

IPASS Press Conference

Professor Tony Mok, Chinese University of Hong Kong

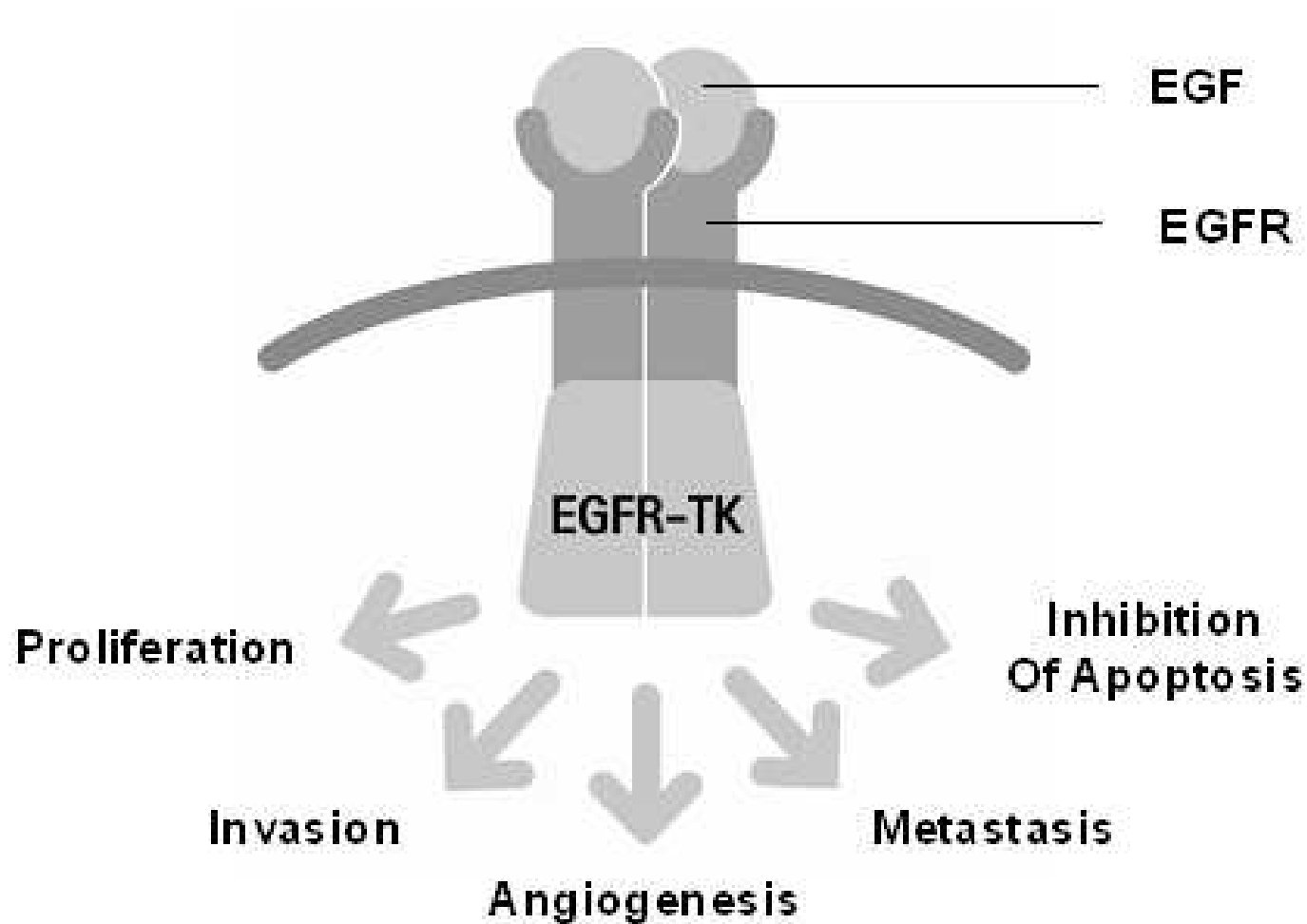


Phase III, randomised, open-label,
first-line study of gefitinib vs carboplatin / paclitaxel in clinically
selected patients with advanced non-small cell lung cancer (IPASS)

