

# 急性肺障害・間質性肺炎の発現時期と転帰

投与開始後4週間以内の発現症例の死亡率: やや高い傾向あり

項目	安全性評価 対象症例	観察人日	発現症例数	発生率 (/100人週)	転帰死亡以外		転帰死亡				
					症例数	発現症例数 中の割合(%)	症例数	発現症例数 中の割合(%)	安全性評価 対象症例 中の割合(%)	死亡となった 副作用の 発生率 (/100人週)	
	3322	206035	215	( 0.7 )	132	( 61.4 )	83	( 38.6 )	( 2.5 )	( 0.3 )	
観察期間	2週	3322	44433	63	( 1.0 )	39	( 61.9 )	24	( 38.1 )	( 0.7 )	( 0.4 )
	4週	2945	38247	72	( 1.3 )	38	( 52.8 )	34	( 47.2 )	( 1.2 )	( 0.6 )
	6週	2470	31527	30	( 0.7 )	18	( 60.0 )	12	( 40.0 )	( 0.5 )	( 0.3 )
	8週	2029	26338	28	( 0.7 )	20	( 71.4 )	8	( 28.6 )	( 0.4 )	( 0.2 )
	8週超	1633	65490	22	( 0.2 )	17	( 77.3 )	5	( 22.7 )	( 0.3 )	( 0.1 )
	不明	0	0	0		0		0			

## Multivariate analysis of risk of ILD (Logistic model)

Variable	Odds ratio	95%CI	P value
Male sex	3.17	1.24-9.98	0.028
Hypoxia*	1.85	1.05-3.18	0.029
Current/former smoker	4.38	1.72-13.79	0.005

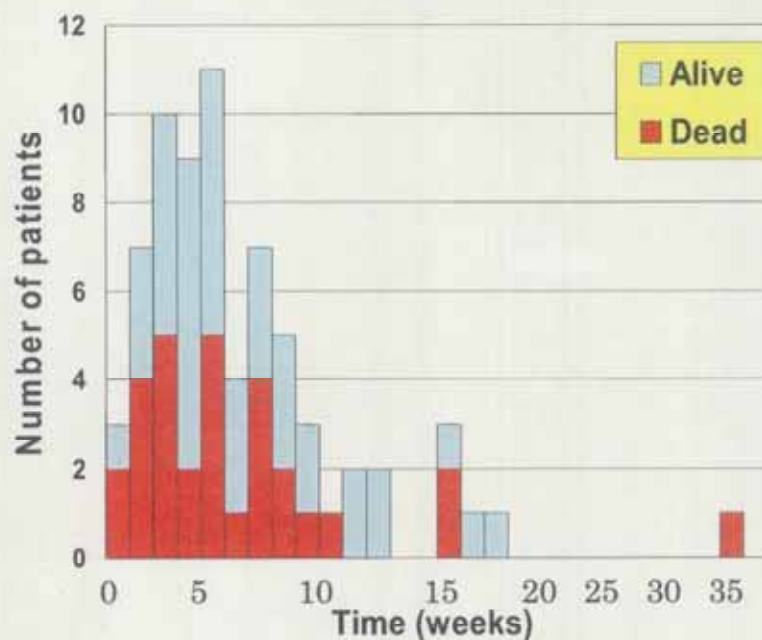
\*: NCI-CTC version II > Grade 1

## Estimated rates of ILD and death

sex	ILD	Death	Smoking	ILD	Death
Male	5.9%	2.8%	current/former	6.6%	3.0%
			never	1.8%	1.8%
Female	1.0%	0.2%	current/former	3.3%	0.8%
			never	0.4%	0.0%

文献13、ASCO 2004から

## Onset time as a prognostic factor in patients with gefitinib-induced ILD



Onset period	Outcome			Total	Mortality (%)
	Imp	NC	Death		
0-2 wks	3	0	6	9	67*
2-4 wks	12	0	7	19	37
4-6 wks	8	1	5	15	40
6+ wks	11	3	12	26	46
<b>Total</b>	<b>34</b>	<b>4</b>	<b>31</b>	<b>69</b>	<b>45</b>

Imp: improvement, NC: no change, \*: Significantly higher

### Multivariate analysis of prognostic factors in patients with ILD (Cox model)

Variable	Hazard ratio	95%CI	P value
PS 2-4	2.50	1.18-5.38	0.02
Onset within 2 weeks	2.65	0.96-6.40	0.06