

TABLE 1A. Patient Characteristics

	PM0	PM1	PM2	M1 (excluding PM2)
No.	6080 (91.49%)	317 (4.8%)	128 (1.9%)	120 (1.8%)
Age	65 ± 10	65 ± 10	63 ± 10	60 ± 11
Sex				
Male	4257 (70%)	208 (65.6%)	69 (53.9%)	88 (73.3%)
Female	1792 (29.5%)	108 (34.1%)	59 (46.1%)	32 (26.7%)
DNA	31 (0.5%)	1 (0.3%)	—	—
Type of operation				
Pneumonectomy	512 (8.4%)	35 (11%)	26 (20.3%)	16 (13.3%)
Lobectomy	5208 (85.7%)	265 (83.6%)	84 (65.6%)	90 (75%)
Segmentectomy	157 (2.6%)	3 (0.9%)	8 (6%)	3 (2.5%)
Wedge resection	157 (2.6%)	11 (3.5%)	9 (7%)	9 (7.5%)
DNA	46 (0.8%)	3 (0.9%)	1 (1%)	2 (1.7%)
Curability				
R0	5529 (90.9%)	232 (73.2%)	77 (60.2%)	
R1	256 (4.2%)	34 (10.7%)	7 (5.5%)	
R2	187 (3.1%)	41 (12.9%)	38 (29.7%)	
RX	58 (1%)	7 (2.2%)	5 (3.9%)	
DNA	50 (0.8%)	3 (0.9%)	1 (0.8%)	

DNA, data not available.

TABLE 1B. Patient Characteristics

	PM0	PM1	PM2	M1 (excluding PM2)
No.	6080 (91.5%)	317 (4.8%)	128 (1.9%)	120 (1.8%)
Histology				
Adenocarcinoma	3522 (57.9%)	201 (63.1%)	101 (78.9%)	82 (68.3%)
Squamous cell carcinoma	2174 (35.8%)	93 (29.3%)	17 (13.3%)	21 (17.5%)
Large cell carcinoma	229 (3.8%)	10 (3.2%)	4 (3.1%)	9 (7.5%)
Adenosquamous carcinoma	155 (2.5%)	13 (4.1%)	6 (4.7%)	8 (6.7%)
pT				
0	4 (0.1%)	—	—	1 (0.8%)
1	2569 (42.3%)	0 (0%)	24 (18.8%)	22 (18.3%)
2	2513 (41.3%)	0 (0%)	62 (48.4%)	43 (35.8%)
3	702 (11.5%)	0 (0%)	12 (9.4%)	28 (23.3%)
4	287 (4.7%)	317 (100%)	30 (23.4%)	26 (21.7%)
DNA	5 (0.15%)	—	—	—
pN				
0	3882 (63.8%)	120 (37.9%)	38 (29.7%)	44 (36.7%)
1	802 (13.2%)	55 (17.4%)	19 (14.8%)	18 (15%)
2	1261 (20.7%)	124 (39.1%)	52 (40.6%)	48 (40%)
3	95 (1.6%)	12 (3.8%)	7 (5.5%)	5 (4.2%)
X	27 (0.4%)	5 (1.6%)	9 (7%)	1 (0.8%)
DNA	13 (0.2%)	1 (0.3%)	3 (2.3%)	4 (3.3%)

DNA, data not available.

included in this registry. There were replies from the 303 institutions for all 7408 patients.

This study focused on adenocarcinoma, squamous cell carcinoma, large cell carcinoma, and adenosquamous carcinoma patients, excluding small cell lung cancers, low-grade tumors, and other rare histologies, totaling 6644 patients. Because of incomplete data on PM status, 119 patients were

excluded, and the remaining 6525 patients were enrolled in this study.

Statistical Analysis

Cumulative survival rates were calculated by Kaplan–Meier estimation, using the date of surgical resection as the starting point and the date of death from any cause or the last

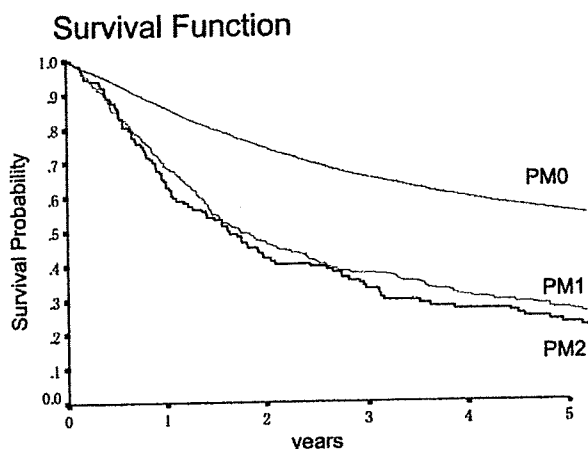


FIGURE 1. Survival curves of patients with PM0, PM1, PM2. The differences in survival between patients with PM0 and PM1 and between patients with PM0 and PM2 were significant ($p < 0.001$, respectively); the difference in survival was not significant between patients with PM1 and PM2 ($p = 0.298$).

follow-up date as the endpoint. The difference in survival was determined by log-rank analysis. A p value of less than 0.05 was considered to indicate a statistically significant difference. All statistical analyses were performed using software packages (SAS version 8.2, SAS Institute, Inc., Cary, NC; and SPSS version 11.5, SPSS, Inc., Chicago, IL).

RESULTS

Table 1 shows the patient characteristics for each population. There were 6080 PM0 (93.2%), 317 PM1 (4.9%), and 128 PM2 (2.0%) patients. There were 505 (7.7%) patients lost to follow-up. There were 3164 (48.5%) deaths. Causes of deaths were recurrent lung cancer in 2282 (73.1%) patients, other cancer in 109 (3.5%) patients, noncancerous causes in 402 (12.9%) patients, and others in 371 (11.7%) patients.

The 3- and 5-year survival rates were 65.4% and 55.1% for PM0 patients, 37.5% and 26.8% for PM1 patients, and 33.0% and 22.5% for PM2 patients, respectively. There was no statistically significant difference between PM1 and PM2 patients ($p = 0.298$; Figure 1). Five-year survival rates were 72.1% for T1 patients, 46.4% for T2 patients, 34.0% for T3 patients, and 17.6% for T4 patients excluding PM1 patients (non-PM1 T4), respectively. The survival of patients with PM1 was between that of the T3 and T4 patients without PM1. Statistically significant survival differences were detected between T3 and PM1 patients ($p = 0.032$) and between PM1 and non-PM1 T4 groups ($p = 0.0083$; Figure 2).

The 5-year survival rates of PM2 patients and M1 patients excluding PM2 patients (non-PM2 M1) were 22.5% and 20.5%, respectively, and there was no significant difference between the groups ($p = 0.434$; Figure 3).

Five-year survival rates of PM1 patients with pathological N0, N1, and N2 node status were 45.8%, 25.3%, and 11.1%, respectively. Significant survival differences were detected between each N-status group (Figure 4). Five-year

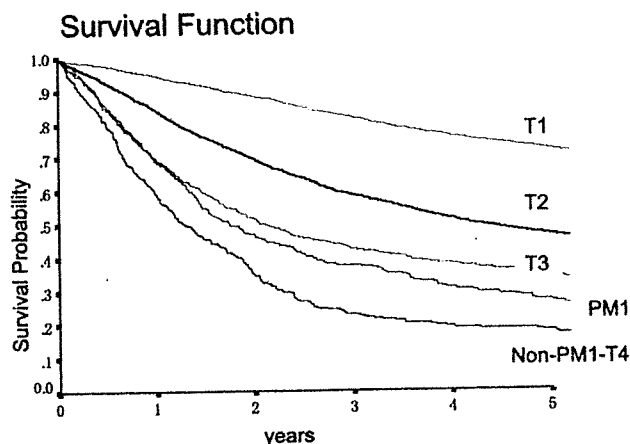


FIGURE 2. Survival curves of patients according to pathological T status. There was a significant survival difference between T1 and T2 patients, between T2 and T3 patients ($p < 0.01$, respectively), between T3 and PM1 patients ($p = 0.032$), and between PM1 and T4 patients excluding PM1 patients ($p < 0.01$).