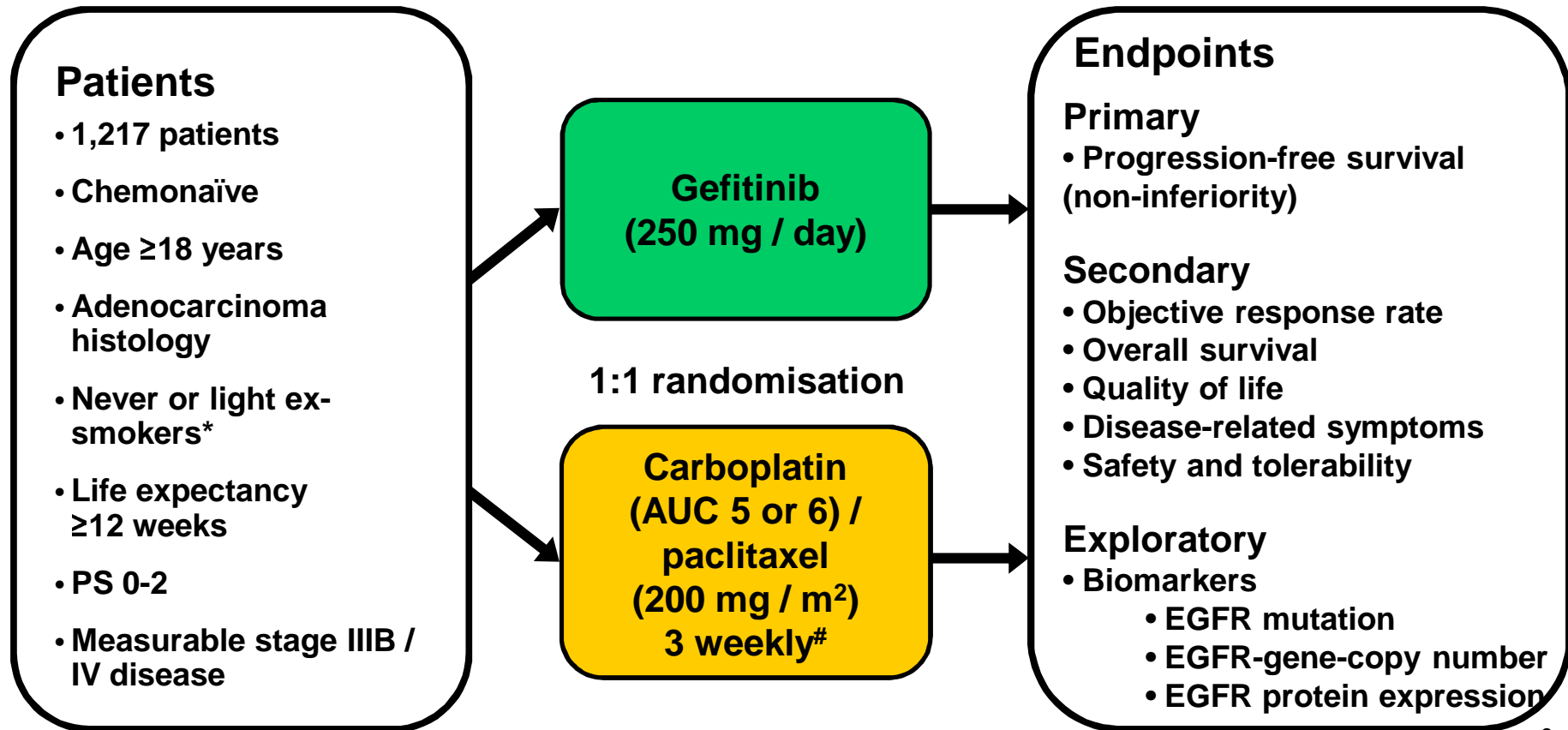
Introduction

- The incidence of lung cancer in Asian countries including China, Korea and Taiwan is high, and on the increase
- There is an unmet medical need for well tolerated, efficacious new treatment options for lung cancer patients
- **Today, I will present the results of a new study that will change the paradigm of first-line lung cancer treatment in Asia**

Epidermal Growth Factor Receptor (EGFR) Inhibitor: Gefitinib



IPASS study design



*Never smokers, <100 cigarettes in lifetime; light ex-smokers, stopped ≥ 15 years ago and smoked ≤ 10 pack years; [#]limited to a maximum of 6 cycles

