Twenty-Two Years of Phase III Trials for Patients With Advanced Non–Small-Cell Lung Cancer: Sobering Results

By Oscar S. Breathnach, Boris Freidlin, Barbara Conley, Mark R. Green, David H. Johnson, David R. Gandara, Michael O'Connell, Frances A. Shepherd, and Bruce E. Johnson

Purpose: **To determine the changes in clinical trials and outcomes of patients with advanced-stage non–small-cell lung cancer (NSCLC) treated on phase III randomized trials initiated in North America from 1973 to 1994.**

Patients and Methods: **Phase III trials for patients with advanced-stage NSCLC were identified through a search of the National Cancer Institute's Cancer Therapy Evaluation Program database from 1973 to 1994, contact with Cooperative Groups, and by literature search of MEDLINE. Patients with advanced NSCLC treated during a similar time interval were also examined in the SEER database. Trends were tested in the number of trials, in the number and sex of patients entered on the trials, and in survival over time.**

Results: **Thirty-three phase III trials were initiated between 1973 and 1994. Twenty-four trials (73%) were initiated within the first half of this period (1973 to 1983) and accounted for 5,359 (64%) of the 8,434 eligible patients. The median number of patients treated per arm of the trials rose from 77 (1973 to 1983) to 121 (1984 to 1994) ($P < .001$). Five trials (15%) showed a statistically significant difference in survival between treatment arms, with a median prolongation of the median survival of 2 months (range, 0.7 to 2.7 months).**

Conclusion: **Analysis of past trials in North America shows that the prolongation in median survival between two arms of a randomized study was rarely in excess of 2 months. Techniques for improved use of patient resources and appropriate trial design for phase III randomized therapeutic trials with patients with advanced NSCLC need to be developed.**

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SYSTEMIC CHEMOTHERAPY for patients with advanced-stage non–small-cell lung cancer (NSCLC) prolongs survival and palliates symptoms compared with best supportive care alone.[1,2] Meta-analysis of patients with advanced NSCLC who were treated with cisplatin-based therapy shows a modest improvement in survival.[1] Despite systemic chemotherapy, lung cancer remains the greatest cause of cancer-related mortality within the United States.[3] The 5-year survival of patients with advanced-stage NSCLC is less than 5%.

Prior analysis of phase III trials for patients with extensive-stage small-cell lung cancer (SCLC) revealed that the median of median survival of patients treated on phase III trials and of patients recorded within the SEER database increased by 2 months between 1972 and 1990.[4] We therefore chose to review all the published North American Cooperative Groups and institutional phase III randomized therapeutic trials for patients with advanced-stage NSCLC initiated during the time period of 1973 to 1994 in order to assess the impact of systemic chemotherapy on survival over time. As platinum-based regimens were used throughout the period under review, we divided the analyzed trials for comparison purposes according to two equivalent time periods: 1973 through 1983 and 1984 through 1994. Trials assessing combined-modality therapy of chemotherapy plus chest irradiation were not included in the analysis.

We investigated whether the number of trials initiated had changed, whether the number of patients enrolled on the trials had increased or decreased over time, and whether survival of patients treated on these trials had improved. The median and 5-year survival information on patients with advanced-stage NSCLC from the last 25 years is available on the SEER database. This database provides the data with which to compare the outcomes of patients with advanced-stage NSCLC in both cooperative groups and in a population database.

From the Lowe Center for Thoracic Oncology, Department of Adult Oncology, Dana-Farber Cancer Institute, and Departments of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA; Biometric Research Branch, Clinical Investigations Branch, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute, Bethesda, MD; Cancer and Leukemia Group B, Chicago, IL; Eastern Cooperative Oncology Group, Pittsburgh, PA; Southwest Oncology Group, San Antonio, TX; North Central Cancer Treatment Group Philadelphia, PA; and National Cancer Institute of Canada Clinical Trials Group, Kingston, Ontario, Canada.

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Address reprint requests to Oscar S. Breathnach, MD, Thoracic Oncology Program, Dana-Farber Cancer Institute, Ste 1234, 44 Binney St, Boston, MA 02115.