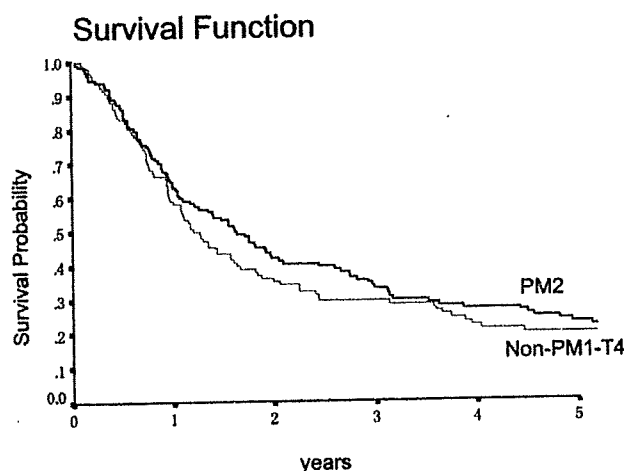


FIGURE 3. Survival curves of patients with PM2 and M1 excluding PM2 (non-PM2 M1). The difference in survival between patients with PM2 and non-PM2 M1 was not significant ($p = 0.434$).

survival rates of PM2 patients with pathological N0, N1, and N2 node status were 42.1%, 7.9%, and 10.0%, respectively. Significant survival differences were detected between N0 and N1 ($p = 0.0016$) and between N0 and N2 ($p = 0.0001$) groups, but there was no significant difference between N1 and N2 groups ($p = 0.644$) (Figure 5). Five-year survival rates of pathological N0 patients with PM0, PM1, and PM2 status were 68.0%, 45.8%, and 42.1%, respectively (Table 2). There were significant survival differences between PM0 and PM1 patients and between PM0 and PM2 patients ($p < 0.01$, respectively). There was no significant survival difference between PM1 and PM2 patients ($p = 0.8775$) (Figure 6). In completely resected (R0) N0 patients, the 5-year survival rates were 69.5% for PM0 patients, 47.3% for PM1 patients, and 46.2% for PM2 patients, respectively. Statistically sig-

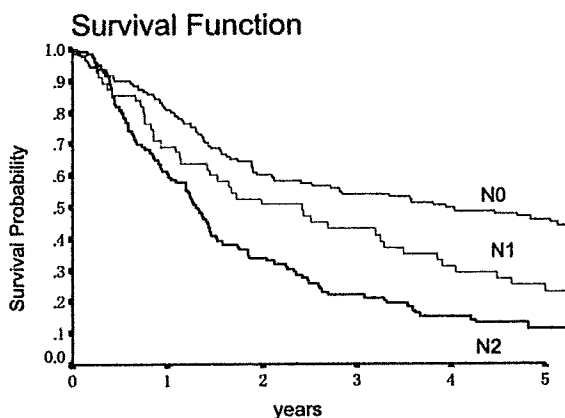


FIGURE 4. Survival curves of PM1 patients according to pathological N status. There were significant survival differences between N0 and N1 patients ($p = 0.0176$) and between N1 and N2 patients ($p = 0.0114$).

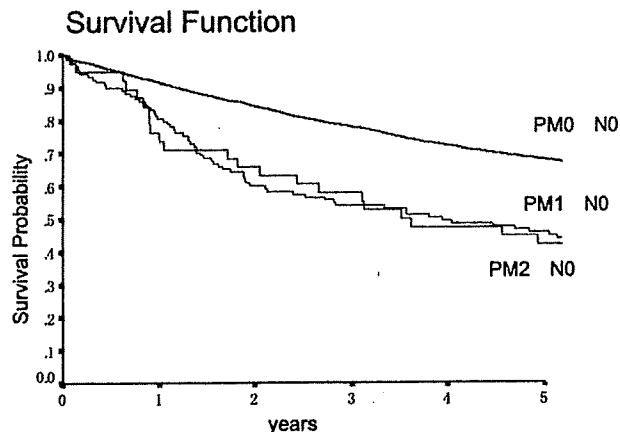


FIGURE 6. Survival curves of pathological N0 patients according to PM status. There were significant survival differences between PM0 and PM1 patients and between PM0 and PM2 patients ($p < 0.01$, respectively). There was no significant survival difference between PM1 and PM2 patients ($p = 0.8775$).

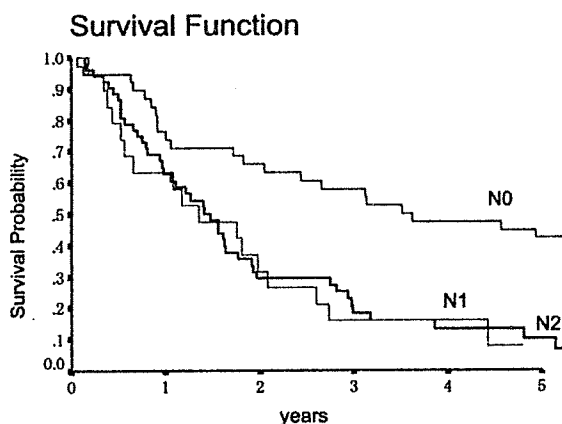


FIGURE 5. Survival curves of PM2 patients according to pathological N status. There were significant survival differences between N0 and N1 patients ($p = 0.016$) and between N0 and N2 patients ($p = 0.0001$). There was no significant survival difference between N1 and N2 patients ($p = 0.644$).

TABLE 2. Five-year Survival Rates of Intrapulmonary Metastasis (PM) and Lymph Node Metastasis

	PM0 (%)	PM1 (%)	PM2 (%)
0	68.0	45.8	42.1
1	44.6	25.3	7.9
2	26.2	11.1	10.2

nificant survival differences were detected between PM0 and PM1 patients ($p < 0.01$) and between PM0 and PM2 patients ($p = 0.004$). There was no significant difference between PM1 and PM2 patients ($p = 0.922$). In pathological N1 cases, there were significant survival differences between PM0 and PM1 patients and between PM0 and PM2 patients ($p < 0.01$, respectively). There was no significant survival difference between PM1 N1 and PM2 N1 patients ($p = 0.0619$). In N2

patients, there were significant survival differences between PM0 and PM1 patients and between PM0 and PM2 patients ($p < 0.01$, respectively). There was no significant survival difference between PM1 N2 and PM2 N2 patients ($p = 0.998$).

DISCUSSION

The current UICC TNM staging system for lung cancer was published in 1997.⁴ The system classifies PM in the primary tumor lobe as T4, and PM in different lobes as M1. Several previous studies support the current UICC PM classification,⁶⁻⁹ but these studies were based on small numbers of PM patients, ranging from 41 to 123. The present study has the greatest number of PM patients ever reported on.

Differentiating PM from synchronous multiple primary lung cancers is often difficult. The criteria proposed by Martini and Melamed¹⁰ in 1975 are still the most practical and commonly used. Pathologists at almost all institutions involved in this study reported that they used these criteria.

