival data was established as the existence of a known follow-up for 85%, or more, of the cases registered in each hospital. In the hospitals that did not meet these conditions, the cases corresponding to the period of problems were excluded. Finally, correct data transmission by a single central office from the paper record to the computer database was verified.

These procedures were designed to control the selection bias of surgical cases, registered cases out of the total number of surgical cases, sample size, type of hospital, prognostic migration due to prolonged case recruitment, classification with low or deficient degrees of certainty, contamination of data from incomplete series or incorrect data, and loss of long-term follow-up.

To establish the corresponding comparisons, we divided the hospitals into three different types, according to the number of cases operated on per year (Tables 1 and 2). To put the groups together we chose as an intermediate group which best reflects the majority of Thoracic Surgery groups in Spain — around 50 cases/year. We also decided to form two further groups, less than 43 and more than 55 cases as the most extreme groups in terms of volume of procedures performed per year.

Considering the number of operations per year in every participant hospital (Table 1), centers have been grouped in quartiles and compared. Quartile 25 (group A) include those centers with a number of interventions equal or less than 40 cases/year. Quartile 75 (group B) include those centers with equal or more than 57 interventions per year. In both the groups, a similar number of pneumonectomies

Table 1
Number of cases/year for every hospital

Hospital	Number of cases/year
1	40
2	42
3	57
4	78
5	53
6	49
7	43
8	27
9	94
10	56
11	79
12	49
13	80
14	26
15	30
16	41
17	45
18	49
19	8

Table 2
Groups of hospitals according to number of cases/year

Group	Number of cases/year	Number of hospitals	Number of cases	Percentage
I	1–43	7	565	18.9
II	44–54	6	1044	34.9
III	≥55	6	1385	46.3
Total		19	2994	

were performed (95/311; 31% in group A and 505/1209; 33% in group B).

This study analyzed the following parameters for each group of hospital: rate of complete surgery, postoperative complications and postoperative mortality. Morbidity and mortality in pneumonectomies and in patients 75 years and above was also specifically evaluated. Overall survival at 5 years and in initial stages (I and II) for each group of hospitals was also evaluated.

The comparison of patient characteristics among the different groups was carried out using one-way analysis of variance (ANOVA). The survival analysis was performed employing the Kaplan–Meier test. Comparisons of survival curves were examined using the log-rank test. Mortality was analyzed by means of a binomial logistic regression model and adjustments were considered for the following risk factors: age, sex, previous tumor, peripheral vascular disease, weight loss, systemic arterial hypertension, diabetes, level of dyspnoea, symptoms, to be bedridden, COPD, ischemic cardiopathy and type of surgery (exploratory thoracotomy and incomplete surgery).

3. Results

Table 3 shows the descriptive data for each of the groups. In general terms, no significant differences were found among the three groups, except for the presence of some characteristics, more frequently different between group I and group II, and, with a tendency towards variable values with a worse prognosis in group I. No differences of statistical significance were found with regard to tumor size, hemoglobin, polymorphonuclear leukocytes, and packages/year among the three works of study. Of the 2994 cases, 1344 were lobectomies, 867 pneumonectomies, 146 bilobectomies, 363 segment resections and 274 exploratory thoracotomies.

Table 3
Descriptive data of the groups

	Group I	Group II	Group III	*p*
Number of cases	565	1044	1385	
Operative mortality	49 (8.7%)	80 (7.7%)	107 (7.7%)	NS
Mortality < 30 days	43 (7.6%)	69 (6.6%)	93(6.7%)	NS
"p" stages certainty				
Ip	248 (49%)	429 (45%)	620 (49%)	NS
IIIA-Bp	171 (34%)	338 (30%	428 (34%	NS
Previous tumor	92 (16%)	173 (17%)	200 (14%)	NS
Ischemic cardiopathy	35 (6%)	68 (6.5%)	102 (7.4%)	NS
Peripheral vascular disease	57 (10%)	101 (9.7%)	153 (11%)	NS
High blood pressure	118 (21%)	164 (16%)	212 (15%)	<0.01 (I/III)[a]
Diabetes	55 (9.7%)	98 (9%)	107 (7.7%)	NS
Dyspnoea > 2[b]	78 (14%)	105 (10%)	46 (3.3%)	<0.001 (I/III)[a]
Performance status > 2[c]	15 (2.7%)	22 (2%)	12 (0.8%)	<0.05 (II/III)[a]
Casual finding	174 (31%)	312 (30%)	392 (29%)	NS
Weight loss	57 (10%)	129 (14%)	115 (8%)	<0.01 (II/III)
Pathological type				
Epidermoid	303 (54%)	570 (55%)	832 (60%)	<0.01 (I/III)[a]
Adenocarcinoma	157 (28%)	242 (23%)	348 (25%)	NS
COPD	304 (55%)	472 (46%)	594 (44%)	<0.001 (I/III)[a]
Age	63.2 ± 10	64.3 ± 9.4	64.5 ± 9.5)	0.010
FEV1%	78.8 ± 20	79.8 ± 19.6	81.6 ± 20	0.006
Albumin	3.78 ± 0.74	4.2 ± 0.6	3.97 ± 0.60	0.0001