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PATIENTS AND METHODS

Phase III Trials

Phase III trials initiated for patients with advanced (inoperable stage III and IV) NSCLC were identified through a search of the National Cancer Institute's Cancer Therapy Evaluation Program database from 1973 to 1994, by computer-based search of MEDLINE, and by direct contact with the Eastern Cooperative Oncology, Southwest Oncology, North Central Cancer Treatment, and National Cancer Institute of Canada-Clinical Trials cooperative groups, and Cancer and Leukemia Group B. We evaluated phase III trials initiated between 1973 and 1994, because this allowed adequate time for patient entry on study, follow-up, and publication of the mature results of the therapeutic trials. This period also included the interval examined in the meta-analysis by the Non-Small Cell Lung Cancer Collaborative Group, which compared systemic chemotherapy and best supportive care with best supportive care alone (11 trials; 1970 to 1985).[1]

The lung cancer committee chairs from each cooperative group in North America were contacted to notify them of this analysis and to inquire whether additional trials had been performed that were not known to the authors. Information was obtained about each trial regarding the years of enrollment within the trials, the number of patients enrolled on study, the sex of the patients, treatment regimens used, response rates, median survivals, the number of patient deaths at the time of the analysis, and differences in overall survival. The median of the median survival times was computed without adjusting for the sample size of the control group, and the median survival time of patients before and after 1983 was not adjusted for trial size. Each study median was entered as a data point. Trials included both patients with unresectable locally advanced-stage III disease and/or metastatic disease, in which chemotherapy was the primary therapeutic modality used in all patients. The inclusion criteria were similar to those of the preceding meta-analysis.[1] The control arms were identified in each of the phase III trials on the basis of the statements of the authors in the published reports. A minority of the phase III trials did not have all of this information available in published articles. In these cases, the author of the study and the cooperative group statistician were contacted and additional data were obtained if available and permitted by the author.

The SEER database was also examined to compare the median and 5-year survival information for patients with advanced-stage NSCLC versus our analysis of patients treated on phase III trials over the same time period. The time period from 1973 to 1995 was examined because the starting year corresponded most closely with the start of the cooperative studies, and 1995 corresponded most closely with the year that the cooperative group trials finished their accrual. In the SEER database, patients with metastatic disease are categorized as "distant disease." The SEER definition of distant disease is a neoplasm that has spread to parts of the body remote from the primary tumor either by direct extension or by discontinuous metastasis. In this analysis, patients from the SEER database with distant disease are termed "advanced stage" to be consistent with the terminology used in the cooperative group studies.

Statistical Method

The information from the phase III trials was evaluated with multiple regression analyses using the ordinary least squares regression method, including year of study initiation, platinum-based chemotherapy, maximum performance status, treatment group, and brain metastases in order to determine whether these factors independently impacted the survival of patients with advanced-stage NSCLC who were treated on the phase III studies over time. The significance of each explanatory variable was tested by a t test. The trend in median survival and 5-year survival among patients with advanced NSCLC from the SEER database was calculated using a least squares regression analysis. The two-sample t test and Wilcoxon test were used to compare data for 1973 to 1983 versus 1984 to 1994 periods. All P values corresponded to two-sided tests.

RESULTS

Phase III Trials

Forty-three randomized, controlled phase III trials initiated between 1973 and 1994 in North America involving 9,215 patients with advanced non–small-cell lung cancer were identified.[5-47] Ten trials were found to be ineligible for the purpose of this analysis. Seven trials with 637 patients did not report the dates of initiation of the trials,[13,14,17,33,36,45] two trials with 333 patients were reported as subgroup analyses, reporting only on their patients with squamous cell lung cancer and epidermoid lung cancers, respectively;[23,31] and one trial with 109 patients included patients with small-cell lung cancer.[8] Several attempts were made to contact the authors of the seven trials that had no reported date of initiation, but we were unsuccessful in gaining this information. The exclusion of this data did not appreciably alter the outcome of the study. We analyzed the treatment arms from the remaining 33 published phase-III trials that were initiated from 1973 to 1994. The results of these 33 trials are listed in Table 1.

