

日本肺癌学会ゲフィチニブ使用ガイドライン説明資料

前治療のない進行非小細胞がんに対する ゲフィチニブの第2相試験

	国立がんセンター東病院 (仁保ら)	金沢大 (笠原ら)	中部呼吸器G (今泉ら)	計
適格例	40	30	30	100
奏効例 (PR)	12	10	8	30
不変 (SD)	16	9	6	31
増悪 (PD)	12	11	14+2	37+2
奏効率 (%)	30	33.3	26.7	30
MST (Mo)	14.5	10.0	NA	
1年生存率 (%)	55	43.3	NA	

未治療例に対して30%の奏効率を示す。
未治療例、既治療例奏効率に差を認めない。

Dr. 西條講演会(2005年2月)資料より
文献8-10

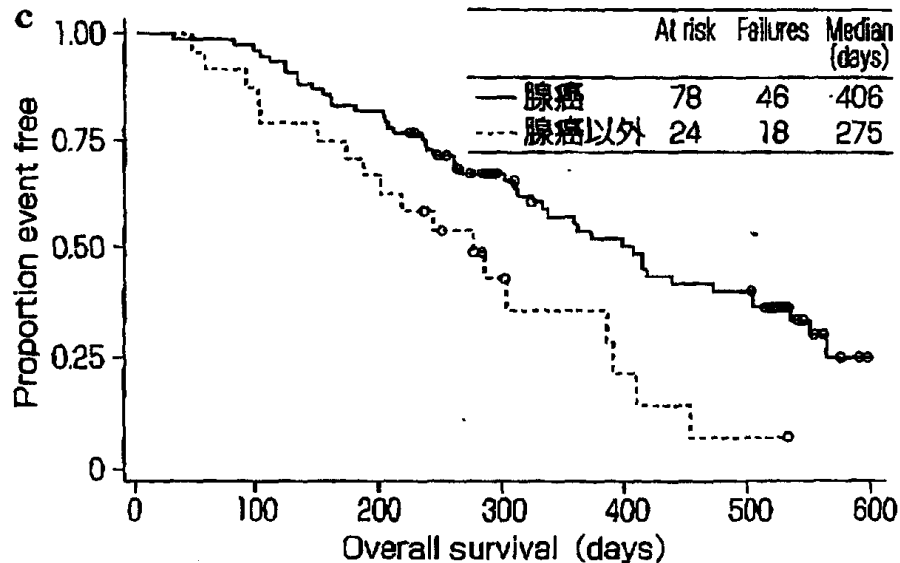
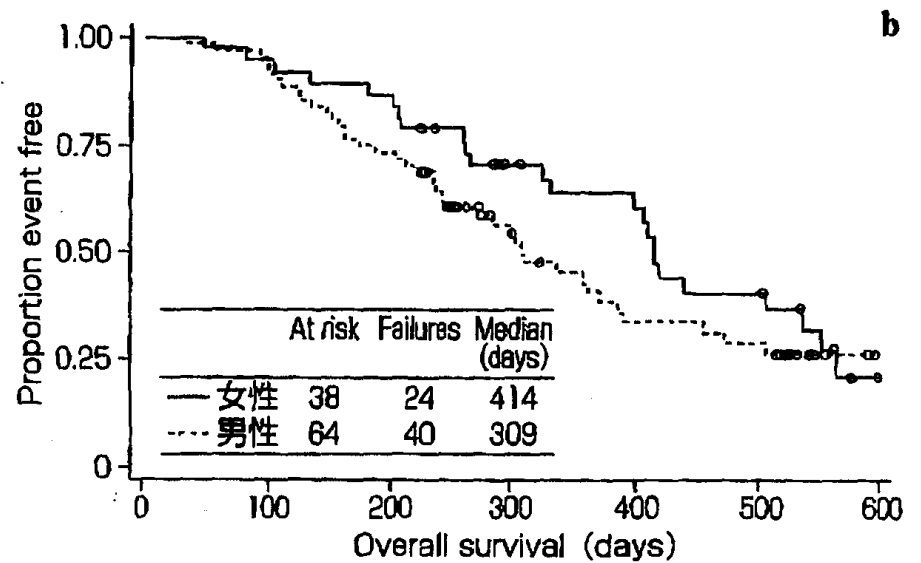
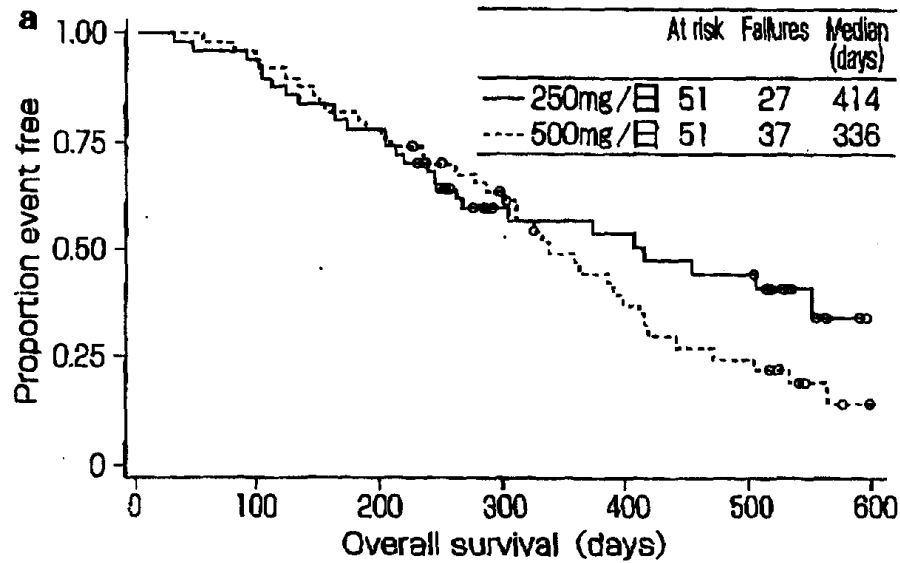
本邦におけるゲフィチニブ第 I 相試験奏効例一覧