"p" postoperatory.
[a] Comparison between the mentioned groups.
[b] Levels of dyspnoea: 0, no dyspnoea; 1, dyspnoea when walking on flat ground; 2, dyspnoea when climbing one floor; 3, dyspnoea when climbing two floors or going uphill; and 4, rest dyspnoea.
[c] Performance status: clinical condition scale from Eastern Operative Oncology Group (ECOG): 0, normal activity; asymptomatic; 1, symptomatic; fully able to walk; 2, symptomatic; bedridden less than 50% of the time; 3, symptomatic; bedridden more than 50% of the time; and 4, permanently bedridden.

The rate of complete surgery was 84% (476 cases/565) for group I, 76% for group II (792 cases/1044) and 83% for group III (946 cases/1140). There were significant differences between groups I and II ($p = 0.001$) and between groups II and III ($p = 0.001$). There were no significant differences between groups I and III.

Neither the overall morbidity nor the operative mortality (overall or <30 days) differs among the three groups (Table 3). Neither was there significant differences between the extreme groups (A and B) (Table 4). After adjusting mortality for the different risk factors, we did not find significant differences among the three groups (Table 5). The variables that increased the postoperative risk were the performance of an exploratory thoracotomy (OR 7.27), to be

Table 4
General mortality in the extreme groups

	Group A	Group B	p
Number of cases	311	1209	
Operative mortality	26 (8.4%)	82 (6.8%)	NS
Mortality $\leq$ 30 days	21 (6.8%)	73 (6%)	NS

Table 5
Adjusted mortality for different risk factors

Variables	P	OR	95.0% CI	
			Lower	Upper
Age	0.000	1.02	1.01	1.03
Sex (woman)	0.118	0.78	0.57	1.07
Previous tumor	0.000	1.59	1.24	2.04
Peripheral vascular disease	0.002	1.59	1.18	2.15
Arterial hypertension	0.477	1.09	0.86	1.37
Diabetes	0.878	1.02	0.76	1.38
No dyspnoea	0.692			
Dyspnoea 3	0.184	1.15	0.94	1.40
Dyspnoea 2	0.353	1.20	0.81	1.77
Dyspnoea 1	0.698	1.19	0.49	2.90
Asymptomatic	0.009			
Symptomatic	0.010	1.34	1.07	1.67
Bedridden <50%	0.008	4.38	1.48	13.04
Weight loss	0.731	0.95	0.71	1.27
COPD	0.258	1.10	0.93	1.31
Volume group I	0.254			
Volume group II	0.354	0.89	0.71	1.13
Volume group III	0.706	1.04	0.83	1.31
Incomplete surgery	0.000	3.13	2.22	4.42
Exploratory thoracotomy	0.000	7.27	4.64	11.40
Ischemic cardiopathy	0.711	1.06	0.76	1.49

Levels of dyspnoea: 0, no dyspnoea; 1, dyspnoea when walking on flat ground; 2, dyspnoea when climbing one floor; 3, dyspnoea when climbing two floors or going uphill; and 4, rest dyspnoea.

bedridden (OR 4.38), the accomplishment of an incomplete surgery (OR 3.13), the presence of a previous tumor (OR 1.59), the existence of peripheral vascular disease (OR 1.59) and to have symptoms (OR 1.34). There were no differences in morbidity or mortality with regard to pneumonectomies or in operations performed on patients above the age of 75 (Table 6). Nevertheless, the differences were close to having statistical significance ($p = 0.1$) for mortality in pneumonectomies between groups I and II.

Regarding prognosis, we consider all patients with prognostic information (postoperative mortality excluded) ($n = 2758$). Tables 7 and 8 show the results expressed as 5-year survival.

Table 7
Prognosis and number of operations/year

	All patients		
	Group I	Group II	Group III
N	516	964	1278
Survival 5 years	0.40	0.37	0.38
Standard error	0.02	0.02	0.01
Median	39.82	32.88	34.39
Log-rank	0.16	0.86	
		0.18 [a]	

[a] Between groups I and III.

Table 8
Prognosis and number of operations/year

	Non-microcytic BC with complete resection in stage I-IIp, excluding operative mortality and those cases treated with induction therapy		
	Group I	Group II	Group III
N	219	362	547
Survival 5 years	0.58	0.57	0.50
Standard error	0.03	0.03	0.02
Median	+60	+60	+60
Log-rank	0.89		0.06
	0.08 [a]		

[a] Between groups I and III.

