

Neo-adjuvant Chemotherapy and Radiation Therapy in Patients with Stage IIIA (N2) Non-Small Cell Lung Cancer (NSCLC): A Retrospective Analysis with Lessons Learned

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Background:

- Neo-adjuvant chemotherapy offers survival benefit compared to surgery alone¹
- Adjuvant chemotherapy and radiation offer survival benefit in patients with documented Stage IIIA (N2+) disease^{2,3,4}
- Preoperative chemotherapy with radiotherapy is active and safe in patients with Stage IIIA/B disease⁵
- The role of surgery following concomitant chemotherapy with radiation is an area of active investigation

¹Pisters K, et al. Proc ASCO (2003) Abstract #2544
²Douillard J-Y, et al. Proc ASCO (2005) Abstract # 7013
³Winton T, et al. NEJM 352: 2589 (2005)
⁴IALT Collaborative Group NEJM 350: 351 (2004)
⁵Albain KS, et al. The Lancet 374: 379 (2009)

Patient Selection:

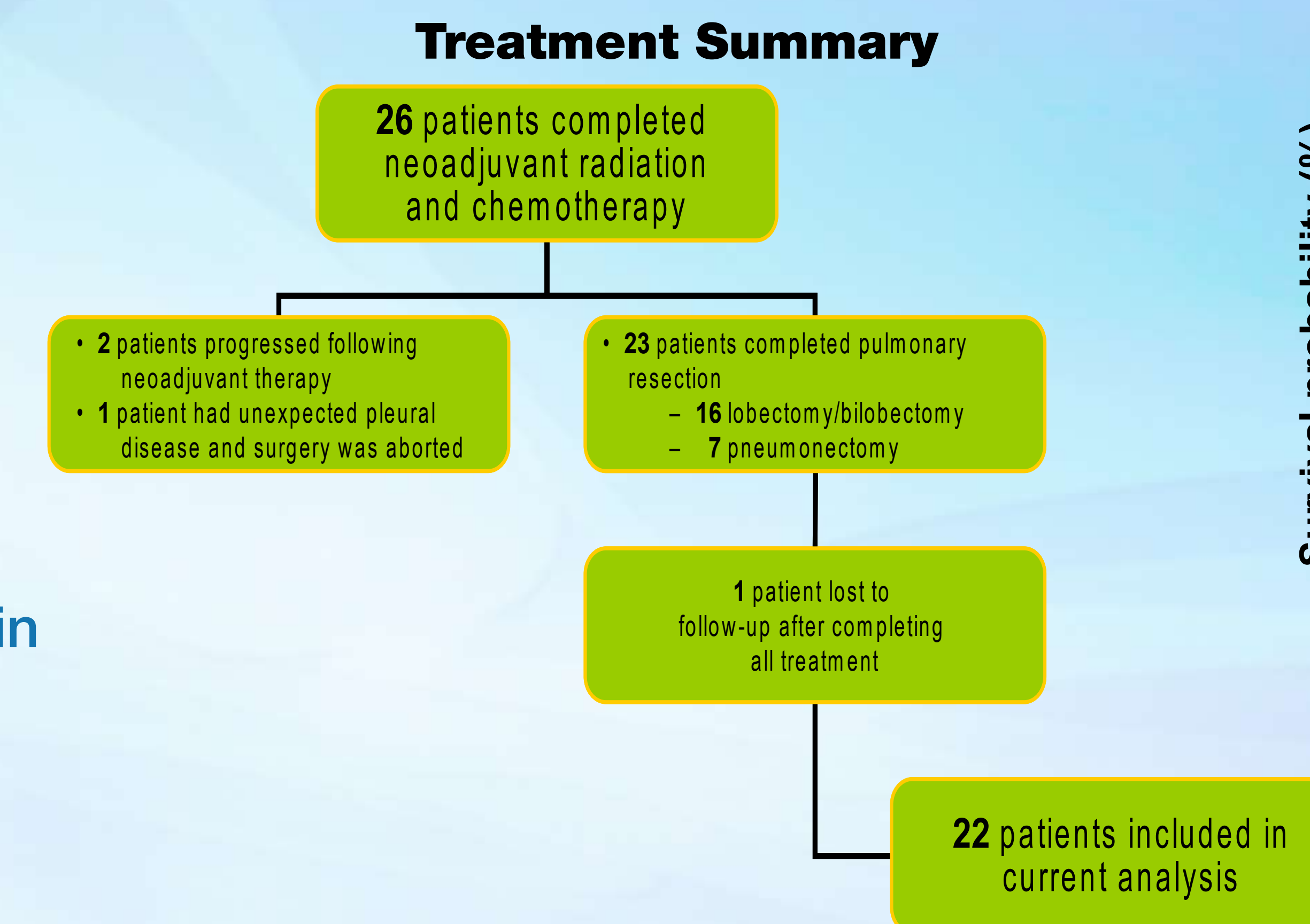
- Patients are evaluated simultaneously at weekly multidisciplinary lung cancer clinic by
 - Medical oncologist
 - Radiation oncologist
 - Thoracic surgeon
 - Pulmonologist
- Patients selected up-front for trimodality therapy (prior to initiation of treatment)
 - Stage IIIA (T₁₋₃ N₂ M₀) NSCLC
 - Non-bulky N2 disease (< 3cm)
 - Good performance status (ECOG 0-1)
 - Surgical candidates