Table 3. Demographics for the 5 patients experiencing partial responses

ZD1839 (mg/day)	Sex	Age (yrs)	Tumor	Previous treatment (month)	ZD1839 treatment cycles	Partial response duration (months)
225	F	51	NSCLC (adenocarcinoma)	cisplatin + docetaxel (2) cisplatin + etoposide (1) cyclophosphamide + etoposide + tegafur-uracil (1.5)	5	4
400	F	63	NSCLC (adenocarcinoma)	bleomycin (1) cisplatin + etoposide (1) etoposide (1)	13	11
525	F	70	NSCLC (adenocarcinoma)	cisplatin + etoposide (3) docetaxel (6)	2	1
525	F	68	NSCLC (adenocarcinoma)	vinorelbine + mitomycin C + cisplatin (10) docetaxel (2)	13 ^a	11 ^a
700	M	67	NSCLC (adenocarcinoma)	irinotecan + docetaxel (3)	12 ^a	10 ^a

^astill dosing

文献11、ASCO 2001から



別紙 3 (文献 12)

「癌と化学療法」
Vol. 31, No. 4, 2004年 } 51
567~573

図 1 用量, 性別および組織型別の生存曲線

a: 生存期間に及ぼす影響 (用量別, 日本人)

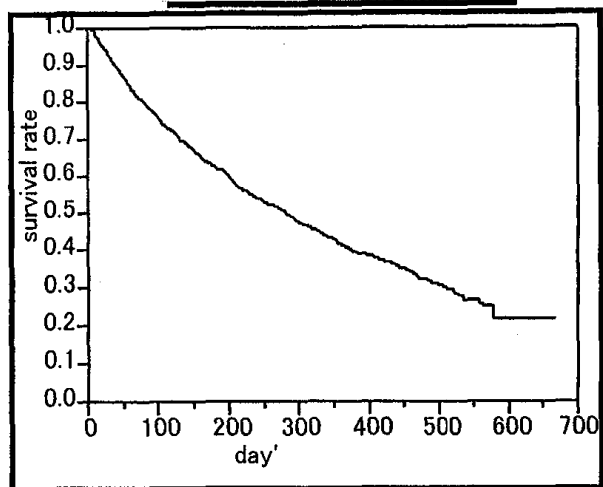
b: 生存期間に及ぼす影響 (性別, 日本人)

c: 生存期間に及ぼす影響 (組織型, 日本人)