Carboplatin / paclitaxel was offered to gefitinib patients upon progression

PS, performance status; EGFR, epidermal growth factor receptor

Progression-free survival in ITT population

**Gefitinib exceeded primary endpoint,
demonstrating superiority relative to carboplatin /
paclitaxel in terms of PFS**

	Gefitinib	Carboplatin / paclitaxel
N	609	608
Events	453 (74.4%)	497 (81.7%)

HR (95% CI) = 0.741 (0.651, 0.845) p<0.0001

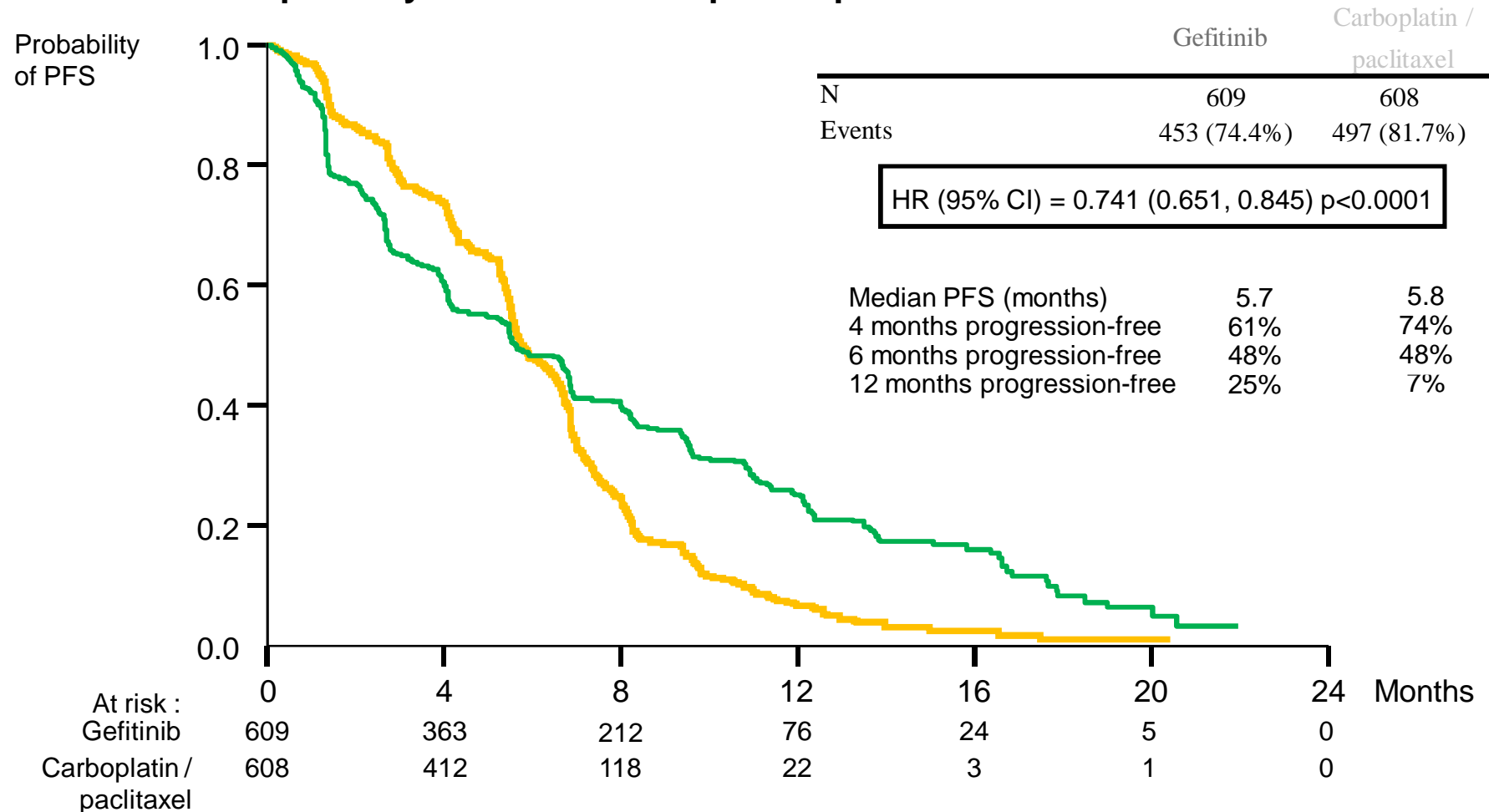
Primary Cox analysis with covariates

HR <1 implies a lower risk of progression on gefitinib

HR, hazard ratio; CI, confidence interval; PFS, progression-free survival

Progression-free survival in ITT population

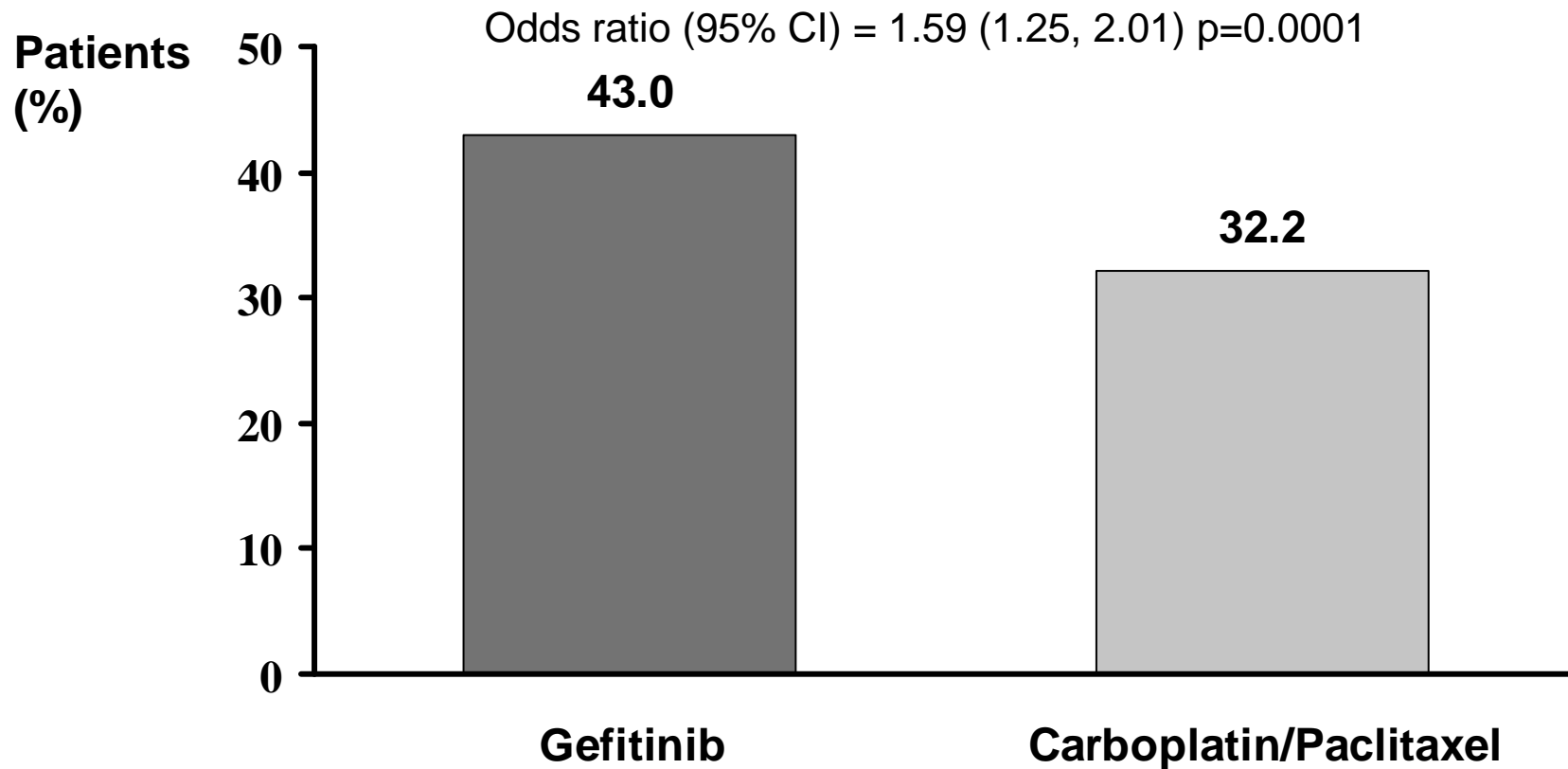
Gefitinib exceeded primary endpoint and demonstrated superiority relative to carboplatin / paclitaxel in terms of PFS



