

# GEFITINIB AS FIRST-LINE THERAPY FOR ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER PATIENTS IN SOUTHERN TAIWAN

Cheng-Ta Yang,<sup>1\*</sup> Jen-Yu Hung,<sup>2,3\*</sup> Chun-Liang Lai,<sup>4,5</sup> Hsin-Chia Hung,<sup>6</sup> Yung-Fa Lai,<sup>7</sup> Meng-Chih Lin,<sup>8</sup> Jiunn-Min Shieh,<sup>9</sup> and Ming-Shyang Huang<sup>2,3</sup>

<sup>1</sup>Department of Respiratory Care, College of Medicine, Chang Gung University, <sup>2</sup>Division of Pulmonary & Critical Care Medicine, Department of Internal Medicine, Kaohsiung Medical University Hospital, <sup>3</sup>Faculty of Medicine, College of Medicine, Kaohsiung Medical University, <sup>4</sup>Department of Internal Medicine, Buddhist Dalin Tzu Chi General Hospital, Chiayi; <sup>5</sup>Department of Medicine, College of Medicine, Tze Chi University, Hualien; <sup>6</sup>Graduate Institute of Health Care, MeiHo Institute of Technology, <sup>7</sup>Department of Internal Medicine, E-Da Hospital, I-Shou University, <sup>8</sup>Division of Pulmonary & Critical Care Medicine, Department of Internal Medicine, Chang Gung Memorial Hospital-Kaohsiung Medical Center, Chang Gung University, College of Medicine, Kaohsiung; and <sup>9</sup>Department of Internal Medicine, Chi Mei Medical Center, Tainan, Taiwan.

Gefitinib, a selective epidermal growth factor receptor tyrosine kinase inhibitor, is effective in treating patients with non-small cell lung cancer (NSCLC) after unsuccessful chemotherapy. However, survival outcomes and predictors for its effectiveness in chemotherapy-naïve NSCLC patients are still not clear. The goal of this study was to investigate the response and survival rates and identify the predictive factors for patients with advanced or metastatic disease receiving gefitinib as first-line therapy. We retrospectively analyzed the response and survival rates of patients with advanced or metastatic NSCLC who had received gefitinib as first-line therapy across six medical institutes in Southern Taiwan between May 2004 and April 2006. The relationship between the response and survival rates to the known predictive factors for gefitinib response and survival was also investigated. A total of 97 patients (65 females and 32 males) were enrolled in this study. Seventy-four patients (76%) had never smoked. Eighty-eight patients (91%) had adenocarcinoma or bronchioloalveolar cell carcinoma. The objective response rate was 56% and the disease control rate (partial response plus stable disease) was 76%. Only poor performance status (Eastern Cooperative Oncology Group score, 3–4) was statistically significantly associated with overall response in this study. The 1-year survival rate was 77%. We suggest that first-line gefitinib monotherapy is promising in some subgroups of Asian patients with NSCLC. Further randomized controlled studies are needed to validate the effectiveness of first-line gefitinib therapy.

**Key Words:** gefitinib, non-small cell lung cancer, target therapy  
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Address correspondence and reprint requests to: Professor Ming-Shyang Huang, 100 Tzyou 1<sup>st</sup> Road, Kaohsiung 807, Taiwan.

E-mail: shyang@kmu.edu.tw

\*Cheng-Ta Yang and Jen-Yu Hung contributed equally to this work.

ELSEVIER

Lung cancer is one of the most common malignancies in many countries, including Taiwan. It remains the leading cause of cancer-related deaths in these countries [1,2]. The incidence of lung cancer is increasing annually, particularly among women [3]. Lung cancer is classified according to histological type as either small cell carcinoma or non-small cell lung cancer (NSCLC), the latter accounting for about 85% of all lung cancer cases [4,5], and consists of large cell carcinoma, adenocarcinoma, and squamous cell carcinoma.

Surgery, chemotherapy and radiotherapy are the primary treatment options for patients with NSCLC. Unfortunately, less than 20% of patients are suitable for potentially curative resection at presentation [6,7]. Around 70% of patients have locally advanced or disseminated disease at presentation, are not candidates for surgery [8] and are generally treated with palliative chemotherapy. The prognosis for patients not suitable for surgery remains unsatisfactory. Thus it is necessary to explore new therapeutic modalities to treat this devastating disease.