A total of 8,434 patients with advanced-stage NSCLC were treated on these 33 phase III trials. Twenty-four trials (73%) were initiated within the first half of the period under analysis (1973 to 1983) and accounted for 64% of treated patients (n = 5,359). The percentage of women treated did not change significantly between the 1973-to-1983 and 1984-to-1994 time periods (40% and 39%, respectively). Eight of the nine trials (89%) initiated between 1984 and 1994 included only patients with performance status 0-2, compared with 50% of trials initiated between 1973 and 1983. Patients with brain metastases were included in three of the trials initiated between 1984 and 1994, which compares to 14 of the trials initiated between 1973 to 1983. In six trials initiated between 1973 and 1983, the authors do not specify whether the presence of brain metastases was considered in the eligibility criteria.[10,11,15,21,26,29] The vast majority of trials (97%) included only patients not previously treated with chemotherapy. Seventeen percent of patients in a single trial had received prior chemotherapy.[15]

A median of 94 patients were treated per regimen in the 33 phase III trials initiated from 1973 to 1994 (range, 19 to 209). The median number of patients treated per arm of the

Table 1. North American Phase III Trials of Advanced-Stage Non–Small-Cell Lung Cancer

First Author (ref)	Study Years	No. of Patients per Arm	Sex Male/Female (no.)	Disease Stage	PS	Brain Metastases	Regimens	No. of Responders CR/PR	Median Survival (months)	1-Year Survival (%)	No. of Deaths (n=)	P
Hoeltgen[21]	1973-75	185	N/A	III/IV	0-4	Not specified	A(50)	0/23	3.9	N/A	181	NS
		156	N/A				A(75)	1/17	4.0	N/A	150	
		197	N/A				C	2/16	3.7	N/A	194	
		61	N/A				A(40)C	0/6	4.1	N/A	55	
Livingston[28]	1974	116	N/A	IV	0-4	Yes	BAC_1ON	24	3.7	N/A	N/A	N/A
		115	N/A				NAC_1	18	3.7	N/A	N/A	
Britell[7]	1976-77	19	9/10	IV	0-3	Yes	CAP	1/4	6.7	N/A	N/A	N/A
		22	13/9				P > AC	1/4	5.7	N/A	N/A	
Davis[10]	1976-78	41	101/23	IV	0-3	Not specified	C	0/2	4.8	9	N/A	.4
		47	(overall)				CC_1	0/4	3.9	2	N/A	
		36					CC_1A	0/2	4.4	4	N/A	
Livingston[29]	1977-78	32	N/A	IV/r	0-4	Not specified	ACh	0/3	4.6	N/A	43	NS
		33	N/A				AT	0/5	3.7	N/A		
Hoffman[22]	1977-80	27	16/11	IV	0-4	Yes	$CAMP_1$-L	0/4	7.3	23	N/A	.13
		29	17/12				M-L > AC	0/1	3.5	10	N/A	
Krook[26]	1977-81	53	37/16	III/IV/r	0-3	Not specified	CAP	7/12	7.9	27	105	.88
		53	36/17				$MACC_1$	4/14	7.5	27		
Davis[11]	1978-79	23	46/4	IV	0-3	Not specified	CAP(50)	0/1	3.5	2	N/A	.3
		27	(overall)				CAP(100)	0/2	5.0	12	N/A	
Gralla[20]	1978-79	41	23/18	III/IV	0-2	Yes	VdP(60)	3/16	N/A	N/A	N/A	N/A
		40	25/15				VdP(120)	5/11	N/A	N/A		
Ruckdeschel[40]	1978-79	77	53/24	IV	0-2	No	HAM	2/8	5.1	N/A	N/A	NS
		77	52/25				$CAMP_1$	5/12	4.4	N/A	N/A	
Einhorn[15]	1978-81	51	N/A	III/IV	0-2	Not specified	CAM	2/9	7.4	31	45	.34
		53	N/A				C → A → M	1/4	5.7	30	47	
Robert[38]	1978-81	185	N/A	III/IV	0-2	Yes	AC	1/6	6.3	21	N/A	NS
		163	N/A				CAP	5/12	5.1	24	N/A	
		140	N/A				CAMF	2/16	6.2	24	N/A	
Ruckdeschel[41]	1979-79	99	67/32	IV	0-2	No	CAE	1/13	4.1	N/A	194	NS
		101	68/33				MiVb	2/11	4.1	N/A		
Kelsen[24]	1979-80	38	53/21	III/IV	0-2	Yes	PCVd	2/12	8.0	N/A	61	NS
		36	(overall)				PACVd	2/7	8.0	N/A		
Ruckdeschel[42]	1979-81	109	73/36	III/IV	0-2	Yes	AFP(30)	0/18	5.0	N/A	408	NS
		107	80/27				CAP(40)	1/23	5.4	N/A		
		112	81/31				CBP(30)	4/18	5.1	N/A		
		104	82/22				MiVbP(40)	5/22	5.4	N/A		
Miller[34]	1980-83	147	N/A	IV	0-3	Yes	FOMi	4/29	4.6	13	399	.04
		156	N/A				FOMi/CAP	5/23	5.3	20		
		149	N/A				CAP	1/21	5.5	13		.14
Kris[25]	1981-82	48	29/19	III/IV	0-2	Yes	VdP	2/6	8.5	N/A	N/A	.176
		49	36/13				VbP	3/7	12.3	N/A		
Dhiangra[12]	1981-83	67	46/21	III/IV/r	0-4	Yes	EP(60-80)	3/14	6.7	33	N/A	N/A
		62	46/16				VdP(120)	3/15	6.7	28	N/A	
		62	38/24				VdEP(50-80)	1/11	6.4	36	N/A	
Ruckdeschel[43]	1981-83	115	79/36	IV/r	0-2	No	$CAMP_1$	1/19	5.8	N/A	440	NS
		121	90/31				MiVbP	6/31	5.1	N/A		
		126	85/41				VdP(120)	6/26	6.0	N/A		
		124	87/37				EP(60)	2/23	6.1	N/A		
Krook[27]	1981-84	92	66/26	III/IV/r	0-2	Yes	MACC	0/6	4.9	17	146	.73
		94	56/38				FAM	0/8	5.6	13		
Einhorn[16]	1982-84	42	N/A	III/IV			Vd	0/6	4.1	14	111	.65
		41	N/A		0-2	Yes	VdP(120)	0/11	6.0	6	(overall)	
		41	N/A				VdP(60)Mi	0/8	3.9	7		
Weick[46]	1982-84	133	97/36	IV	0-3	Yes	FOMi/CAP	1/12	5.0	N/A	133	.61
		135	90/45				EP	3/19	5.3	N/A	134	
		136	105/31				PE MBGB	7/38	4.9	N/A	135	