Primary Cox analysis with covariates

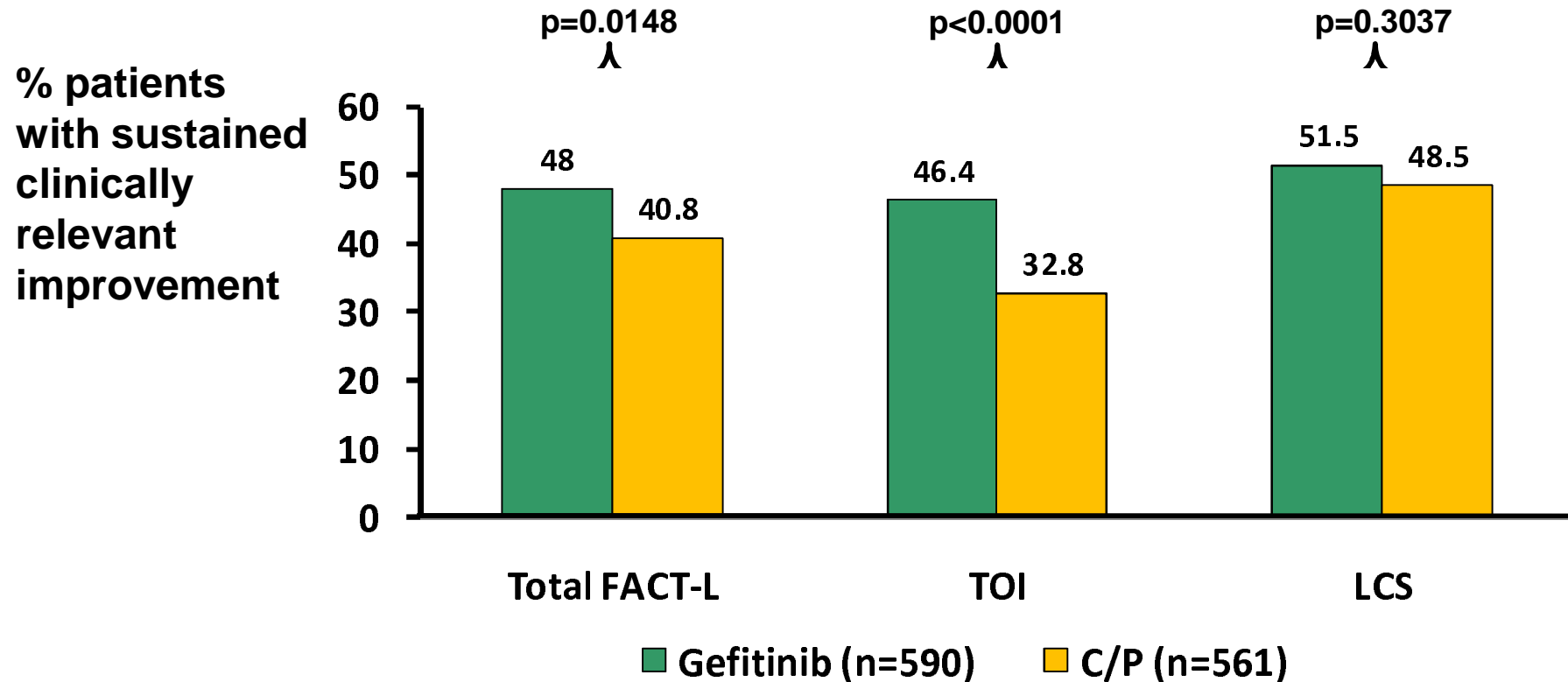
HR <1 implies a lower risk of progression on gefitinib

Objective tumour response (RECIST) (ITT population)



Odds ratio >1 implies a greater chance of response on gefitinib
Odds ratio and p-value from logistic regression with covariates
RECIST, Response Evaluation Criteria In Solid Tumours

Quality of life and symptom improvement rates (EFQ population)