Our analyses show a significant survival difference between patients with PM and those without, whereas there was no statistical difference between PM1 and PM2. When analyzing survival rates of pathological N0 patients according to PM status, there were significant survival differences between PM0 and PM1 patients and between PM0 and PM2 patients, but there was no significant survival difference between PM1 and PM2 patients. We conclude that PM is a sign of advanced disease and that PM1 and PM2 should be combined into a single PM category.

The 5-year survival rate was 34.0% for pathological T3 patients, 26.8% for PM1 patients, and 17.6% for non-PM1 T4 patients. PM1 patients fared significantly better than non-PM1 T4 patients. PM2 patients, whose survival curve almost overlapped that of PM1 patients, had almost the same outcome as non-PM2 M1 patients. These findings do not agree with the current UICC staging system,⁴ in which M1 patients, including PM2 patients, are classified as stage IV, and in

which T4 patients, including PM1 patients, are classified as stage IIIB. This may be partly explained by the fact these non-PM1 T4 and non-PM2 M1 patients undergoing surgical intervention were highly selected, thus creating to a certain amount of bias. Further studies are necessary to decide the appropriate classification of PM in the TNM staging system revision that is scheduled for 2007.

Within the group of patients with PM1, there was a significant difference in survival in relation to pathological N status. In previous reports, there were no significant survival differences between the different pathological N statuses.^{6,7,9} The large number of lung cancer patients with PM1 in the present study resulted in a survival difference in relation to N status being recognized.

In conclusion, there was no significant survival difference between NSCLC patients with PM1 and PM2. The survival of patients with PM1 was between that of the T3 patients and the T4 patients excluding PM1. Further studies are necessary to define PM classification in the TNM staging system.

ACKNOWLEDGMENTS

We express our thanks to Dr. Junji Yoshida, MD, Department of Thoracic Oncology, National Cancer Center Hospital East and Yoshihiko Koshiishi, MD, Department of Surgery, Kyorin University for their help in this study. We thank Hisao Asamura, MD, Division of Thoracic Surgery,

National Cancer Center Hospital and Kosei Yasumoto, Department of Surgery, University of Occupational and Environmental Health School of Medicine for their advice in this study. We are indebted to Prof. J Patrick Barron, International Medical Communication Center, Tokyo Medical University, for reviewing the English manuscript.

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1999年肺癌外科切除例の全国集計に関する報告

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肺癌登録合同委員会

要 旨

日本肺癌学会および日本呼吸器外科学会では、肺癌登録合同委員会を共同で運営し、2002年に報告された1994年の肺癌切除症例の全国集計に引き続き、1999年に切除された肺癌症例についての全国集計を2006年に行なった。症例数は13,344、全体の5年生存率は60.6%であった。男性(8878例)の5年生存率は55.4%、女性(4344例)では74.2%であった。c-STAGE別の5年生存率はIA(n=5939):77.0%、IB(n=3242):60.1%、IIA(n=226):53.8%、IIB(n=1304):43.6%、IIIA(n=1723):38.0%、IIIB(n=567):33.6%、IV(n=221):27.0%であった。p-STAGE別の5年生存率はIA(n=5007):83.3%、IB(n=2803):66.4%、IIA(n=400):60.1%、IIB(n=1388):47.2%、IIIA(n=1944):32.8%、IIIB(n=1179):30.4%、IV(n=397):23.2%であった。組織型別5年生存率は腺癌67.3%、扁平上皮癌52.5%、大細胞癌45.5%、小細胞癌48.1%、腺扁平上皮癌42.1%であった。術死は123例(0.9%)、在院死は146例(1.1%)に認められた。

本登録は個人を特定できる情報を除いて行なわれており、集計成果は世界に類を見ない大規模かつ詳細なものと考ええる。今後予定されている2004年切除例の登録への参加有資格施設の積極的取り組みを期待したい。

はじめに

日本肺癌学会・日本呼吸器外科学会で運営している肺癌登録合同委員会の活動の一環として、2002年に1994年切除例の集計結果を報告した¹⁾。その目的は①登録参加施設での肺癌症例の把握、②年齢別・性別頻度、③組織型別頻度、④c-TNMとp-TNM各因子の集計、⑤それぞれの病期別の生存率を求めることとされた。これらの基本資料は学会員に提示されるとともに、治療成績について英文でも報告された^{2,3)}。

今回も前回同様に肺癌に関する基礎資料を収集することを目的に集計を行なったので、報告する。

調査対象と集計方法

対象施設は2005年時点での日本呼吸器外科学会の認

定施設(226施設)、関連施設(275施設)および日本肺癌学会評議員勤務施設で上記以外の施設(13施設)とした。登録参加施設は386施設で、不参加は80施設、1999年当時肺癌切除を行なっていなかった施設が47あった。登録方法はエクセルシートを用いた登録票を作成、各施設に郵送し(2005年6月)、施設内で連結可能匿名化を行なった上で情報入力をお願いし、郵送で回収した(2005年12月)。

内容は「資料編」に掲載されている 1)性別以下32)術後合併症までの32項目である。2002年報告との主な相違は前回最終項目「リンパ節転移および郭清」を削除し、新たに 3)Performance Status, 31)併存疾患, 32)術後合併症を追加した点である。

統計処理は前回同様に行い、必要な変数の欠損は集計・解析から除外し、生存時間分布関数は手術月から最終生死確認月を生存期間、最終生死確認月における死亡をイベント、生存を打ち切りとし、Kaplan-Meier法によって推定した。予後項目の不明は打ち切り症例とした。

連絡先

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Table 1 Age distribution and sex.

Age	Sex		Number
	male	female	
10~	1	7	8
20~	9	6	15
30~	72	49	121
40~	457	269	726
50~	1386	912	2298
60~	3102	1475	4577
70~	3389	1389	4778
80~	388	206	594
90~	3	1	4
Total	8807	4314	13121

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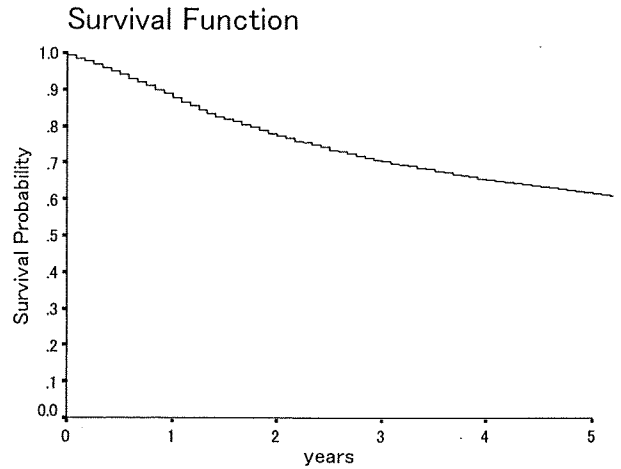


Fig. 1 Survival function of overall cases.

Table 2 Overall survival rate.