Table 1. (Cont'd)

First Author (ref)	Study Years	No. of Patients per Arm	Sex Male/ Female (no.)	Disease Stage	PS	Brain Metastases	Regimens	No. of Responders CR/PR	Median Survival (months)	1-Year Survival (%)	No. of Deaths (n=)	
		142	111/31				PVb	4/30	5.9	N/A	141	
		134	99/35				PVbMi	5/17	5.0	N/A	133	
Niell[35]	1983-85	52	N /A	III/IV/r	0-2	Yes	MiMVbP	0/13	6.3	16	94	> .5
		53	N /A				Mi → Vb → M → BSC	0/10	5.4	6	(overall)	
Rapp[37]	1983-86	50	38/12	IIIb/IV	0-2	No	BSC	0/0	3.9	N/A	N/A	.01
		92	71/21				CAP	0/13	5.2	20	N/A	
		91	69/22				VdP	1/21	7.9	20	N/A	
Bonomi[6]	1984-85	176	125/51	IV/r	0-2	No	MiVbP	1/35	5.2	N/A	168	.09
		88	62/26				I → MiVbP (on progression)	1/4	6.0	N/A	88	
		88	59/29				Pb → MiVbP (on progression)	0/8	7.3	N/A	87	
		175	115/60				Vb iv D.1,2/P days 1-3 bolus.	2/21	5.8	N/A	168	
		172	128/44				MiVbP + CAMP	4/18	5.7	N/A	165	
Luedke[32]	1984-86	128	N /A	III/IV	0-2	Yes	Vd	0/1	3.4	13	N/A	.06
		122	N /A				VdMi	1/32	4.7	13	N/A	
		125	N /A				VdP	2/22	5.7	20	N/A	
Veeder[44]	1985-90	64	51/13	III/IV/r	0-3	Yes	Mi	0/17	3.7	8.2	N/A	.09
		69	55/14				MiVP	3/19	5.4	7.9	N/A	
Goldberg[19]	1987-88	54	32/22	III/IV/r	0-2	Yes	EP(30) iv days 1-3 bolus	0/11	4.9	17	N/A	.71
		54	33/21				E days 1-3/P(45) D.2-3 (civi)	0/13	5.2	26	N/A	
Gandara[18]	1988-90	105	70/35	IV	0-2	No	P(50)	0/13	6.9	21	103	.53
		108	88/20				P(100)	3/12	5.3	19	103	
		110	88/22				P(100)Mi	4/25	7.2	21	107	
Loprinzi[30]	1990-92	118	78/40	IIIb/IV	0-2	No	EP-X	2/18	8.0	26	88	.14
		119	82/37				EP-H	1/21	5.8	26	93	
Crawford[9]	1990-92	68	48/20	IV/r	0-1	No	F	0/2	5.1	16	N/A	.03
		143	102/41				Vn	0/17	6.9	25	N/A	
Bonomi[5]	1993-94	193	127/66	IIIb/IV			EP	ORR 12%	7.6	32		.05
		190	118/72		0-1	No	Pa(135) × 24h/P	ORR 27%	9.5	37	529	
		191	120/71				Pa(225) × 24h/P ı G-CSF	ORR 32%	10.1	40		
Wozniak[47]	1993-95	209	139/70	IIIb/IV	0-1	No	P	0/25	6.0	20	187	.002
		206	140/66				PVn	4/50	8.0	36	170	