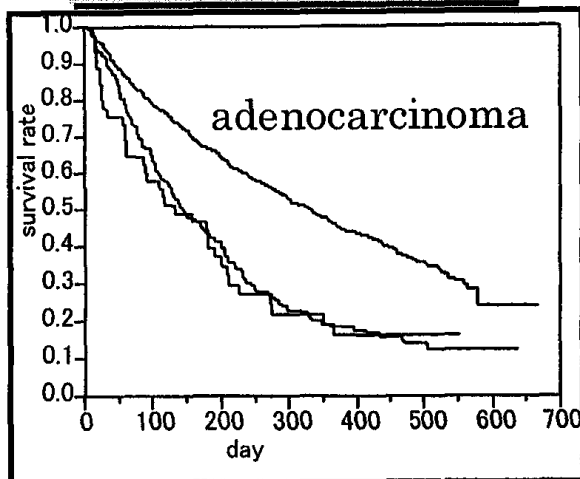
*ITT (intention to treat)₃ 解析 (250 mg 群+500 mg 群)

Survival after second-line setting gefitinib in patients with metastatic NSCLC (n=1055)

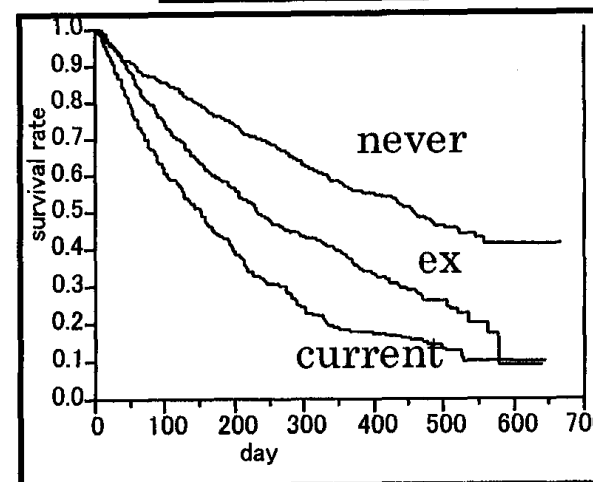
all patients



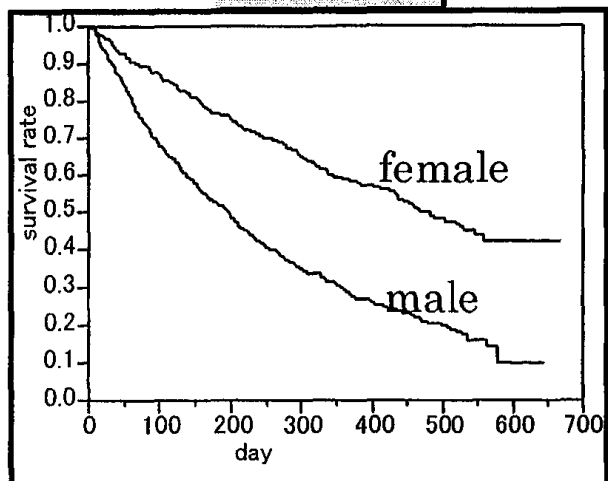
Histologic type