①1999

year	1 Y(%)	2 Y(%)	3 Y(%)	4 Y(%)	5 Y(%)
survival rate	87.9	77.5	70.3	65.3	61.6

(Number of Cases: 13344)

②1994

year	1 Y(%)	2 Y(%)	3 Y(%)	4 Y(%)	5 Y(%)
survival rate	84.1	71.3	62.3	56.1	51.9

(Number of Cases: 7238)

結 果

集計症例数は前回より大幅に増加し、13,344例となった。欠損値が多かった項目は 3)PS, 9)術前治療, 14)手術根治度, 20)胸水細胞診, 21)腫瘍最大径, 22)p-T, 25)p-STAGE, 27)病理学的腫瘍遺残であった。1994年切除例の集計の際よりやや増加した理由として、前回は欠損値について再三事務局から確認を行なったのに対し、今回は基本的に欠損値に対する補完の依頼を行なわなかったためと考えている。残る24項目の欠損値は1%以下であった。

統計結果：性別は男性8878、女性4344で、各々の年齢構成はTable 1に示す。最小13歳、最高91歳、平均は65.8歳、標準偏差は9.8(資料編：記述統計量：年齢)であった。前回調査と比較し、女性の比率が約3.1%増加し年齢は1.3歳増加していた。予後の判明率は

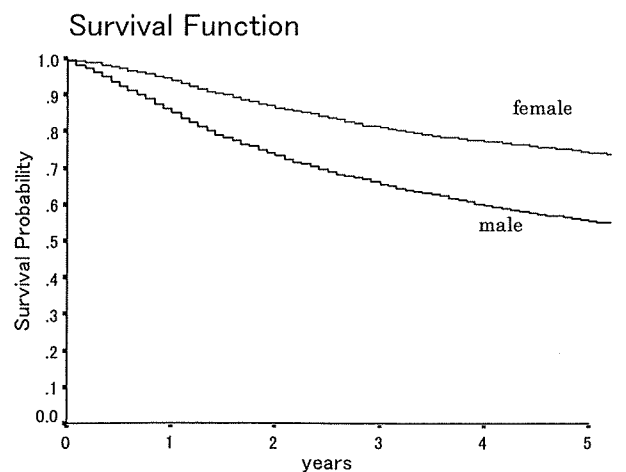


Fig. 2 Survival function according to sex.

90.5%で、前回は1.0%下回った(資料編(28)予後)。全体の5年生存率は61.6%で、前回は9.7%上回った(Fig. 1, Table 2)。男女別では前回同様女性の生存

Table 3 Survival rates according to sex.

①1999

Sex	Cases	1 Y(%)	2 Y(%)	3 Y(%)	4 Y(%)	5 Y(%)
Male	n=8878	85.0	73.1	65.2	59.6	55.4
Female	n=4344	93.7	86.4	80.9	77.1	74.2

Log Rank Statistic analysis; female vs. male (Significance; p=0.0000) n=13222

②1994

Sex	Cases	1 Y(%)	2 Y(%)	3 Y(%)	4 Y(%)	5 Y(%)
Male	n=5029	81.2	67.9	58.6	52.4	48.2
Female	n=2150	91.0	78.8	71.0	65.0	61.0

n=7179

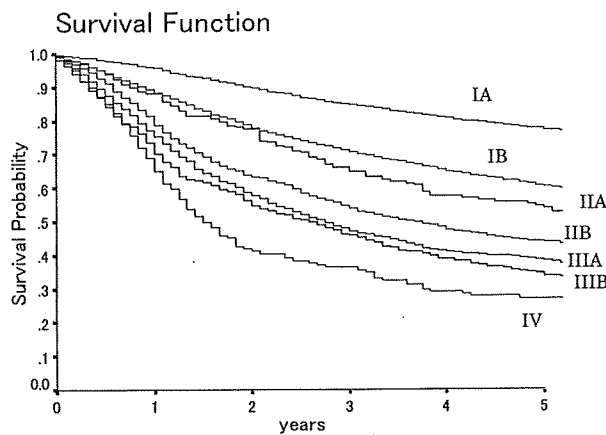


Fig. 3 Survival function according to c-STAGE.

Table 4 Survival rates according to c-STAGE.

c-STAGE	1999						1994
	Cases	1 Y(%)	2 Y(%)	3 Y(%)	4 Y(%)	5 Y(%)	5 Y(%)
IA	5939	95.6	89.5	84.4	80.4	77.0	71.5
IB	3242	88.5	77.9	70.3	64.8	60.1	50.1
IIA	226	88.1	77.5	64.8	57.3	53.8	47.8
IIB	1304	78.6	63.2	53.6	47.3	43.6	40.4
IIIA	1723	75.3	57.7	46.9	41.0	38.0	34.6
IIIB	567	70.1	54.6	45.8	38.6	33.6	27.6
IV	211	64.9	41.3	36.3	28.8	27.0	19.9
Total	13212						7168

Log Rank Statistic analysis revealed that there are no significant difference between IB vs. IIA (p=0.0780) and IIIA vs. IIIB (p=0.1163) in 1999.

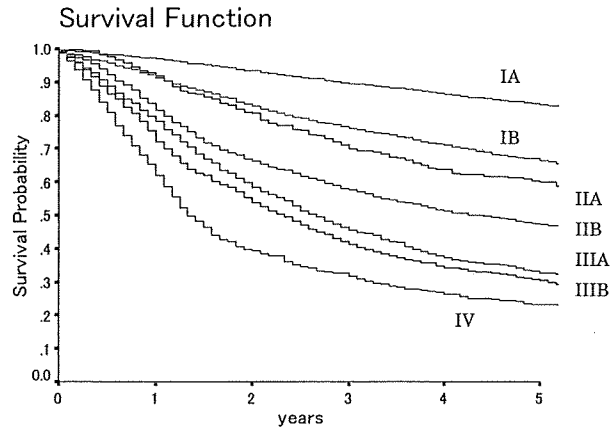


Fig. 4 Survival function according to p-STAGE.

Table 5 Survival rates according to p-STAGE.

p-STAGE	1999						1994
	Cases	1 Y(%)	2 Y(%)	3 Y(%)	4 Y(%)	5 Y(%)	5 Y(%)
IA	5007	97.0	93.2	89.5	86.2	83.3	79.2
IB	2803	91.1	82.6	76.0	71.0	66.4	60.1
IIA	400	91.8	80.3	69.9	63.8	60.1	58.6
IIB	1388	81.5	66.0	57.7	51.2	47.2	42.2
IIIA	1944	77.9	58.3	45.5	37.3	32.8	28.4
IIIB	1179	72.0	53.6	41.1	34.1	30.4	20.2
IV	397	61.9	39.2	31.7	26.1	23.2	19.3
Total	13118						7047

Log Rank Statistic analysis revealed that there are significant difference between all stages. The largest p-value (0.0245) was observed between IIIA and IIIB in 1999.

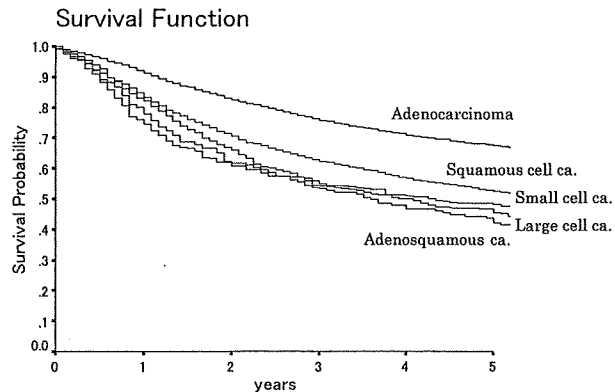


Fig. 5 Survival function according to histologic type.

Log Rank Statistic analysis revealed that there are significant difference between adenocarcinoma and other all histologic types ($p=0.0000$). There are also significant difference between Squamous cell carcinoma and Large cell carcinoma ($p=0.0002$) and Adenosquamous carcinoma ($p=0.0026$).