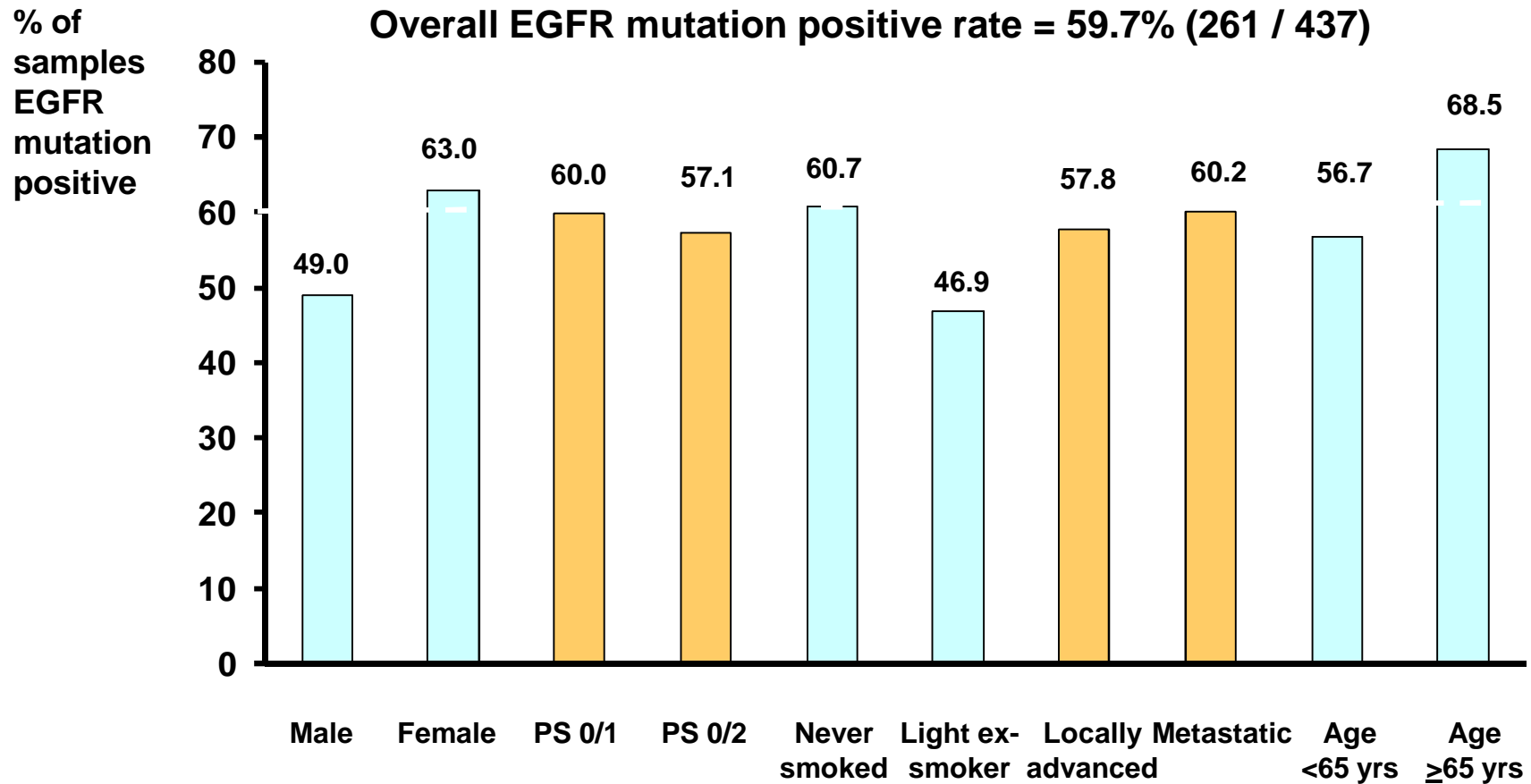


p-values from logistic regression with covariates

Clinically relevant improvement pre-defined as 6-point improvement for FACT-L and TOI; 2-point improvement for LCS, maintained for at least 21 days