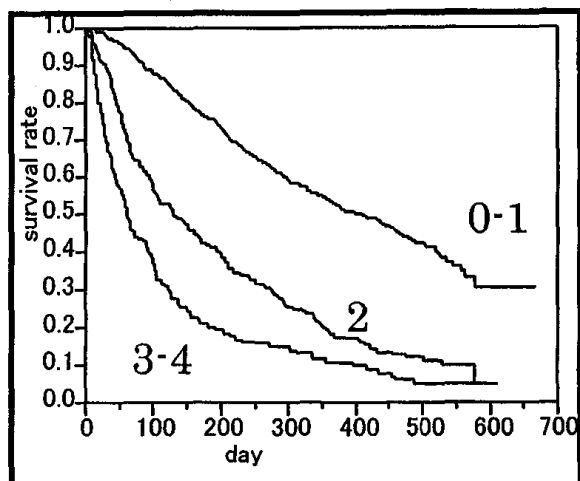
smoking



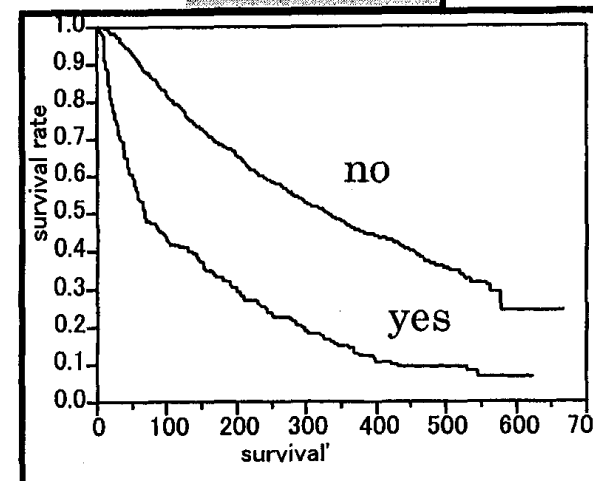
gender



ECOG PS



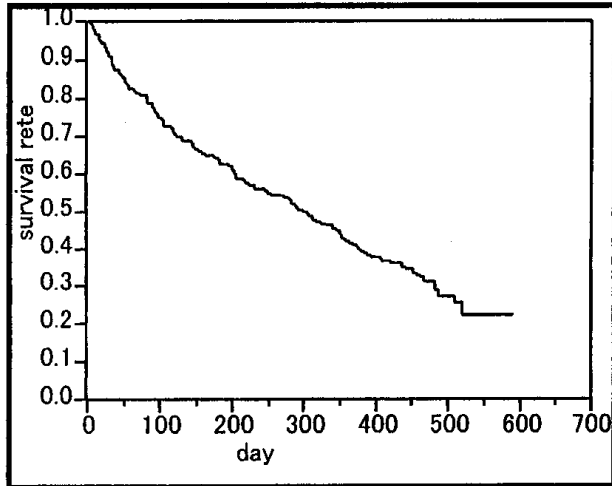
hypoxia



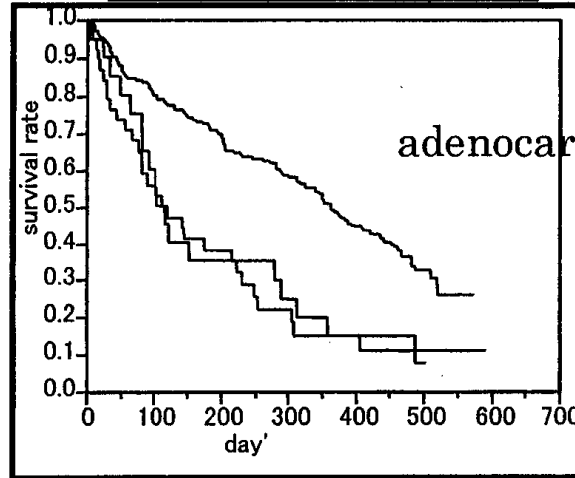
文献13、ASCO 2004から

Survival after first-line setting gefitinib in patients with metastatic NSCLC (n=254)