NOTE. Patients had either unresectable locally-advanced disease, stage IV disease, or recurrent disease.

Abbreviations: PS, performance status; CR, complete response; PR, partial response; N/A, data not available; NS, not statistically significant; iv, intravenously; PO, orally; MTH/YR, month/year; M/F, male/female; A, doxorubicin; B, bleomycin; C, cyclophosphamide; C_1, CCNU (lomustine); Ch, chlorambucil; E, etoposide; F, fluorouracil; G-CSF, granulocyte colony stimulating factor; H, hydrazine; HEM, hexymethylmelamine; I, iproplatin; L, leucovorin; M, methotrexate; Mi, mitomycin C; MBGB, methylglyoxal bisguanylhydrazone; N, mechlorethamine; O, vincristine; P, cisplatin; Pa, paclitaxel; Pb, carboplatin; P_1, procarbazine; V, vinblastine; Vb, vinblastine; Vd, vindesine; Vn, vinorelbine; T, thiabendazole; X, placebo; BSC, best supportive care; →, followed by; r, recurrent.

trials increased from 77 (time period, 1973 to 1983) to 121 (time period, 1984 to 1994) ($P < .001$). Twenty-three trials (70%) included a platinum-based regimen in at least one arm of the trial. Eight of the nine (89%) trials in the 1984-to-1994 time period included a platinum-based regimen, compared with 15 of the 24 (63%) in the 1973-to-1983 time period.

The overall response rate with chemotherapy ranged from 1% (vindesine alone) to 46% (vindesine and cisplatin), with a median of 17% over all therapeutic regimens.[20,32] Three trials compared the response rate of low dose versus higher dose cisplatin. No significant difference was detected in the overall response rates between patients treated with low (50 mg/m^2 to 60 mg/m^2) or high doses (100 mg/m^2 to 120 mg/m^2) of cisplatin.[11,18,20] The overall response rates in the 128 patients treated on the two trials with single-agent cisplatin at 50 mg/m^2 were 4% (n = 1/23) and 12% (n = 13/105) compared with 7% (n = 2/27) and 14% (n = 15/108) in the 135 patients treated with single-agent cisplatin at 100 mg/m^2, respectively.[11,18] The third trial compared cisplatin at two dose levels (60 mg/m^2 *v* 120 mg/m^2) in association with a fixed dose of vindesine (3 mg/m^2). The overall response rate in the 41 patients who received the 60-mg/m^2 dose of cisplatin and vindesine was 46% compared with 40% in the 40 patients who received a 120-mg/m^2 dose of cisplatin plus vindesine.[20]

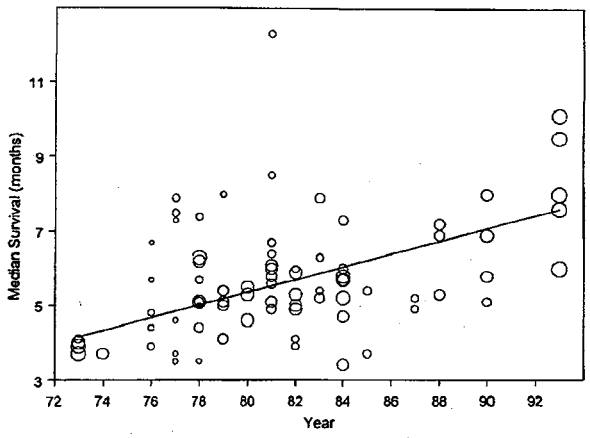

Fig 1. Median survival time of all patients treated on the phase III trials. Each study is represented by a circle, the size of each circle is proportional to the sample size of the treated patients (univariate analysis, $P < .0001$).