Table 6 Survival rates according to histologic type. n=13010

Histologic type	Cases	1 Y(%)	2 Y(%)	3 Y(%)	4 Y(%)	5 Y(%)
Small cell ca.	390	82.1	65.8	54.2	50.8	48.1
Squamous cell ca.	3700	83.3	70.5	62.3	56.7	52.5
Adenocarcinoma	8239	91.2	82.4	75.8	70.8	67.3
Large cell ca.	474	74.4	61.6	55.0	49.9	45.5
Adenosquamous	207	77.7	60.5	53.2	46.8	42.1
Total	13010					

率が有意差をもって良好であった (Fig. 2, Table 3). 前回との比較でも5年生存率の改善は女性が13.2%であり, 男性の7.2%を上回っていた.

臨床病期別の症例数, 生存率を Table 4, Fig. 3 に示す. 5年生存率は各病期とも前回を上回っており, とくにIBでは10%以上向上した. 各病期間の有意差検定では, IBとIIA, IIIAとIIIBの間に有意差が見られなかった.

病理病期別の症例数, 生存率を Table 5, Fig. 4 に示す. 病理病期でも5年生存率は各病期で前回を上回っており, 特にIIIB期では10%以上の改善を認めた. 各病期間の有意差検定では各病期間に有意差を認めた.

組織型別の頻度は資料編(26)組織型に示す. 腺癌が5.0%増加し, 扁平上皮癌は5.3%減少していた. 組織型別の生存率を Table 6, Fig. 5 に示す. 腺癌の生存率が他の組織型と比較して有意に良好であったほか, 前回集計と異なり, 扁平上皮癌と大細胞癌および腺扁平上皮癌との間にも有意差が認められた.

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(以上症例数50以上92施設 郵便番号順)

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JA 長野厚生連北信総合病院，JA 長野厚生連小諸厚生総合病院，健康保険岡谷塩嶺病院，飯田市立病院，国立病院機構中信松本病院，伊南行政組合昭和伊南総合病院，市立甲府病院，国立病院機構静岡医療センター，富士宮市立病院，国立病院機構静岡富士病院，静岡市立静岡病院，榛原総合病院，静岡済生会総合病

院, 静岡市立清水病院, 焼津市立総合病院, 藤枝市立総合病院, 市立島田市民病院, 社会福祉法人総合病院聖隷浜松病院, 浜松医科大学医学部附属病院, 県西部浜松医療センター, 袋井市立袋井市民病院, 磐田市立総合病院外科, 豊橋市民病院, 豊川市民病院, 愛知県がんセンター愛知病院, 西尾市民病院, JA 愛知厚生連安城更生病院, 碧南市民病院, 医療法人豊田会刈谷総合病院, 名古屋掖済会病院, 社会保険中京病院, 国立病院機構名古屋医療センター, 名古屋市立東市民病院, 名古屋大学医学部附属病院, 名古屋第二赤十字病院, 藤田保健衛生大学病院, トヨタ記念病院, 愛知医科大学附属病院, 小牧市民病院, 公立陶生病院, 岐阜大学医学部附属病院, 医療法人蘇西厚生会松波総合病院, 大垣市民病院, 国立病院機構三重中央医療センター, JA 三重厚生連松阪中央総合病院, 山田赤十字病院, 滋賀医科大学医学部附属病院, 大津赤十字病院, 市立長浜病院, 長浜赤十字病院, (財)住友病院, 大阪府済生会中津病院, (財)田附興風会医学研究所北野病院, 淀川キリスト教病院, 社会福祉法人恩賜財団済生会大阪府済生会野江病院, 大阪警察病院, NTT 西日本大阪病院, 大阪厚生年金病院, 大阪市立北市民病院, 大阪府立急性期・総合医療センター, 箕面市立病院, 市立吹田市民病院, 高槻赤十字病院, 医療法人愛仁会高槻病院, 医療法人仙養会北摂総合病院, 大阪医科大学附属病院, 関西医科大学附属病院, (財)結核予防会大阪府支部大阪病院, 東大阪市立総合病院, 耳原総合病院, 市立岸和田市民病院, りんくう総合医療センター市立泉佐野病院, 京都府立医科大学附属病院, 社会保険京都病院, 京都市立病院, 京都第一赤十字病院, 医療法人社団洛和会音羽病院, 国立病院機構京都都病院, 和歌山県立医科大学附属病院, 国立病院機構和歌山病院, 公立那賀病院, 和歌山県立医科大学附属病院紀北分院, 神戸大学医学部附属病院, 兵庫県立淡路病院, 兵庫県立尼崎病院, 兵庫県立塚口病院, 西宮市立中央病院, 公立学校共済組合近畿中央病院, 公立豊岡病院, 国立病院機構兵庫中央病院, 兵庫県立柏原病院, 姫路赤十字病院, 鳥取県立中央病院, 鳥取市立病院, 鳥取赤十字病院, 鳥取県立厚生病院, 松江赤十字病院, 島根県立中央病院, 岡山済生会総合病院, 総合病院岡山赤十字病院, 川崎医科大学, 国立病院機構南岡山医療センター, 津山中央病院, (財)淳風会倉敷第一病院, 公立学校共済組合中国中央病院, 国立病院機構福山医療センター,

福山市民病院, 尾道市立市民病院, JA 広島厚生連尾道総合病院, 三菱三原病院, 広島赤十字・原爆病院, 県立広島病院, 広島大学医学部歯学部附属病院, KKR 呉共済病院, 総合病院社会保険徳山中央病院, 山口県立中央病院, 下関市立中央病院, 山口県済生会下関総合病院, 山口大学医学部附属病院呼吸器外科, 宇部興産株式会社中央病院, 国立病院機構山陽病院, 高松赤十字病院, 香川県立中央病院, 屋島総合病院, 香川労災病院, 国立病院機構善通寺病院, 三豊総合病院, 徳島大学病院, 国立病院機構東徳島病院, 高知赤十字病院, 愛媛県立中央病院, (財)永頼会松山市民病院, 松山赤十字病院, 国立病院機構愛媛病院, 愛媛大学医学部附属病院, 愛媛県立新居浜病院, 住友別子病院, KKR 新小倉病院, 福岡県済生会八幡総合病院, 北九州市立八幡病院, 医療法人社団新日鐵八幡記念病院, 九州厚生年金病院, 福岡県済生会福岡総合病院, KKR 浜の町病院, 国立病院機構福岡東医療センター, 麻生飯塚病院, 田川市立病院, 社会保険田川病院, 社会保険久留米第一病院, 医療法人雪ノ聖母会聖マリア病院, 公立八女総合病院, 国立病院機構大牟田病院, 聖フランシスコ病院, 日本赤十字社長崎原爆病院, 健康保険諫早総合病院, 国立病院機構長崎医療センター, 熊本大学医学部附属病院, 国立病院機構大分医療センター, KKR 新別府病院, 大分県厚生連鶴見病院, 大分大学医学部附属病院, 宮崎県立日南病院, 済生会日向病院, 宮崎大学医学部附属病院, 鹿児島大学病院, 財団法人昭和会今給黎総合病院, 医療法人友愛会豊見城中央病院, 特定医療法人仁愛会浦添総合病院, 那覇市立病院, 琉球大学医学部附属病院, 福井医科大学医学部附属病院, 市立敦賀病院, 福井赤十字病院, 福井県済生会病院, 石川県済生会金沢病院, 富山医科薬科大学附属病院, 富山赤十字病院, JA 富山厚生連高岡病院, 富山県済生会高岡病院, 氷見市民病院, 黒部市民病院, 市立砺波総合病院, 富山市立富山市民病院, 新潟市民病院, 福島県立医科大学医学部附属病院第一外科, 福島赤十字病院, (財)慈山会医学研究所付属坪井病院, (財)太田総合病院附属太田西ノ内病院, (財)竹田総合病院, 東北大学医学部附属病院, 宮城県立がんセンター, 山形県立中央病院, 鶴岡市立荘内病院, 山形県立日本海病院, 市立酒田病院