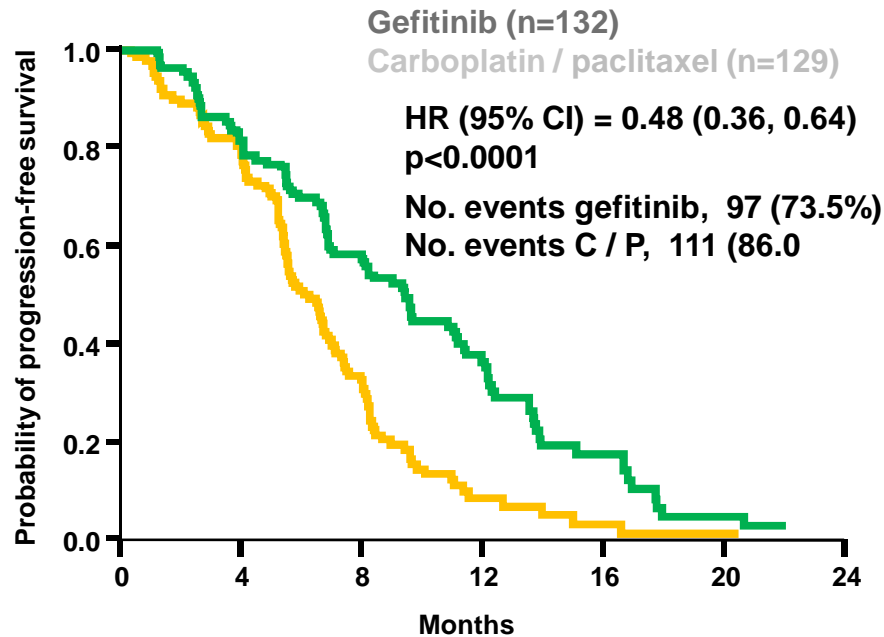
EFQ, evaluable for quality of life; FACT-L, Functional Assessment of Cancer Therapy-Lung; TOI, Trial Outcome Index; LCS, Lung Cancer Subscale

EGFR mutation positive status and clinical characteristics



Progression-free survival in EGFR mutation positive and negative patients

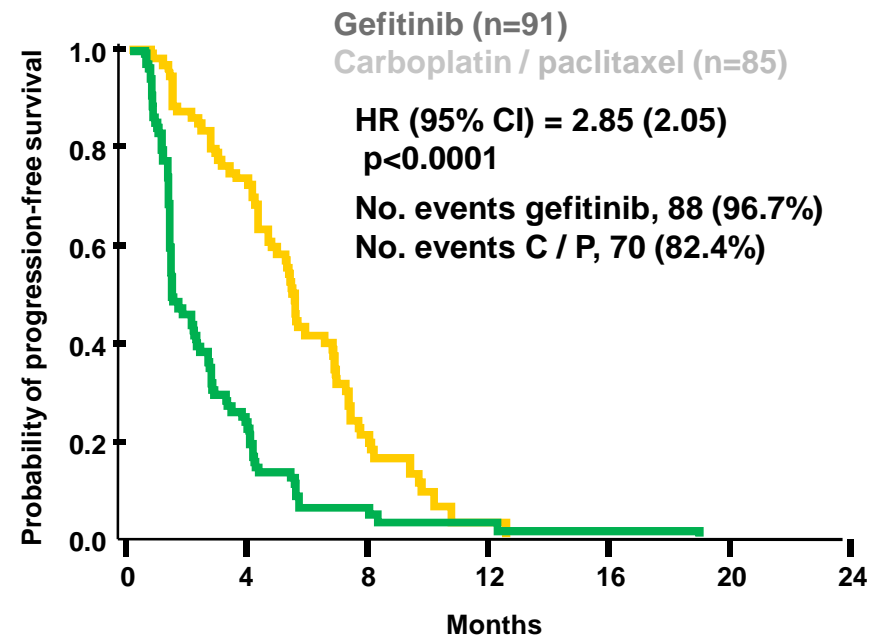
EGFR mutation positive



At risk :