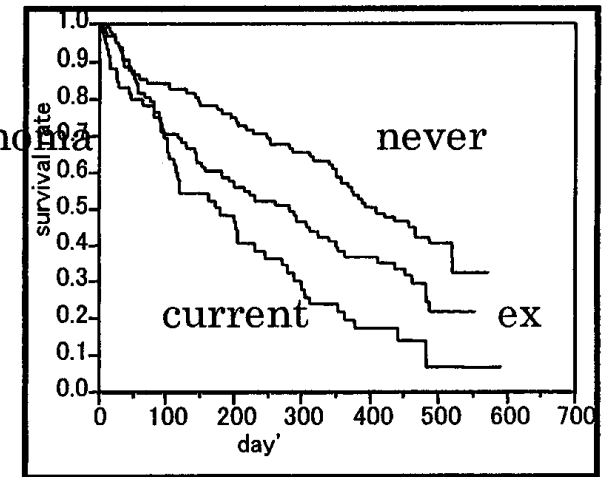
all patients



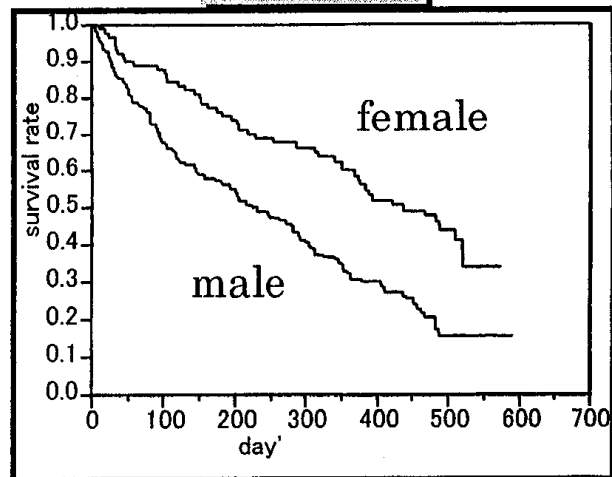
histologic type



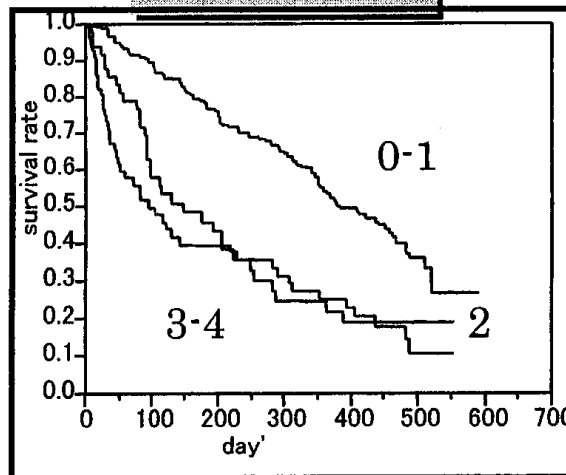
smoking



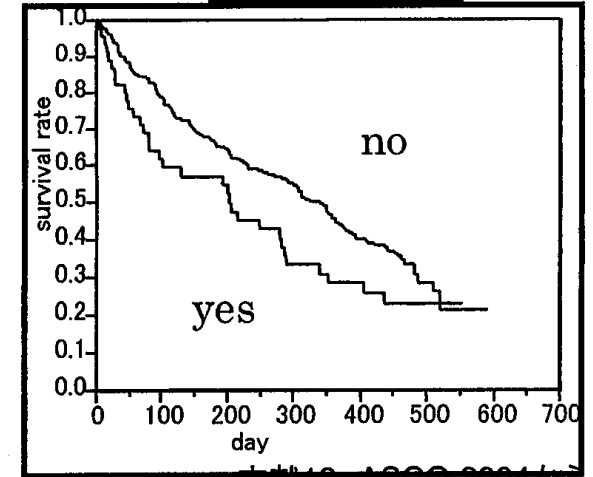
gender



ECOG PS



hypoxia



文献13、ASCO 2004から

Multivariate analysis of factors predicting survival after start of gefitinib treatment (Cox model)

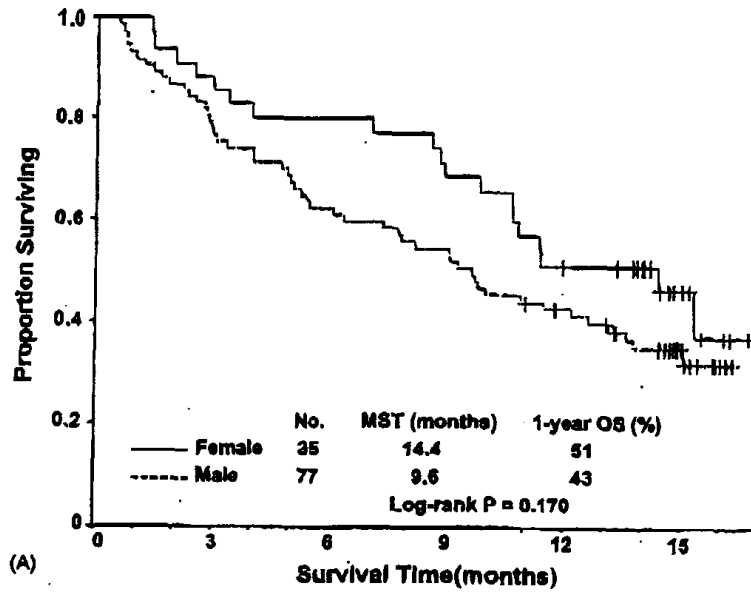
Variable	Hazard ratio	95%CI	P value
Male sex	1.66	1.37-2.02	<0.001
Metastatic disease	1.62	1.37-1.91	<0.001
PS 2-4	2.73	2.36-3.15	<0.001
Adenocarcinoma	0.68	0.58-0.79	<0.001
Hypoxia*	1.19	1.10-1.30	<0.001
Current/former smoker	1.43	1.20-1.70	<0.001