(以上症例数49以下290施設 郵便番号順)

1999年肺癌登録結果
全13344症例

資料編

(1) 性別

性別	1999		1994	
	症例数	%	症例数	%
男性	8878	66.5	5154	69.7
女性	4344	32.6	2197	29.7
欠損値	122	0.9	42	0.6
合計	13344	100.0	7393	100.0

(2) 年齢

年齢	1999		1994	
	症例数	%	症例数	%
10代	9	0.1	2	0.0
20代	15	0.1	17	0.2
30代	122	0.9	84	1.1
40代	731	5.5	512	6.9
50代	2312	17.3	1334	18.0
60代	4610	34.5	2984	40.4
70代	4823	36.1	2222	30.1
80代	598	4.5	232	3.1
90代	4	0.0	1	0.0
欠損値	120	0.9	5	0.1
合計	13344	100.0	7393	100.0

(3) PS 1999のみ

	症例数	パーセント
PS0	10158	76.1
PS1	2319	17.4
PS2	230	1.7
PS3	21	0.2
欠損値	616	4.6
合計	13344	100.0

(4) cTNM_T

	1999		1994	
	症例数	%	症例数	%
T0	—	—	8	0.1
T1	6586	49.4	3162	42.8
T2	5066	38.0	3092	41.8
T3	1111	8.3	786	10.6
T4	521	3.9	317	4.3
Tis	—	—	12	0.2
TX	—	—	7	0.1
不明	—	—	7	0.1
欠損値	60	0.4	2	0.0
合計	13344	100.0	7393	100.0

(5) T4の根拠(複数回答可) 1999のみ

	症例数
隣接臓器(含気管分岐部)	235
胸水	75
心嚢水	12
肺内転移	143
胸膜播種	36

(6) cTNM_N

	1999		1994	
	症例数	%	症例数	%
N0	10164	76.2	4904	66.3
N1	1211	9.1	874	11.8
N2	1789	13.4	1458	19.7
N3	99	0.7	131	1.8
NX	—	—	9	0.1
不明	—	—	17	0.2
欠損値	81	0.6	—	—
合計	13344	100.0	7393	100.0

(7) cTNM_M

	1999		1994	
	症例数	%	症例数	%
M0	13022	97.6	7208	97.5
M1	210	1.6	167	2.3
不明	—	—	14	0.2
欠損値	112	0.8	4	0.1
合計	13344	100.0	7393	100.0

(8) cSTAGE

	1999		1994	
	症例数	%	症例数	%
0	—	—	26	0.4
IA	5939	44.5	2677	36.2
IB	3242	24.3	1677	22.7
IIA	226	1.7	175	2.4
IIB	1304	9.8	809	10.9
IIIA	1723	12.9	1418	19.2
IIIB	567	4.2	400	5.4
IV	211	1.6	163	2.2
不明	—	—	28	0.4
欠損値	132	1.0	20	0.3
合計	13344	100.0	7393	100.0

(9) 術前治療

	1999		1994	
	症例数	%	症例数	%
なし	12255	91.8	6841	92.5
あり	751	5.6	451	6.1
不明	29	0.2	14	0.2
欠損値	309	2.3	87	1.2
合計	13344	100.0	7393	100.0

(10) 手術日 1999年1月1日～12月31日まで

(11) 手術術式

	1999		1994	
	症例数	%	症例数	%
全摘	703	5.3	646	8.7
葉切	10892	81.6	6250	83.9
区切	674	5.1	190	2.6
部切	952	7.1	282	3.8
その他	30	0.2	9	0.1
欠損値	93	0.7	61	0.8
合計	13344	100.0	7393	100.0

(12) リンパ節郭清度

	1999		1994	
	症例数	%	症例数	%
ND0	1381	10.3	566	7.7
ND1	1792	13.4	1050	14.2
ND2a	8979	67.3	4627	62.6
ND2b	900	6.7	994	13.4
ND3	171	1.3	122	1.7
不明	81	0.6	15	0.2
欠損値	40	0.3	19	0.3
合計	13344	100.0	7393	100.0

(13) 原発部位

	1999		1994	
	症例数	%	症例数	%
RUL	4132	31.0	2317	31.3
RML	822	6.2	433	5.9
RLL	2940	22.0	1568	21.3
LUL	3197	24.0	1890	25.6
LLL	2024	15.2	1132	15.3
その他	88	0.7	28	0.4
不明	49	0.4	9	0.1
欠損値	92	0.7	16	0.2
合計	13344	100.0	7393	100.0

(14) 手術根治度

	1999		1994	
	症例数	%	症例数	%
完全切除	11803	88.5	6430	87.0
非完全切除	1143	8.6	892	12.1
判定不能手術	189	1.4	58	0.8
欠損値	209	1.6	13	0.2
合計	13344	100.0	7393	100.0

(15) 合併切除部位 1999のみ

	症例数	パーセント
あり	1480	11.1
なし	11731	87.9
欠損値	133	1.0
合計	13344	100.0

	症例数
壁側胸膜	478
胸壁	438
縦隔胸膜	84
横隔膜	106
心膜	149
左心房	46
右心房	7
上大静脈	40
下大静脈	1
肺動脈	64
肺静脈	8
大動脈	19
食道	16
椎体	25
その他	180

(16) 胸膜浸潤

	1999		1994	
	症例数	%	症例数	%
p0	8185	61.3	4332	58.6
p1	2351	17.6	1299	17.6
p2	1000	7.5	561	7.6
p3	1549	11.6	972	13.1
葉間 p3	—	—	166	2.2
不明	128	1.0	23	0.3
欠損値	131	1.0	40	0.5
合計	13344	100.0	7393	100.0

(17) 浸潤臓器

	1999	1994
浸潤臓器	症例数	症例数
他肺葉	349	—
壁側胸膜	392	358
胸壁	381	354
縦隔胸膜	107	118
横隔膜	61	71
心膜	87	143
縦隔	25	—
左心房	33	53
右心房	3	6
上大静脈	23	45
下大静脈	1	1
肺動脈本幹	17	58
大動脈	24	40
食道	13	18
椎体	22	30
気管分岐部	11	—
その他	38	61

(18) 胸膜播種

	1999		1994	
	症例数	%	症例数	%
d0	12772	95.7	7185	97.2
d1	164	1.2	93	1.3
d2	160	1.2	95	1.3
不明	151	1.1	11	0.1
欠損値	97	0.7	9	0.1
合計	13344	100.0	7393	100.0

(19) 肺内転移

	1999		1994	
	症例数	%	症例数	%
pm0	12289	92.1	6856	92.7
pm1	587	4.4	353	4.8
pm2	199	1.5	146	2.0
不明	182	1.4	26	0.4
欠損値	87	0.7	12	0.2
合計	13344	100.0	7393	100.0

(20) 胸水細胞診

	1999		1994	
	症例数	%	症例数	%
胸水なし	11473	86.0	6300	85.2
陽性	260	1.9	146	2.0
陰性	724	5.4	516	7.0
細胞診せず	536	4.0	230	3.1
欠損値	351	2.6	201	2.7
合計	13344	100.0	7393	100.0

(21) 最大径

	1999		1994	
	症例数	%	症例数	%
1.0cm 以下	746	5.6	249	3.4
1.1-1.5	1227	9.2	526	7.1
1.6-2.0	1972	14.8	942	12.7
2.1-2.5	1824	13.7	952	12.9
2.6-3.0	1527	11.4	926	12.5
3.1-4.0	2693	20.2	1621	21.9
4.1-5.0	1426	10.7	887	12.0
5.1-6.0	740	5.5	510	6.9
6.1以上	949	7.1	727	9.8
欠損値	240	1.8	53	0.7
合計	13344	100.0	7393	100.0