4. Discussion

The existence of some studies discussing the greater volume of cases with resection surgery for BC with a better outcome in a given hospital has motivated the authors to write this paper, in an attempt to put this hypothesis to the test. Back et al. in the year 2000 published an interesting experience in which an 11% higher survival rate was found in patients who had undergone BC resection in high-volume hospitals (67—100 procedures per year) as compared to low-volume hospitals (1—8 procedures per year) [14]. The referred study found slightly lower complication rates (20% vs 44%) between hospitals with more experience and those with a lower volume of interventions. Postoperative mortality rates also appeared to be lower (3% vs 6%). The 5-year survival was also found to be better in the group with more experience (44% vs 33%), being also better when university hospitals were compared against non-university hospitals. Previous studies had yielded similar results, with a higher postoperative mortality in hospitals with less volume [16]. A more recent study compared mortality rates in resections performed by general surgeons as opposed to thoracic surgeons, being statistically higher in resections

Table 6
General morbidity and mortality in pneumonectomies and in operations in patients above the age of 75

Group	Number	Global	In $\geq$ 75 years	Pneumonectomy
Morbidity				
I	565	197 (34.9%)	25/62 (40.3%)	62/151 (41.1%)
II	1044	376 (36%)	41/106 (38.7%)	101/259 (39%)
III	1385	484 (34.9%)	68/175 (38.9%)	171/457 (37.4%)
Mortality				
I	565	49 (8.7%)	8/62 (12.9%)	29/151 (19.2%)
II	1044	80 (7.7%)	9/106 (8.5%)	31/259 (12%)
III	1385	107 (7.7%)	17/175 (9.7%)	61/457 (13.3%)

performed by general surgeons [18]. Birkmeyer's latest study analyzes the existing relationship between the volume of operations and mortality for various types of cardiovascular surgery and oncology. With regard to resections performed to treat BC, it is concluded that, even though the number of operations performed by each surgeon is an important factor for surgical mortality, it is less important than the hospital's volume [13]. These studies, however, are conducted in the United States, a country with a healthcare system and specialist training very different to the Spanish one.

Our paper presents very specific characteristics. The first of these characteristics is that our study has been carried out within the framework of a national multicenter setting, a particularity unseen in other studies. The study required the prospective compilation of data case-by-case. No loss of data occurred thanks to a continued revision by the Coordinating group in charge of the study. Previously established common criteria, agreeable to all the participating hospitals, were selected, giving the sample very high homogeneity, as verified by all the audits performed throughout the course of the study.

Operative mortality showed identical percentages for groups II and III and somewhat higher percentages but with no statistical significance for group I. As a whole (around 8%), operative mortality does not present values that would make it higher than the international standards or higher than those reported in similar works [10–12]. Postoperative morbidity was not significantly different among the three groups either, reaching around 35%. This is not a figure that differs greatly from the usual standards in this type of surgery [19]. The rate of curative surgery was better in low-volume hospitals, followed by larger-volume hospitals and, lastly, by hospitals with an intermediate volume, a rate of 76%. These data are hard to explain, and in any case, appear to indicate that departments with less volume achieve even better figures in relation to this parameter.

One of the most feared interventions because of the morbidity and mortality it entails is pneumonectomy. A number of authors claim that the indication of this type of operation must always be considered with extreme caution in the elderly [20], being an operation with one of the highest morbidity rates [10]. In our paper, we have compared morbimortality in this type of intervention in the three groups but have failed to find any statistical significance. We also performed the same comparison in patients over the age of 75, obtaining identical results. This defers from previous papers in which the biggest and most significant differences are obtained in pneumonectomies [10,12] and in elderly patients [12].

As far as long-term survival is concerned, several parameters seem to play a role, making it difficult to ascribe the experience of the department as just "a single factor". However, equalness of outcome results has been noted among the three studied groups and overall figures are very similar to those reported in papers dealing with survival in BC. A survival rate of around 40% was found in the three groups similar to one reported in the study by Bach et al. [15] for the most experienced group. This appears to confirm the good results that, in any case, groups I and II have despite a lower volume of interventions.

Our findings show a high level of equality among the different Spanish hospitals. These data contradict previous studies in the surgery of BC [10–12,15,16] and in other types of surgery [1,3,5–12]. The fact that the majority of thoracic surgery is performed in specialized referral centers, by the hand of thoracic surgeons that have trained in a common standardized national program can prompt these very similar results among the different participating departments. Previous studies show the improvement that for the healthcare system represents operating BC by properly trained specialists in thoracic surgery [21,22], as supported by the findings yielding by this study. Very recent studies mention the little importance that hospital or department volume appears to have on the better outcome of a given technique, emphasizing the need to identify other quality parameters [23–25].

We, thus, conclude that in our medium, the procedural volume of lung resection interventions for BC performed in Departments of Thoracic Surgery does not appear to influence, in general, a better or worse outcome.

Acknowledgments

This study was partly financed by FIS grant 97/0011, FEPAR-1995 grant, Red-Respira-RTIC-C-03-011 grant, and financial aid from the Castilla-León regional government and the Menarini Foundation.

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Appendix A

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