Patient Characteristics: (n=26)

- Mean age
 - 57.6 years (19-79)
- Gender
 - 13 male, 13 female
- Pathology
 - Adenocarcinoma - 10/25
 - Squamous Cell Carcinoma - 13/25
 - Adenosquamous 1/26
 - NSCLC NOS - 2/26
- PET/CT scan positive with pathological confirmation
 - 10/26 (38%)
- PET/CT scan positive only
 - 16/26 (62%)

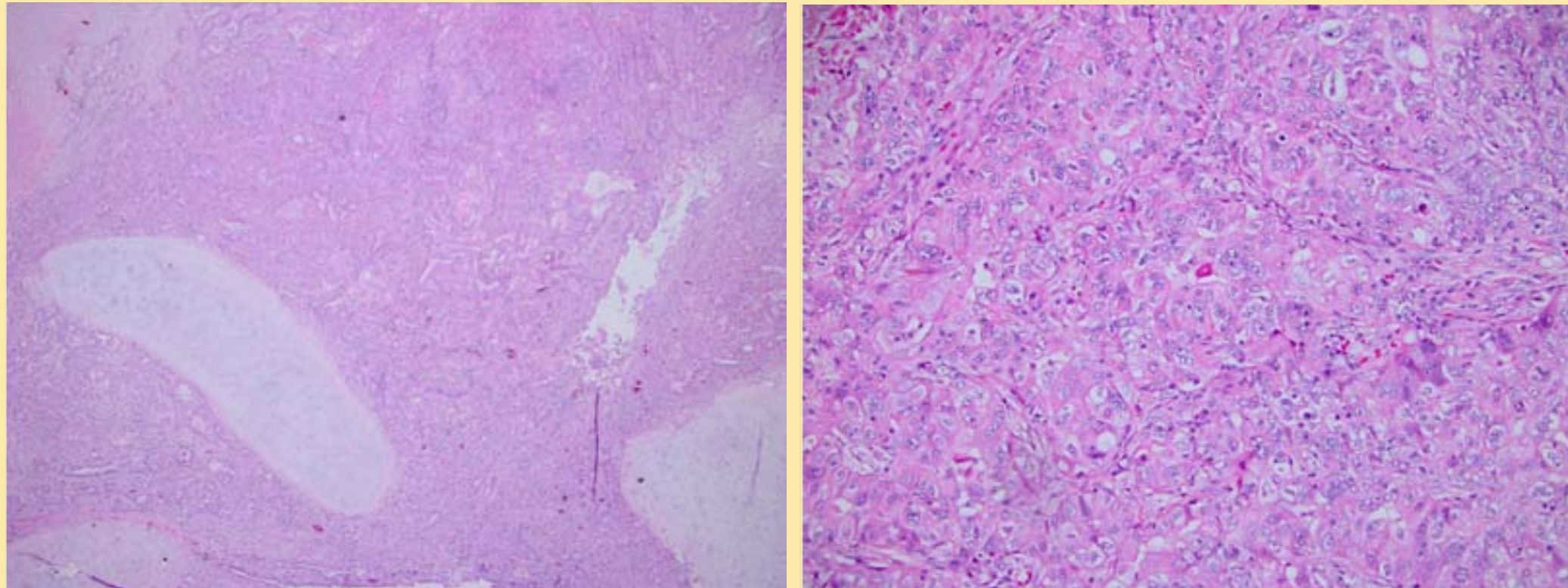
Treatment:

- Chemotherapy regimens
 - Paclitaxel 50mg/m² + Carboplatin AUC 2 weekly (n = 15)
 - Vinorelbine 25mg/m² d1, 8, 15 Paclitaxel 140mg/m² by continuous 24-hour infusion d1 Carboplatin AUC 5 d2 (n=6)
 - Paclitaxel 175mg/m² + carboplatin AUC 6 q3wks (n = 4)
 - Etoposide 50mg/m² d 1-5 + Cisplatin 50mg/m² d1 and 8 (n = 1)
- Radiation Therapy
 - 4500 – 5040 cGy (concomitant with chemotherapy)
- Surgery
 - Pneumonectomy (n = 7)
 - Lobectomy / bilobectomy (n = 16)



Post Treatment Pathology

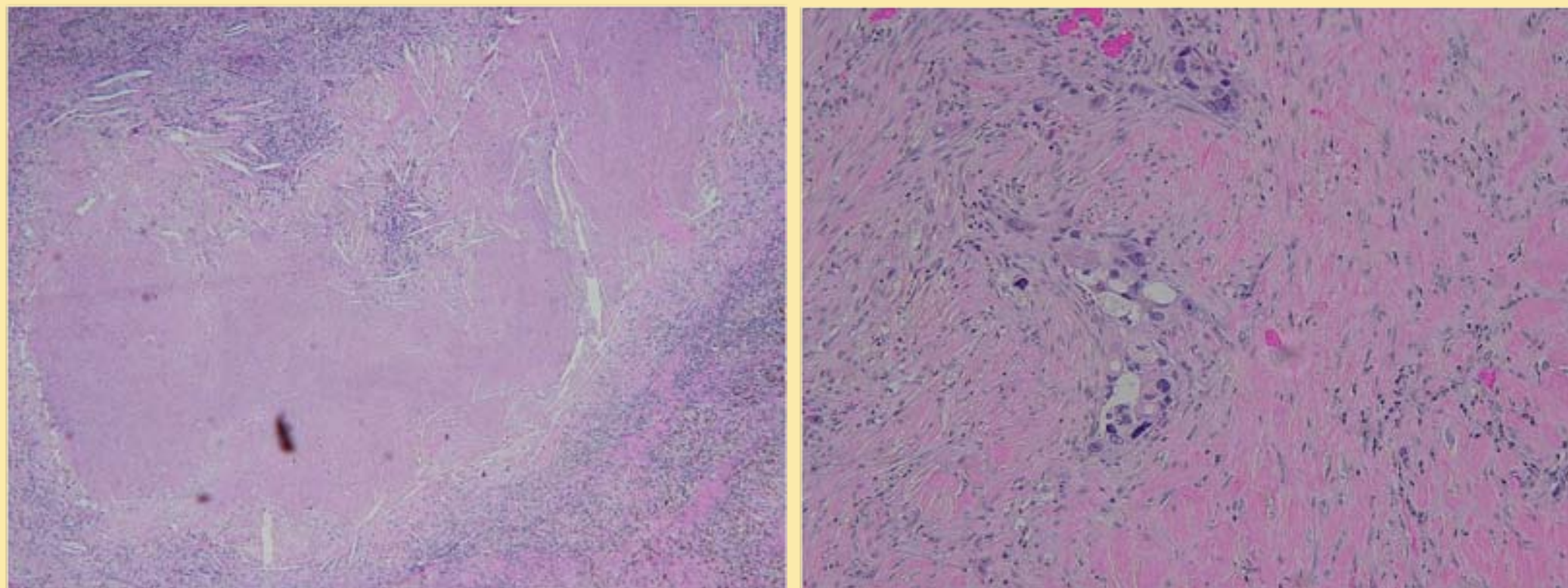
Viable (n=11) Measurable tumor with active cancer cells