Gefitinib [Iressa (ZD1839); AstraZeneca Pharmaceuticals, Wilmington, DE, USA] is a selective epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor. After two large-scale phase II studies showing that gefitinib was beneficial in terms of response for patients with locally advanced or metastatic NSCLC who had previously received platinum-based chemotherapy [9,10], gefitinib was approved for the treatment of patients with previously treated advanced NSCLC in Japan, the United States of America and other countries [11]. Unfortunately, two multinational, randomized, double-blind, placebo-controlled phase III studies failed to demonstrate improved tumor response rate or survival rate for gefitinib in combination with standard platinum-based first-line chemotherapeutic regimens [12,13]. In addition, in a large randomized, placebo-controlled trial, gefitinib monotherapy failed to increase survival of chemotherapy-resistant patients [14]. However, in the same study, a statistically significant improvement in overall survival was noted in gefitinib-treated patients over placebo-treated patients with Asian ethnicity. These findings are consistent with the better response rate reported in Japanese patients in one of the phase II studies, the Iressa Dose Evaluation in Advanced Lung Cancer study [9]. In addition to the beneficial effects of gefitinib in chemotherapy-treated NSCLC patients, there have been several small, single-arm

studies in Asia showing the effectiveness of gefitinib in chemotherapy-naïve NSCLC patients [15–17].

Based on its effectiveness and good safety profile, an increasing number of patients with NSCLC in Taiwan have been using gefitinib as first-line therapy. In this study, we retrospectively analyzed the response and 1-year survival of patients with advanced or metastatic NSCLC who used gefitinib as first-line treatment across six medical institutes in Southern Taiwan. We examined the response and survival rates of these patients and the relationship between these rates and known predictive factors.

## METHODS

### *Patients*

All stage IIIB or IV NSCLC patients who received gefitinib as their first-line therapy at one of the six institutes in Southern Taiwan between May 2004 and April 2006 were included in this study. Their medical charts, images and image reports were reviewed. Patients were required to meet the following inclusion criteria: cytological or histological diagnosis of NSCLC [stage IIIB (with pleural effusion) or IV disease] and an age > 18 years. Patients must also have had measurable lesion(s). Patients who were administered gefitinib for less than 1 month and patients with symptomatic brain metastases were excluded from this study. Clinical data were collected from each institute's registry and included the patient's sex, age, Eastern Cooperative Oncology Group (ECOG) performance status, tumor histology, tumor stage, smoking status, dates of diagnosis, treatment, progression, death and follow-up.

### *Efficacy assessment*

Objective tumor response was assessed by chest X-rays of these patients performed at least 4 weeks after treatment, using the Response Evaluation Criteria in Solid Tumors system [18], which defined responses as complete response, partial response (PR), stable disease (SD) or progressive disease (PD).

### *Statistical methods*

A total of 97 patients met the criteria and were included in this study. Two definitions of response to gefitinib were used in this study: overall response and disease stabilization. The associations between these

and factors such as sex, smoking history, histology, disease stage and performance status were examined with  $\chi^2$  tests and odds ratios were calculated using logistic regression to evaluate associations with the response. Logistic regression models, including factors with  $p$  values  $<0.15$ , were developed to adjust for possible confounding effects and identify the major predictors for the response. For survival status, 1-year survival rates were computed and the Cox proportional-hazards model was used to determine the associations of these factors with mortality. Adjusted hazard ratios were calculated, and these included factors with  $p$  values  $<0.15$ .

## RESULTS

Of these 97 patients, no patient had a complete response. For 54 patients, the best response to gefitinib was PR, corresponding to an objective response rate of 56%. Another 19 patients had SD and the overall disease control rate (PR+SD) was 76%. The characteristics of these patients are summarized in Table 1. For overall response, sex, smoking history, stage and poor performance status seemed to be predictors.

However, only poor performance status (ECOG score, 3–4) was statistically significantly associated with overall response [odds ratio: 0.26, 95% confidence interval (CI): 0.09–0.75,  $p=0.009$ ]. For disease stabilization, sex, performance status, smoking history and stage seemed to be predictors, but sex was not statistically related to disease stabilization.

For survival status, the 1-year survival rates and hazard ratios are shown in Table 2. For all 97 patients, the mean follow-up time was 43.2 weeks and the mean 1-year survival rate was 77%. Predictors such as sex, ECOG performance status, smoking status and stage seemed to be associated with survival. The hazard ratio (95% CI) was 2.34 (0.90–6.07) for sex (male *vs.* female); 8.32 (3.10–22.36) for ECOG performance status (0–2 *vs.* 3–4); 3.02 (1.16–7.85) for smoking status (ever smoker *vs.* never smoker) and 7.36 (0.95–55.88) for stage (IIIB *vs.* IV). Patients who showed response or stabilization with gefitinib also had a higher 1-year survival rate compared with patients with PD (94% and 89.7% *vs.* 45.9%, respectively). The HR (95% CI) was 0.06 (0.01–0.26) for patients with PR versus patients with PD and 0.14 (0.05–0.38) for patients with SD versus patients with PD.