*NCI-CTC version II > Grade 1

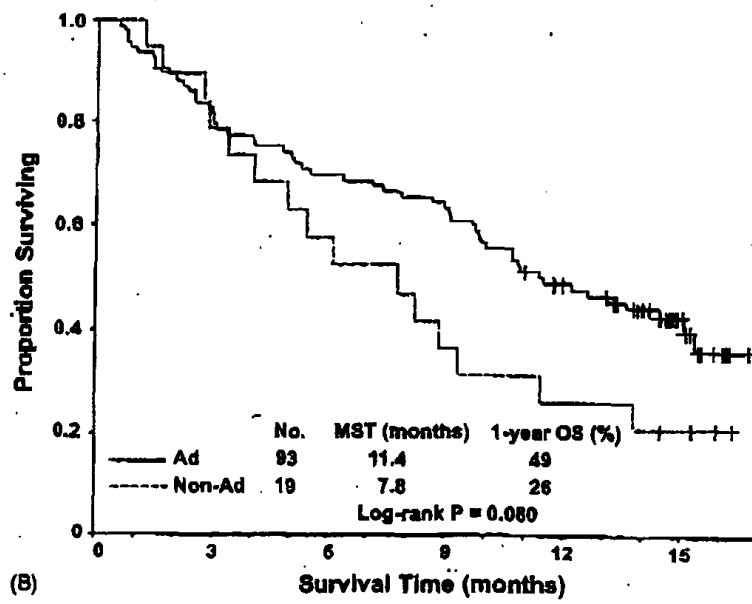
N = 1550; median survival time = 317 days; censored cases = 582

別紙
4-2
(文庫大14)

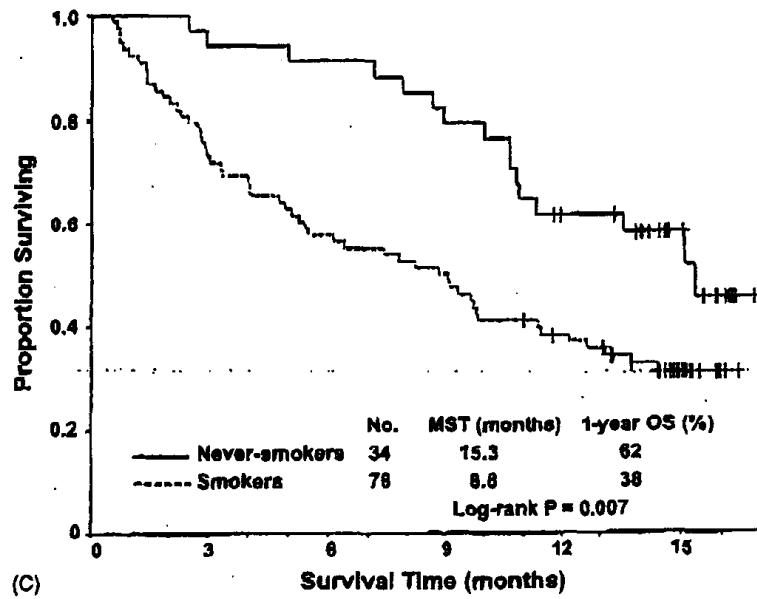
{「Lung
Cancer」
Vol 45
93-104,
2004年
5月}



(A)

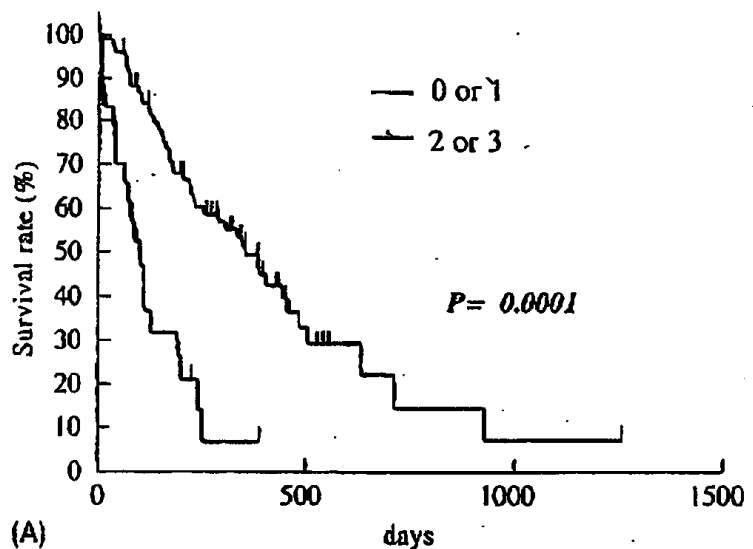


(B)

