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## BACKGROUND

### Chemotherapy for advanced NSCLC

- First-line platinum-based chemotherapy (first-line CT) is standard of care.
- Second-line chemotherapy (second-line CT) is recommended for patients who have experienced disease progression after first-line CT.
- However, not all patients could receive appropriate second-line CT.

### Maintenance therapy in the treatment of advanced NSCLC

- Maintenance therapy after first-line CT is reported to be beneficial.
- However, its impact on overall survival appears to be marginal or negligible, if those without maintenance receive active second-line CT, which is initiated at disease progression.

## OBJECTIVE

- To investigate the proportion of patients with NSCLC who had progression during observation after CR/PR/SD of first-line CT and further received appropriate second-line CT
- To elucidate the reasons and factors which hinder patients from receiving second-line CT

## METHODS

### Study design

- Cohort study

### Primary endpoint

- Proportion of patients who received second-line CT for progression during observation after CR/PR/SD of first-line CT

### Patient inclusion

- Patients with advanced or recurrent NSCLC who were initiated on first-line CT
- Between April 2010 and September 2011 from 30 institutions in Japan
- Without history of other active malignancy

### Data collection

- Patient characteristics including age, sex, PS (ECOG), smoking status, comorbidities (diabetes mellitus, cardiac disease, interstitial lung disease), body mass index, histological subtype, EGFR/ALK status, CBC/chemistry at registration
- Details of first-, second-, third-line CT and maintenance therapy; including regimen, response
- Reason for administration or omitting second-line CT
- Survival

### Data cutoff

- This interim report describes from patients with at least 6 months of follow up at April 2012.

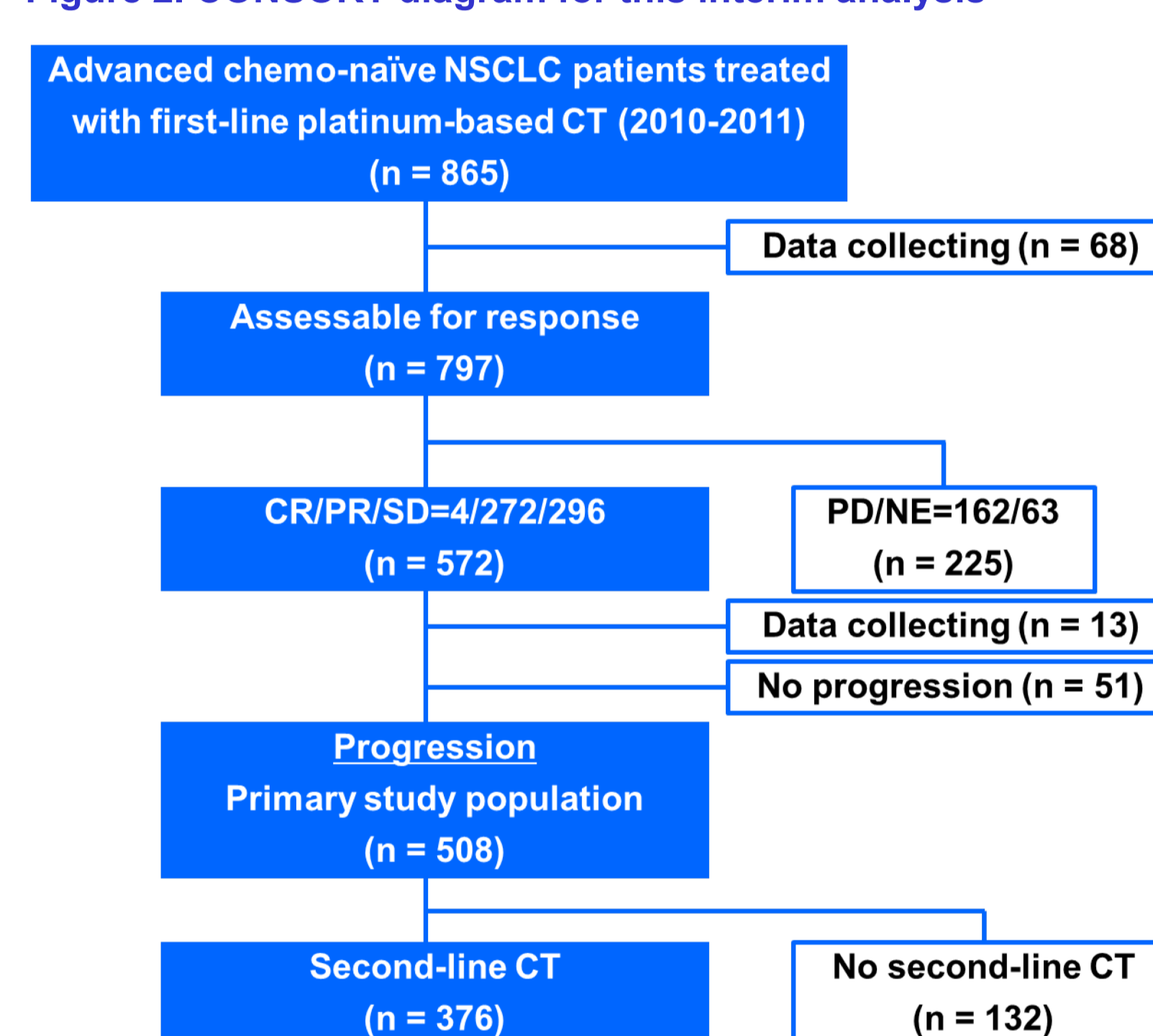
## RESULTS

- A total of 865 eligible patients with advanced NSCLC provided patient characteristics and details of first-line CT (Table 1 and Figure 1).
- At this data cut off of patients who were followed up for at least 6 months, 797 patients were assessable for response and the response rate was 35% (276/797) (Figure 2).