**Table 1.** Characteristics and gefitinib treatment response of the patients\*

Characteristics	Patients	Overall response	OR (95% CI)	$p$	Disease stabilization	OR (95% CI)	$p$
Total	97 (100)	54 (56)					
Sex							
Female	65 (67)	40 (62)	1		52 (80)	1	
Male	32 (33)	14 (44)	0.49 (0.21–1.15)	0.10	21 (66)	0.48 (0.19–1.23)	0.12
Age (yr)							
<70	40 (41)	20 (50)	1		28 (70)	1	
$\geq$ 70	57 (59)	34 (60)	1.48 (0.65–3.34)	0.35	45 (79)	1.61 (0.64–4.07)	0.32
ECOG PS							
0–2	77 (74)	48 (62)	1		64 (83)	1	
3–4	20 (26)	6 (30)	0.26 (0.09–0.75)	0.009	9 (45)	0.17 (0.006–0.48)	<0.001
Smoking status							
Never smoker	74 (76)	45 (61)	1		61 (82)	1	
Current/former smoker	23 (24)	9 (39)	0.41 (0.16–1.08)	0.07	12 (52)	0.23 (0.08–0.64)	0.003
Histology							
Adenocarcinoma	88 (91)	51 (58)	1		67 (76)	1	
Non-adenocarcinoma	9 (9)	3 (33)	0.36 (0.09–1.55)	0.16	6 (67)	0.63 (0.14–2.73)	0.53
Stage							
IIIB	24 (25)	15 (63)	1		22 (92)	1	
IV	73 (75)	39 (53)	0.69 (0.27–1.77)	0.44	51 (70)	0.21 (0.05–0.98)	0.03

\*Data presented as  $n$  (%) or mean (range). OR = odds ratio; CI = confidence interval; ECOG PS = European Cooperative Oncology Group performance status.

**Table 2.** Overall survival in each subgroup of the patients

Characteristics	<i>n</i>	Mean follow up time (wk)	1-year survival rate (%)	HR (95% CI)	<i>p</i>
Total	97	43.2	77.34		
Sex					
Female	65	44.0	83.40	1	
Male	32	41.0	66.40	2.34 (0.90–6.07)	0.08
Age (yr)					
<70	40	40.0	76.50	1	
≥70	57	46.0	77.60	0.90 (0.34–2.37)	0.83
ECOG PS					
0–2	77	47.0	90.60	1	
3–4	20	30.0	15.30	8.32 (3.10–22.36)	<0.001
Smoking status					
Never smoker	74	44.0	83.60	1	
Current/former smoker	23	40.0	60.60	3.02 (1.16–7.85)	0.02
Histology					
Adenocarcinoma	88	43.0	76.20	1	
Non-adenocarcinoma	9	43.0	88.90	0.62 (0.08–4.66)	0.62
Stage					
IIIB	24	54.0	100	1	
IV	73	40.0	68.60	7.36 (0.97–55.88)	0.053
Response					
PD	24	36.14	45.90	1	
SD	19	35.38	78	0.45 (0.14–1.42)	0.17
Partial response	54	49.09	94	0.06 (0.01–0.26)	<0.001
Disease stabilization (PD+SD)	73	45.52	89.70	0.14 (0.05–0.38)	<0.001

HR = hazard ratio; CI = confidence interval; ECOG PS = Eastern Cooperative Oncology Group performance status; PD = progressive disease; SD = stable disease.

**Table 3.** Multivariate models show the adjusted odds ratios for response and disease stabilization and adjusted hazard ratios for survival status

Patient subset	Response OR (95% CI)	<i>p</i>	Disease stabilization OR (95% CI)	<i>p</i>	Death HR (95% CI)	<i>p</i>
Sex (male vs. female)	–		–		2.11 (0.80–5.55)	0.13
Smoking (ever vs. never)	0.39 (0.14–1.06)	0.07	0.22 (0.07–0.65)	0.007	–	
Histology (non-adenocarcinoma vs. adenocarcinoma)	0.26 (0.06–1.16)	0.07	–		–	
Stage (IIIB vs. IV)	–		–		5.21 (0.67–40.26)	0.11
ECOG PS	0.24 (0.08–0.72)	0.01	0.16 (0.05–0.49)	0.001	6.46 (2.40–17.43)	<0.001

OR = odd ratios; HR = hazard ratio; CI = confidence interval; ECOG PS = Eastern Cooperative Oncology Group performance status.