(22) pTNM_T

	1999		1994	
	症例数	%	症例数	%
T0	131	1.0	23	0.3
T1	6022	45.1	2925	39.6
T2	4654	34.9	2854	38.6
T3	1120	8.4	781	10.6
T4	1217	9.1	771	10.4
Tis	—	—	20	0.3
TX	—	—	4	0.1
不明	—	—	8	0.1
欠損値	200	1.5	7	0.1
合計	13344	100.0	7393	100.0

(23) pTNM_N

	1999		1994	
	症例数	%	症例数	%
N0	9163	68.7	4464	60.4
N1	1587	11.9	980	13.3
N2	2333	17.5	1616	21.9
N3	140	1.0	126	1.7
NX	—	—	124	1.7
不明	—	—	77	1.0
欠損値	121	0.9	6	0.1
合計	13344	100.0	7393	100.0

(24) pTNM_M

	1999		1994	
	症例数	%	症例数	%
M0	12838	96.2	7092	95.9
M1	407	3.1	275	3.7
不明	—	—	18	0.2
欠損値	99	0.7	8	0.1
合計	13344	100.0	7393	100.0

(25) pSTAGE

	1999		1994	
	症例数	%	症例数	%
0	—	—	31	0.4
IA	5007	37.5	2194	29.7
IB	2803	21.0	1521	20.6
IIA	400	3.0	264	3.6
IIB	1388	10.4	800	10.8
IIIA	1944	14.6	1366	18.5
IIIB	1179	8.8	773	10.5
IV	397	3.0	278	3.8
不明	—	—	138	1.9
欠損値	226	1.7	28	0.4
合計	13344	100.0	7393	100.0

(26) 組織型

	1999		1994	
	症例数	%	症例数	%
小細胞癌	390	2.9	248	3.4
扁平上皮癌	3700	27.7	2441	33.0
腺癌	8239	61.7	4116	55.7
大細胞癌	474	3.6	266	3.6
腺扁平上皮癌	207	1.6	185	2.5
カルチノイド腫瘍	125	0.9	73	1.0
粘表皮癌	28	0.2	19	0.3
腺様嚢胞癌	23	0.2	4	0.1
多形, 肉腫様	49	0.4	—	—
分類不能癌	40	0.3	—	—
その他	—	—	33	0.4
欠損値	69	0.5	8	0.1
合計	13344	100.0	7393	100.0

(27) 病理学的腫瘍遺残 1999のみ

	症例数	パーセント
あり	951	7.1
なし	11844	88.8
欠損値	549	4.1
合計	13344	100.0

(28) 予後

	1999		1994	
	症例数	%	症例数	%
死亡	4985	37.4	3612	48.9
生存中	7094	53.2	3147	42.6
不明	1265	9.5	582	7.9
欠損値	—	—	52	0.7
合計	13344	100.0	7393	100.0

(29) 死因

	1999		1994	
	症例数	%	症例数	% (総数7393に対する割合)
術死 (30日以内)	123	0.9	101	1.4
院内死 (31日以後)	146	1.1	122	1.7
肺癌死	3397	25.4	2635	35.6
他病死	680	5.1	461	6.2
他癌死	183	1.4	124	1.7
不明死	272	1.9	148	2.0
生存・不明・ 死因不詳	8543	64.2	3612	48.9
合計	13344	100.0	7372	99.7

(30) 最終生存確認日, 死亡確認日 報告データ略

(31) 併存疾患 1999のみ

	症例数	パーセント
あり	3451	25.9
なし	9792	73.4
欠損値	101	0.8
合計	13344	100.0

併存疾患	症例数
喫煙歴 (術前1ヵ月以内)	1871
肥満 (BMI:30以上)	75
脳神経疾患 (登録医判断)	324
慢性閉塞性肺疾患 (FEV1.0%:40%以下)	309
間質性肺炎 (胸部CTで明らかな間質肺炎像)	239
虚血性心疾患 (負荷心電図陽性)	422
腎障害 (血清クレアチニン2.0g/dl以上)	73
肝硬変 (Child-Turcotte分類B以上)	38
糖尿病 (HbA1c:8.0%以上)	449
貧血 (Hb8.0g/dl以下)	26
自己免疫疾患 (治療歴のあるもの)	80

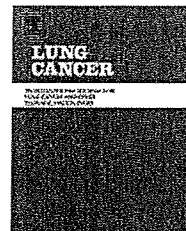
(32) 術後合併症 1999のみ

	症例数	%
あり	1422	10.7
なし	11913	89.3
欠損値	9	0.1
合計	13344	100.0

術後合併症	症例数
創感染 (縫合不全を伴う)	57
出血 (500ml/hr以上)	93
肺胞瘻 (2週間以上持続)	332
乳糜胸 (1500ml/day以上)	55
気管支胸膜瘻 (登録医判断)	88
気管支血管瘻 (登録医判断)	7
肺塞栓症 (登録医判断)	43
膿胸 (登録医判断)	141
肺炎 (胸部エックス線写真での肺炎像)	411
呼吸不全 (術後3日以上レスピレーター装着)	144
心筋梗塞 (登録医判断)	29
脳梗塞 (登録医判断)	47

記述統計量: 年齢, 原発巣最大径

	症例数	最小値	最大値	平均値	標準偏差
age	13224	13.00	91.00	65.8029	9.80349
原発巣径	13104	0.00	26.00	3.2942	1.96817



Postoperative radiotherapy for non-small-cell lung cancer: Results of the 1999–2001 patterns of care study nationwide process survey in Japan

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Received 29 November 2006; received in revised form 4 January 2007; accepted 17 January 2007

KEYWORDS

Non-small-cell lung
cancer;
Postoperative
radiation therapy;
Patterns of care
study;
Practice;
Survey;
PORT meta-analysis

Summary To investigate the practice process of postoperative radiation therapy for non-small-cell lung cancer (NSCLC) in Japan. Between April 2002 and March 2004, the Patterns of Care Study conducted an extramural audit survey for 76 of 556 institutions using a stratified two-stage cluster sampling. Data on treatment process of 627 patients with NSCLC who received radiation therapy were collected. Ninety-nine (16%) patients received postoperative radiation therapy between 1999 and 2001 (median age, 65 years). Pathological stage was stage I in 8%, II in 17%, IIIA in 44%, and IIIB in 20%. The median field size was 9 cm × 11 cm, and median total dose was 50 Gy. Photon energies of 6 MV or higher were used for 64 patients, whereas a cobalt-60 unit was used for five patients. Three-dimensional conformal treatment was used infrequently. Institutional stratification influenced several radiotherapy parameters such as photon energy and planning target volume. Smaller non-academic institutions provided worse quality of care. The study confirmed continuing variation in the practice of radiotherapy according to stratified institutions. Outdated equipment such as Cobalt-60 units was used, especially in non-academic institutions treating only a small number of patients per year.