Survival Time of Patients

Eighteen trials included data on the number of patients who had died at the time of analysis (median percentage of patients deceased per trial at time of publication, 90%; range, 66% to 99%). The median of the median survival times of all patients treated on phase III trials initiated between 1973 to 1983 and between 1984 to 1994 were 5.2 months (range, 3.5 to 12.3 months) and 5.8 months (range, 3.4 to 10.1 months), respectively ($P < .001$; Fig 1). The median of median survivals of patients treated with platinum-based regimens (n = 5,317) compared with those treated with nonplatinum-containing regimens (n = 2,976) during the 33 trials were 5.8 months and 4.6 months, respectively ($P < .01$). The median of median survivals in patients treated on trials initiated between 1973 and 1983 were 5.6 months and 4.5 months for patients treated with a platinum-based regimens and nonplatinum-containing regimens, respectively ($P < .001$). The median of median survivals in patients treated on trials initiated between 1984 and 1994 were 6.0 months and 4.7 months for patients treated with a platinum-based regimens and nonplatinum-containing regimens, respectively ($P < .037$). Platinum-containing regimens were not introduced into phase III trials until 1976.[7] Analysis of the data following exclusion of the 2 trials initiated before 1975 did not impact on the time trend for improved survival over the subsequent time period ($P < .0001$; regression analysis).

A multivariate regression analysis that included the year of study initiation, platinum-based regimen indicator, treatment group indicator, brain metastases indicator, and the maximum performance status showed that platinum-based regimen and the year of study initiation (more recent years) were significantly related to median survival ($P = .0318$ and $P = .0214$, respectively).

Five (15%) of the 33 phase III trials showed a statistically significant difference in survival time, and all were in favor of the patient cohort that received the experimental therapy compared with the control group (median, 2 months; range, 0.9 to 2.7).[5,9,34,37,47] These five studies[5,9,34,37,47] included a significantly larger number of patients per treatment arm (median, 149 patients per arm; range, 50 to 209) than did the studies that did not show a significant difference in median survival time (median, 88 patients per arm; range, 19 to 197; Wilcoxon test $P = .026$). Four of the five trials involved platinum-based regimens. Wozniak et al compared cisplatin versus cisplatin and vinorelbine (median survival, 6 *v* 8 months, respectively).[47] Bonomi et al compared etoposide and cisplatin to 24-hour infusional paclitaxel at two dose levels in association with bolus cisplatin (median survival, 7.6 *v* 9.9 months, respectively).[5] Crawford et al compared fluorouracil and leucovorin versus vinorelbine (median survival, 5.1 *v* 6.9 months, respectively).[9] Rapp et al compared cyclophosphamide, doxorubicin, and cisplatin (CAP) versus vindesine and cisplatin (median survival, 5.2 *v* 7.9, respectively).[37] The study also included an arm that evaluated patients treated with best supportive care alone (median survival, 3.9 months), which was not included in this current analysis; however, for the sake of completeness, the results of the best supportive care arm are included in Table 1. Miller et al compared fluorouracil, vincristine, and mitomycin C (FOMi) versus CAP versus alternating FOMi/CAP (median survival, 4.6 *v* 5.5 *v* 5.3 months, respectively).[34] Nineteen of the other 28 trials that showed no significant difference in survival included platinum-based regimens.

SEER Database

Information on the median survival times of patients with distant non–small-cell lung cancer is available in the SEER population database. SEER survival data is recorded from the time of diagnosis, rather than initiation of therapy under review, and therefore the data on median survival is not directly comparable to the survival data from the phase III trials. In the SEER database, the median survival time of patients with distant non–small-cell lung cancer increased from a median of 6.9 months between 1973 and 1974 to 7.3 months for those treated between 1993 and 1994 ($P = .001$; Fig 2). There was also a significant increase in 3-year survival from 2.3% to 3.6% between 1973 through 1974 and 1993 through 1994, respectively (P value $< .0009$).

The survival of all patients with non–small-cell lung cancer in the SEER database was also examined to determine potential change. There was a statistically significant

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