The multivariate models that included factors with *p* value <0.15 are shown in Table 3. For overall response, we found that patients who had ever smoked, had non-adenocarcinoma histology or poor ECOG performance status were less likely to respond

to gefitinib, while patients who had ever smoked or those with poor ECOG performance status were less likely to show disease stabilization with gefitinib treatment. For survival, we found that patients who were male or patients with poor ECOG performance status

had poor survival when receiving gefitinib as first-line treatment.

## DISCUSSION

In this study, the overall response rate and disease control rate were 56% and 76%, respectively, both of which are higher than those in other reports [19–22], where the response rates ranged from 15.2% to 42%, and the disease control rates ranged from 25.8% to 60%. Gefitinib is effective in treating NSCLC patients with EGFR gene mutations [23–26]. Females, never smokers, adenocarcinoma histology and patients of Asian origin are more likely to have such mutations [26,27]. Although EGFR gene mutations were not determined in this study, the linkage between EGFR gene mutations and female sex, no smoking history, adenocarcinoma and East Asian patients is well-known. This may explain why the response rate and the disease control rate in this study are still less than those reported in the phase II study by Lee et al [15]. They reported better overall response (69%) and disease control (80%) rates for 37 patients with NSCLC (all with adenocarcinoma histology, no smoking history and predominantly female). Because our study was conducted retrospectively by reviewing patients' medical charts between 2004 and 2006, pre-selection bias should be considered for the high response rate and disease control rate.

None of the well-known predictive factors in the literature, such as female sex, smoking status or histology, significantly predicted the overall response or disease stabilization associated with gefitinib in our study. Although patients with these factors still seemed to respond better to gefitinib than patients without these factors in our study, only smoking status was a statistically significant predictor for disease stabilization (PD and SD). The small sample size and selection bias might be reasons why these factors were not statistically significant predictors.

ECOG performance status, originally not considered a predictive factor for overall response or disease stabilization, was thus correlated in this study. Similarly, Hoang et al reported that performance status and another five independent factors were correlated with response rate and survival time for patients with stage IIIB or IV NSCLC receiving third-generation chemotherapy regimens [28]. In addition,

in a recent study of chemotherapy-naïve patients with advanced or metastatic NSCLC treated with gefitinib in East Asia, the overall response rate and disease stabilization rate for patients with good (ECOG score, 0–2) versus poor performance status (ECOG score, 3–4) were 52% versus 28% and 70% versus 45%, respectively [21]. Thus the correlation between performance status and overall response and disease stabilization in patients with NSCLC treated with gefitinib seems reasonable, although further studies are warranted to validate its significance.

The log-rank test was used to compare the 1-year survival rates in each subgroup. As above, patients who never smoked or patients with better ECOG performance status had a better survival after gefitinib therapy. Although female patients had a better 1-year survival rates than males (83.40% vs. 66.40%,  $p=0.08$ ), statistical significance was not achieved, which could be due to the small sample size of this study. Patients with adenocarcinoma are predicted to show better survival than patients with other types of lung cancer [29]. Unfortunately, we did not achieve similar results to other studies. The 1-year survival rates for patients with adenocarcinoma and non-adenocarcinoma were 76.2% and 88.9%, respectively. Nine patients were diagnosed with non-adenocarcinoma in this study. One of these patients was diagnosed with squamous cell carcinoma, and the other eight patients did not have a definite histological diagnosis because of small specimens, or only had cytological diagnosis. Some of these patients might have had adenocarcinoma. Thus the beneficial effects of adenocarcinoma might not be validated in this study because of the small size of the comparative group or the absence of a comparative group.

Kaplan-Meier survival analysis also demonstrated that patients with PR or SD had significantly better survival than patients with PD. Multivariate analysis showed that only patients with better performance status had better treatment response and survival.

In this multicenter, retrospective analysis, gefitinib showed excellent anti-tumor effects when prescribed as first-line therapy against advanced or metastatic NSCLC. Considering our data and the results from other studies, first-line gefitinib monotherapy offers a promising therapy for some subgroups of Asian patients with NSCLC. Further randomized controlled studies are needed to validate the effectiveness of first-line gefitinib therapy and its cost-effectiveness

compared with traditional first-line chemotherapeutic regimens.