Table 1. Patient characteristics

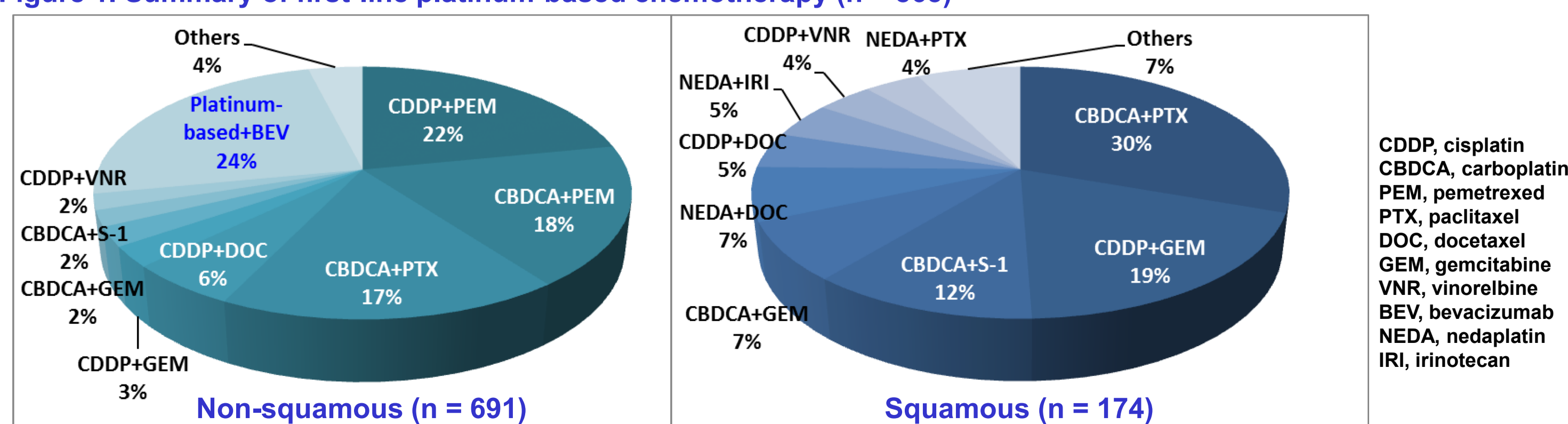
Characteristics	No. of patients (n = 865)	%
<b>Sex</b>		
male/female	628/237	73/27
<b>Age</b>		
median (range)	65 (24-86)	
70 or more	250	29
<b>Histology</b>		
Adeno	602	70
Squamous	174	20
NSCLC (NOS)	73	8
Others	16	2
<b>PS (ECOG)</b>		
0/1/2/3-4	343/449/65/7	40/52/7/1
unknown	1	
<b>Smoking</b>		
never/ever	173/687	20/79
unknown	5	
<b>Comorbidities</b>		
none	654	76
any	211	24
<b>EGFR status</b>		
mutant	87	10
wild	515	60
unknown	263	30

Figure 2. CONSORT diagram for this interim analysis



- At this data cut off, 194 patients received maintenance therapy after first-line CT and were excluded from primary study population.

Figure 1. Summary of first-line platinum-based chemotherapy (n = 865)



- Among the 508 patients who had progression after CR/PR/SD, 376 patients (74%) could receive second-line CT at disease progression and 132 patients (26%) not receive second-line CT (Table 2).
- Declined PS was the most common reason for hindering second-line CT (Table 3).
- Advanced age, declined PS and smoking history were correlated with hindrance to second-line CT in univariate analysis (Table 4).

Table 2. Summary of second-line treatment

Second-line treatment	No. of patients (n = 508)	%
BSC (none)	132	26
Docetaxel	152	30
Pemetrexed	68	13
Erlotinib	30	6
S-1	18	4
Gefitinib	16	3
Any single agent	18	4
Any combination CT	74	14

Table 3. The reasons for not receiving second-line CT

Reasons	n = 132 (%)
Declined PS	79 (60)
Patient refusal	28 (21)
Death of any cause	6 (5)
Loss of follow-up and others	19 (14)

Table 4. Association between baseline characteristics and administration of second-line CT (n = 508)

Characteristics	Second line CT (yes/no)		P
	n	(%)	
All of patients	376/132	(74/26)	
<b>Sex</b>			
male	272/103	(73/27)	0.21
female	104/29	(78/22)	
<b>Age</b>			
< 65	175/45	(80/20)	0.01
≥ 65	201/87	(70/30)	
<b>PS</b>			
0	179/31	(85/15)	< 0.0001
1-4	197/101	(66/34)	
<b>Smoking</b>			
never	81/15	(84/16)	0.01
ever	295/117	(72/28)	
<b>Comorbidities</b>			
none	288/90	(76/24)	0.06
any	88/42	(68/32)	
<b>Platinum-regimen</b>			
CDDP	144/40	(78/22)	0.11
other	232/92	(72/28)	

## CONCLUSIONS

- Preliminary results of this large observational study in Japan indicated that around 30% of patients missed an opportunity to receive appropriate second-line CT despite observation after first-line CT.
- Final analysis will be performed using data that all patients were followed up for at least 1.5 years.
- Our goal is to elucidate the selection criteria of patients that may benefit the most from maintenance therapy, not second-line CT which is initiated at disease progression.

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