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1. Introduction

Postoperative radiation therapy (PORT) decreases the risk of local–regional recurrence in patients with resected non-small-cell lung cancer (NSCLC) [1–3]. However, reduction in the frequency of local recurrence has not translated into a survival benefit in most studies. In 1998, the impact of PORT for NSCLC was analyzed in a meta-analysis of phase III trials [4]. After publication of the PORT meta-analysis, which emphasized deleterious effects in patients receiving PORT for completely resected N0-1 cases, much of the clinical focus on adjuvant therapy shifted to chemotherapy [5,6]. Thus, the role of PORT for patients at high risk for locoregional failure such as those with N2 disease remains unclear. Adjuvant chemotherapy trials have often permitted use of PORT as an option for patients with N2 disease [5,7]. One clinical study reported promising results for combined PORT and chemotherapy for patients with pathologic stage II or IIIA disease [8]. The results of these trials imply that PORT delivered using modern radiotherapy techniques may potentially provide a survival advantage for selected high-risk patients.

The Patterns of Care Study (PCS) is a retrospective study designed to investigate the national practice for cancer patients during a specific period [9,10]. In April 2002, the PCS started a nationwide survey for patients with NSCLC treated with radiation therapy in Japan. In the present report, we provide results of analyses focused on patients who received PORT for NSCLC during the study period. The objectives of this study were to reveal clinical practice patterns regarding PORT after publication of the PORT meta-analysis and to assess variation in clinical practice according to stratified institutions.

2. Materials and methods

Between April 2002 and March 2004, the PCS conducted a national survey of radiation therapy for patients with lung cancer in Japan. The Japanese PCS developed an original data format and performed an extramural audit survey for 76 of 556 institutions using a stratified two-stage cluster sampling. Data collection consisted of two steps of random sampling. Prior to random sampling, all institutions were classified into one of four groups. Criteria for stratification have been described elsewhere [10]. Briefly, the PCS stratified Japanese institutions as follows: A1, academic institutions such as university hospitals or national/regional cancer center hospitals treating ≥ 430 patients per year; A2, academic institutions treating < 430 patients; B1, non-academic institutions treating ≥ 130 patients per year; and B2, < 130 patients. The cut-off values in number of patients treated per year between A1 and A2 institutions and B1 and B2 institutions, respectively, were increased from those used in the previous PCS study because of the increase in the number of patients treated by radiation therapy in Japan [10]. Eligible patients had 1997 International Union Against Cancer (UICC) stage I–III NSCLC that was treated with PORT between 1999 and 2001, a Karnofsky Performance Status (KPS) > 50 prior to start of treatment, and no evidence of other malignancies within 5 years. The current PCS collected specific information on 627 patients

(A1:157, A2:117, B1:214, B2:139) who were treated with radiation therapy between 1999 and 2001. Of those, 99 (16%) patients (A1:15, A2:17, B1:45, B2:22) who received PORT constitute the subjects of the present analysis. The practice of PORT was investigated by reviewing items in each medical chart such as demographics, symptoms, history, work-up examinations, pathology, clinical stage, treatment course including radiation therapy, surgery and chemotherapy, and radiotherapy parameters. In addition, simulation films and linacgraphy of each patient were also reviewed by surveyors.

The PCS surveyors consisted of 20 board-certified radiation oncologists. For each institution, one radiation oncologist visited and surveyed data by reviewing patient charts. In order to validate the quality of collected data, the PCS utilized an internet mailing-list among all surveyors. In situ real-time check and adjustment of data input were available between each surveyor and the PCS committee. In tables, "missing" indicates that the item in the data format was left empty, whereas "unknown" means that the item in the format was completed with data "unknown". We combined "missing" and "unknown" in tables because their meanings were the same in most cases; no valid data were obtained in the given resources. Cases with missing or unknown values were included when both the percentage and significance value were calculated. Statistical significance was tested by the χ^2 test. A *p*-value less than 0.05 was considered statistically significant. Overall survival was assessed from the day of surgery and was estimated by the Kaplan–Meier product limit method using the Statistical Analysis System, Version 6.12.

3. Results

3.1. Patient and tumor characteristics

Patient and clinical tumor characteristics are shown in Table 1. Of the 99 patients who received PORT, 32 were treated at academic institutions and 67 at non-academic institutions. The proportion of patients with NSCLC who received PORT was significantly higher in non-academic institutions than in academic institutions (19% versus 12%, $p = 0.013$). Overall, median age was 65 years (range, 39–82), and the male to female ratio was 4:1. Ninety-three percent of patients had a KPS greater than or equal to 80%. Preoperative examinations included chest computed tomography (CT) in 97% of patients, bronchoscopy in 87%, brain CT or magnetic resonance imaging (MRI) in 75%, abdominal CT in 75%, bone scintigraphy in 83%, and mediastinoscopy in 4%. The primary tumor site was the upper lobe in 62 patients, middle lobe in 7, and lower lobe in 27. The remaining 2 patients had a primary tumor near the border of the upper and middle lobes that involved both lobes, and they were allocated to "others". Peripheral tumors were twice as common as central tumors. When tumors were analyzed by laterality, the ratio of right to left side primary site was 1.5. Clinical T- and N-classifications were T1 in 28 patients, T2 in 35, T3 in 24, T4 in 11, and N0 in 33, N1 in 19, N2 in 40, and N3 in 6, resulting in clinical stage I in 27 patients, II in 14, IIIA in 41, and IIIB in 16. The numbers less than 99 are due to missing or unknown data.

Table 1 Patient and tumor characteristics

No. of patients	99
Men	79
Women	20
Age (years)	
Median	65
Range	32–89
% KPS \geq 80	93
Preoperative work-up (%)	
Chest CT	97
Bronchoscopy	87
Brain CT or MRI	75
Abdominal CT	75
Bone scan	83
Mediastinoscopy	4
Primary tumor site	
Upper lobe	62
Middle lobe	7
Lower lobe	27
Other	2
Missing	1
Tumor location	
Central	30
Peripheral	60
Missing	9
Laterality	
Left lung	38
Right lung	59
Missing	2
Clinical T factor	
TX	1
T1	28
T2	35
T3	24
T4	11
Clinical N factor	
NX	1
N0	33
N1	19
N2	40
N3	6
Clinical stage	
IA	14
IB	13
IIA	7
IIB	7
IIIA	41
IIIB	16
Missing	1

KPS, Karnofsky performance status score.

3.2. Surgery and tumor pathology characteristics (Table 2)

The primary surgical procedure was a lobectomy in 78 patients, pneumonectomy in 12, and segmentectomy in 9.

Table 2 Surgical procedure and tumor pathology characteristics

Type of surgery	
Lobectomy	78
Pneumonectomy	12
Segmentectomy	9
Histopathology	
Squamous cell carcinoma	47
Adenocarcinoma	43
Large cell carcinoma	7
Adenosquamous carcinoma	2
Surgical margin status	
Negative	55
Positive	31
Missing	13
Pathological T factor	
T1	22
T2	35
T3	23
T4	18
Missing	1
Pathological N factor	
N0	15
N1	19
N2	56
N3	4
Missing	5
Pathologically involved mediastinal nodes (%) ^a	
No. 1	16
No. 2	23
No. 3	26
No. 4	34
No. 5	28
No. 6	5
No. 7	34
No. 8	12
Pathological stage	
IA	4
IB	5
IIA	9
IIB	8
IIIA	45
IIIB	20
Missing/unknown	8

^a Nearly half of the data for this item were "missing/unknown".

Among all 99 patients, complete resection was accomplished for 55 patients. Surgical margin status was positive in 31 patients. Histopathology was squamous cell carcinoma in 47 patients, adenocarcinoma in 43, large cell carcinoma in 7, and adenosquamous carcinoma in 2. Predominantly involved mediastinal nodes confirmed pathologically to contain tumor were No. 7 (34%), No. 4 (34%), No. 5 (28%), and No. 3 (26%) according to the lymph node mapping system of the Japan Lung Cancer Society [11], although nearly half of the data for this item were "missing/unknown." The pathological T-