## REFERENCES

1. Loeb LA, Ernster VL, Warner KE, et al. Smoking and lung cancer: an overview. *Cancer Res* 1984;44:5940–58.
2. Silverberg E. Cancer statistics, 1985. *CA Cancer J Clin* 1985;35:19–35.
3. Jemal A, Chu KC, Tarone RE. Recent trends in lung cancer mortality in the United States. *J Natl Cancer Inst* 2001;93:277–83.
4. Ihde DC. Chemotherapy of lung cancer. *N Engl J Med* 1992;327:1434–41.
5. Hoffman PC, Mauer AM, Vokes EE. Lung cancer. *Lancet* 2000;355:479–85.
6. Chen WJ. The clinical and experimental studies on “the therapeutic principle of huoxue huayu” in traditional Chinese medicine. *Proc Chin Acad Med Sci Peking Union Med Coll* 1988;3:236–8.
7. Martini N, Flehinger BJ. The role of surgery in N2 lung cancer. *Surg Clin North Am* 1987;67:1037–49.
8. Ihde DC, Minna JD. Non-small cell lung cancer. Part I: biology, diagnosis, and staging. *Curr Probl Cancer* 1991; 15:61–104.
9. Fukuoka M, Yano S, Giaccone G, et al. Multi-institutional randomized phase II trial of gefitinib for previously treated patients with advanced non-small-cell lung cancer (The IDEAL 1 Trial) [corrected]. *J Clin Oncol* 2003;21:2237–46.
10. Kris MG, Natale RB, Herbst RS, et al. Efficacy of gefitinib, an inhibitor of the epidermal growth factor receptor tyrosine kinase, in symptomatic patients with non-small cell lung cancer: a randomized trial. *JAMA* 2003;290:2149–58.
11. Blackledge G, Averbuch S. Gefitinib (‘Iressa’, ZD1839) and new epidermal growth factor receptor inhibitors. *Br J Cancer* 2004;90:566–72.
12. Giaccone G, Herbst RS, Manegold C, et al. Gefitinib in combination with gemcitabine and cisplatin in advanced non-small-cell lung cancer: a phase III trial—INTACT 1. *J Clin Oncol* 2004;22:777–84.
13. Herbst RS, Giaccone G, Schiller JH, et al. Gefitinib in combination with paclitaxel and carboplatin in advanced non-small-cell lung cancer: a phase III trial—INTACT 2. *J Clin Oncol* 2004;22:785–94.
14. Thatcher N, Chang A, Parikh P, et al. Gefitinib plus best supportive care in previously treated patients with refractory advanced non-small-cell lung cancer: results from a randomised, placebo-controlled, multicentre study (Iressa Survival Evaluation in Lung Cancer). *Lancet* 2005;366:1527–37.
15. Lee DH, Han JY, Lee HG, et al. Gefitinib as a first-line therapy of advanced or metastatic adenocarcinoma of the lung in never-smokers. *Clin Cancer Res* 2005;11:3032–7.
16. Kimura H, Kasahara K, Shibata K, et al. EGFR mutation of tumor and serum in gefitinib-treated patients with chemotherapy-naive non-small cell lung cancer. *J Thorac Oncol* 2006;1:260–7.
17. Niho S, Kubota K, Goto K, et al. First-line single agent treatment with gefitinib in patients with advanced non-small-cell lung cancer: a phase II study. *J Clin Oncol* 2006;24:64–9.
18. Therasse P, Arbuck SG, Eisenhauer EA, et al. New guidelines to evaluate the response to treatment in solid tumors. European Organization for Research and Treatment of Cancer, National Cancer Institute of the United States, National Cancer Institute of Canada. *J Natl Cancer Inst* 2000;92:205–16.
19. Su WP, Yang CH, Yu CJ, et al. Gefitinib treatment for non-small cell lung cancer—a study including patients with poor performance status. *J Formos Med Assoc* 2005; 104:557–62.
20. Chang GC, Chen KC, Yang TY, et al. Activity of gefitinib in advanced non-small-cell lung cancer with very poor performance status. *Invest New Drugs* 2005;23:73–7.
21. Yang CH, Shih JY, Chen KC, et al. Survival outcome and predictors of gefitinib antitumor activity in East Asian chemo-naive patients with advanced nonsmall cell lung cancer. *Cancer* 2006;107:1873–82.
22. Lin WC, Chiu CH, Liou JL, et al. Gefitinib as front-line treatment in Chinese patients with advanced non-small-cell lung cancer. *Lung Cancer* 2006;54:193–9.
23. Takano T, Ohe Y, Sakamoto H, et al. Epidermal growth factor receptor gene mutations and increased copy numbers predict gefitinib sensitivity in patients with recurrent non-small-cell lung cancer. *J Clin Oncol* 2005; 23:6829–37.
24. Rosell R, Ichinose Y, Taron M, et al. Mutations in the tyrosine kinase domain of the EGFR gene associated with gefitinib response in non-small-cell lung cancer. *Lung Cancer* 2005;50:25–33.
25. Inoue A, Suzuki T, Fukuhara T, et al. Prospective phase II study of gefitinib for chemotherapy-naive patients with advanced non-small-cell lung cancer with epidermal growth factor receptor gene mutations. *J Clin Oncol* 2006;24:3340–6.
26. Tomizawa Y, Iijima H, Sunaga N, et al. Clinicopathologic significance of the mutations of the epidermal growth factor receptor gene in patients with non-small cell lung cancer. *Clin Cancer Res* 2005;11:6816–22.
27. Paez JG, Janne PA, Lee JC, et al. EGFR mutations in lung cancer: correlation with clinical response to gefitinib therapy. *Science* 2004;304:1497–500.
28. Hoang T, Xu R, Schiller JH, et al. Clinical model to predict survival in chemo-naive patients with advanced non-small-cell lung cancer treated with third-generation chemotherapy regimens based on Eastern Cooperative Oncology Group data. *J Clin Oncol* 2005;23:175–83.
29. Miller VA, Kris MG, Shah N, et al. Bronchioloalveolar pathologic subtype and smoking history predict sensitivity to gefitinib in advanced non-small-cell lung cancer. *J Clin Oncol* 2004;22:1103–9.