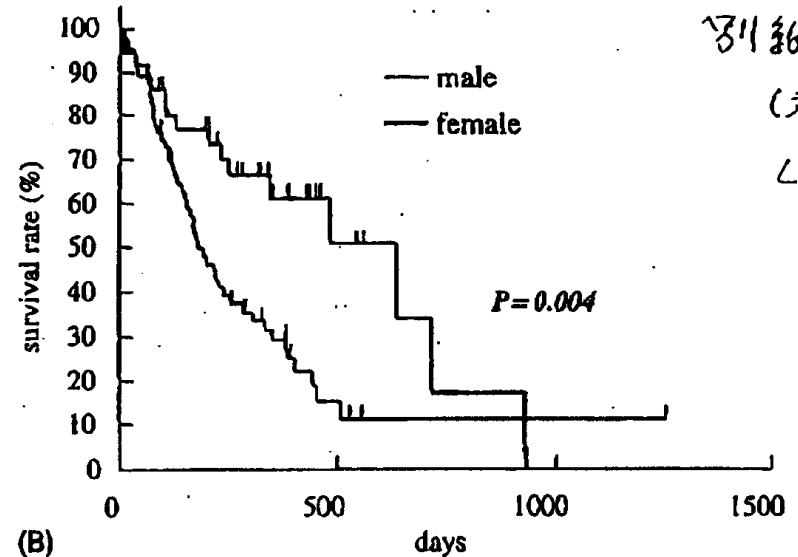


(C)

Fig. 2 Kaplan-Meier plot of overall survival according to subgroups: (A) female versus male; (B) adenocarcinoma versus non-adenocarcinoma; (C) never-smokers versus moderate/heavy smokers. MST: median survival time, OS: overall survival, Ad: adenocarcinoma.

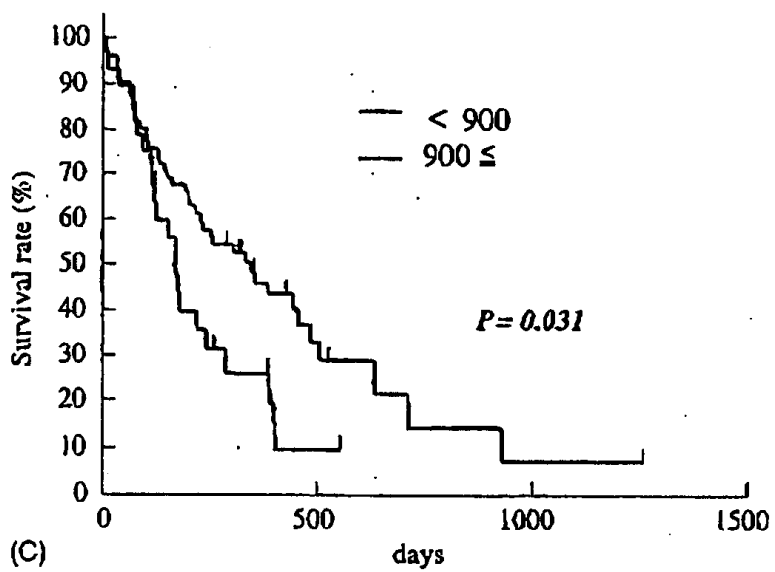


(A)

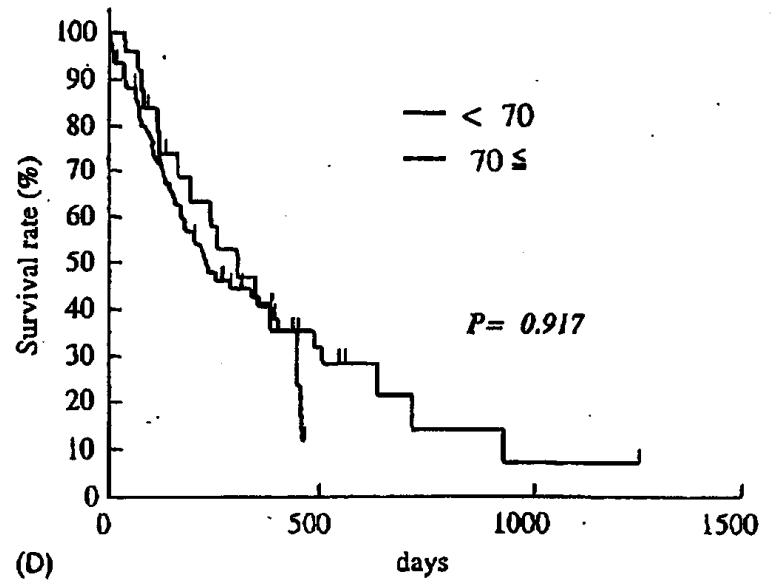


(B)