Gefitinib	132	108	71	31	11	3	0
C / P	129	103	37	7	2	1	0

EGFR mutation negative

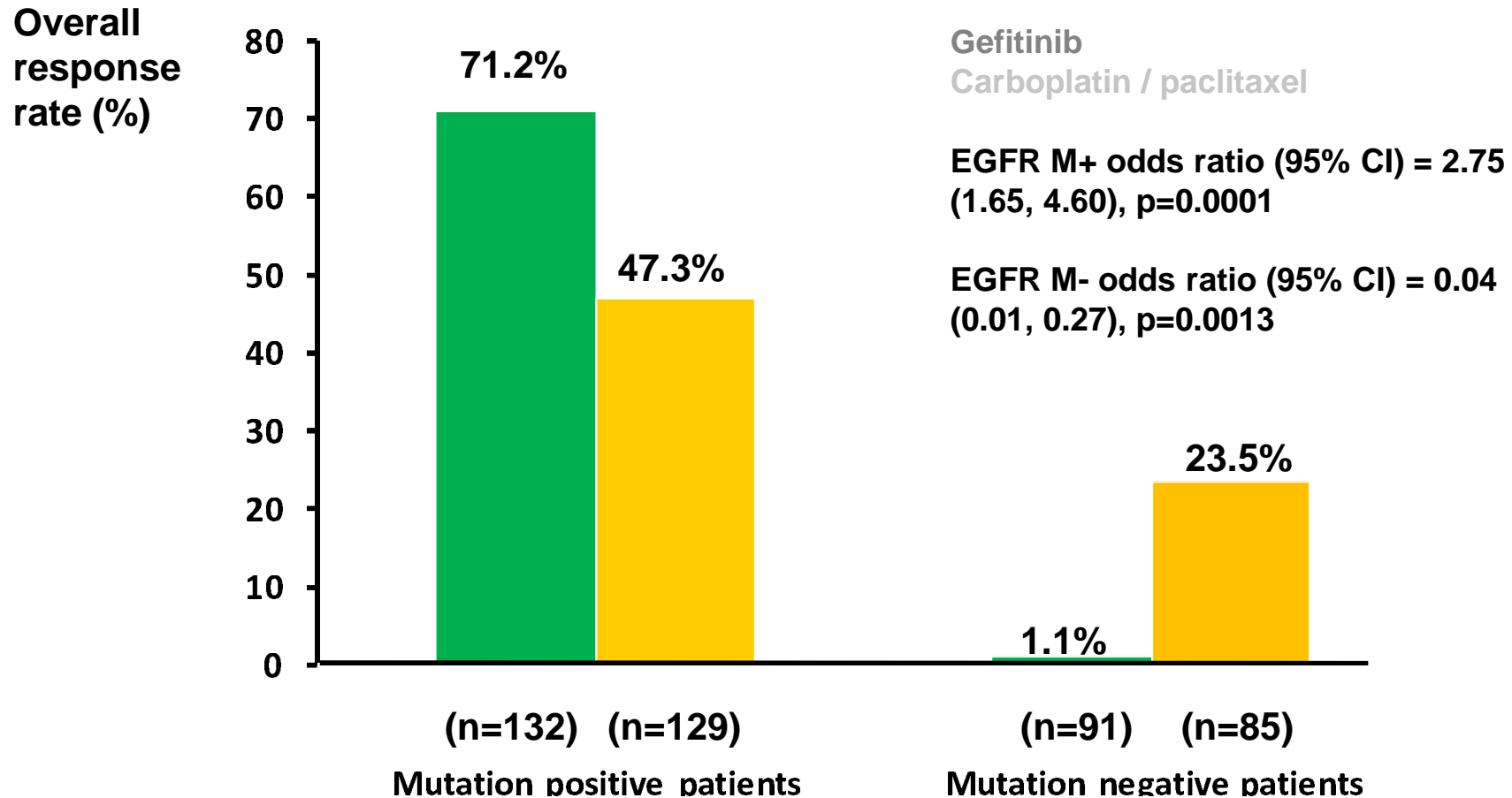


Gefitinib	91	21	4	2	1	0	0
C / P	85	58	14	1	0	0	0

Treatment by subgroup interaction test, p<0.0001

ITT population
 Cox analysis with covariates

Objective response rate in EGFR mutation positive and negative patients



What are the clinical implications of the IPASS results?

- Physicians can now consider gefitinib as first line therapy for advanced stage lung cancer patients if they are a non/former-light smoker with adenocarcinoma
- EGFR mutation is proven as an important predictive marker for EGFR TKI

Why are the IPASS results so important?

- Around 15% of all lung cancer patients in Western countries and up to 30% in Asia are non-smoking patients with adenocarcinoma
- Gefitinib is well tolerated, offering superior quality of life compared to chemotherapy (i.e. no hair loss, less nausea and vomiting, less bone marrow suppression)
- This study will change the paradigm of first-line lung cancer treatment in Asia