# 以 Gefitinib 為第一線藥物治療南台灣晚期 非小細胞肺癌病患之經驗

楊政達<sup>1</sup> 洪仁宇<sup>2,3</sup> 賴俊良<sup>4,5</sup> 洪信嘉<sup>6</sup> 賴永發<sup>7</sup> 林孟志<sup>8</sup> 謝俊明<sup>9</sup> 黃明賢<sup>2,3</sup>

<sup>1</sup>長庚大學 呼吸照護學系 <sup>2</sup>高雄醫學大學附設醫院 胸腔內科

<sup>3</sup>高雄醫學大學 醫學院 醫學系 <sup>4</sup>嘉義大林慈濟醫院 內科部

<sup>5</sup>慈濟大學 醫學院 醫學系 <sup>6</sup>美和技術學院 健康照護研究所

<sup>7</sup>義守大學 義大醫院 內科部 <sup>8</sup>高雄長庚醫院 胸腔內科

<sup>9</sup>奇美醫學中心 內科部

**Gefitinib**，為表皮生長激素受體酪胺酸激酶的專一抑制劑，是第一個當非小細胞肺癌病患在接受化學治療失敗之後，被核准可以使用的標靶治療藥物。過去曾有一些較小型的臨床試驗證實 **gefitinib** 對於未曾接受過化學治療的病患也有療效。本研究之目的在探討轉移與晚期非小細胞肺癌患者第一線即使用 **gefitinib** 這一標靶治療藥物時之反應率、病患整體存活率與其預測因子。本文以回溯性方式蒐集南台灣 6 家醫院所有在 2004 年 5 月至 2006 年 4 月接受 **gefitinib** 為第一線治療之轉移與晚期非小細胞肺癌患者，分析病患對藥物之反應率與病患存活率，及這二者與一些已知可預測因子之相關性。本研究共收納 97 位患者，對藥物之反應率為 56%，疾病控制率為 76%。在本研究中，只有病患之生活功能狀態與病患對於 **gefitinib** 是否產生反應有明顯相關。在本研究中，以 **gefitinib** 為第一線藥物治療轉移與晚期非小細胞肺癌患者，病患可以存活超過一年的機率為 77%。我們認為第一線使用單一藥物 **gefitinib** 來治療特定族群之亞洲非小細胞肺癌病患是極具前景的。以控制隨機之臨床試驗進一步來驗證第一線 **gefitinib** 之療效是必須的。

關鍵詞：**gefitinib**，非小細胞肺癌，標靶治療  
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通訊作者：黃明賢教授

高雄醫學大學附設醫院胸腔內科

高雄市 807 三民區自由一路 100 號