引数 4-3
(文献 15)
Lung Cancer
vol 46
~~92-104~~
247-254
2004 年刊



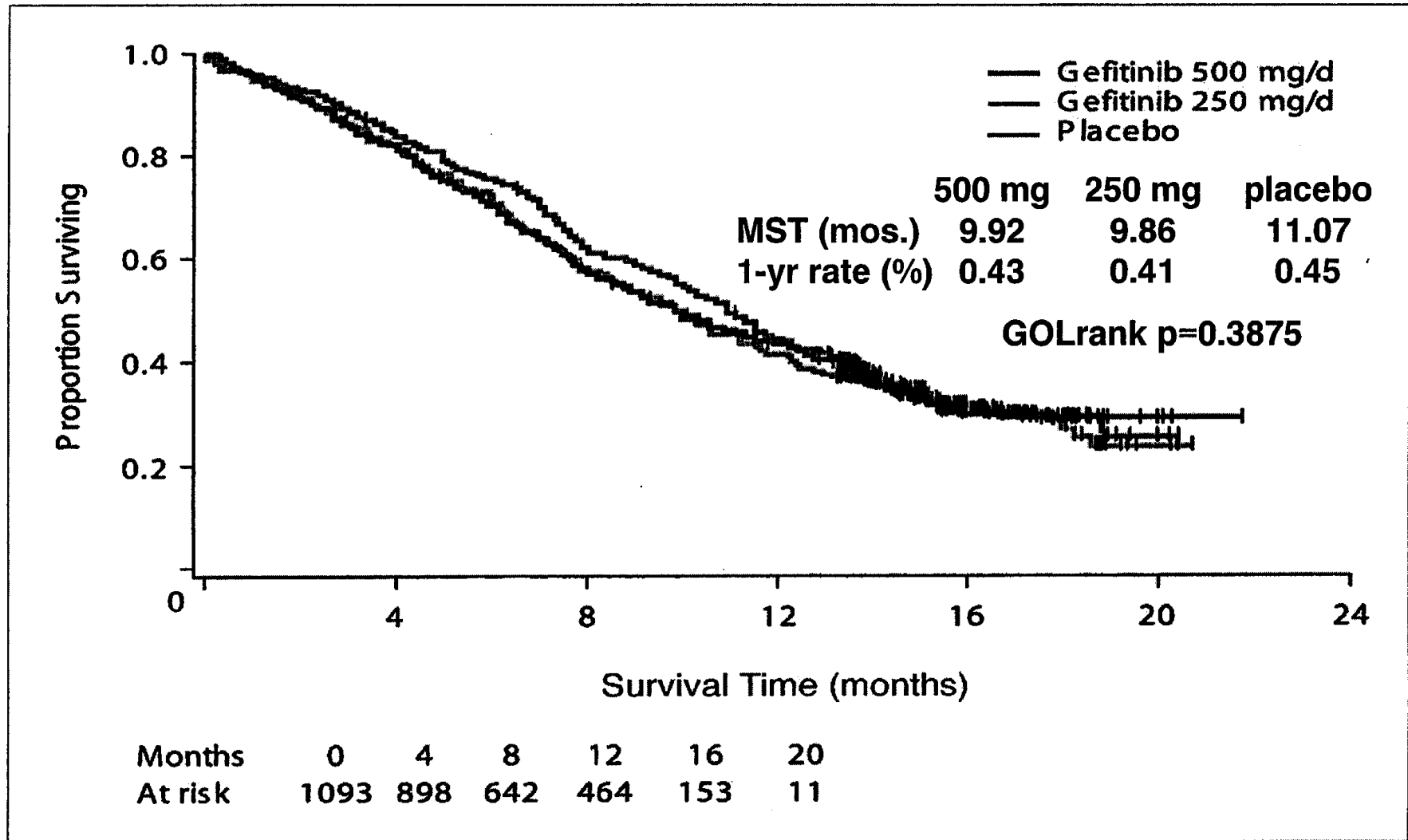
(C)



(D)

Fig. 2 A comparison of survival of: (A) PS 0, 1 vs. PS 2, 3; (B) gender: male vs. female; (C) smoking index: <900 vs. ≥900; and (D) age: <70 vs. ≥70.

Survival - INTACT 1



文献24、J Clin Oncol 2004; 22: 777-784から

Survival - INTACT 2