40x H&E stain
Large sheets of viable tumor with no significant fibrosis or necrosis
Tumor wrapped around bronchus

200x H&E stain
Large sheets of viable tumor with no significant fibrosis or necrosis

Fibrosis (n=11) <10% active cancer cells in fibrotic/necrotic matrix



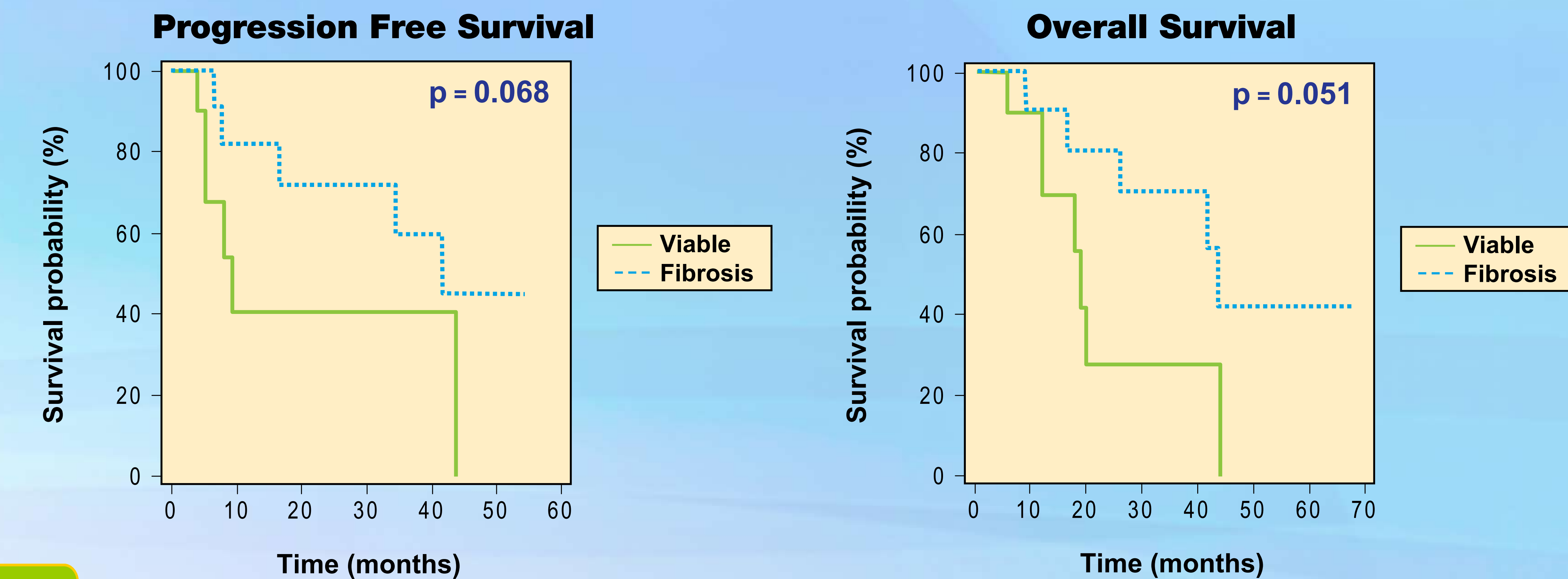
40x H&E stain
Small residual nest of tumor cells with marked tumor necrosis

400x H&E stain
Small residual nest of tumor cells in dense fibrous background

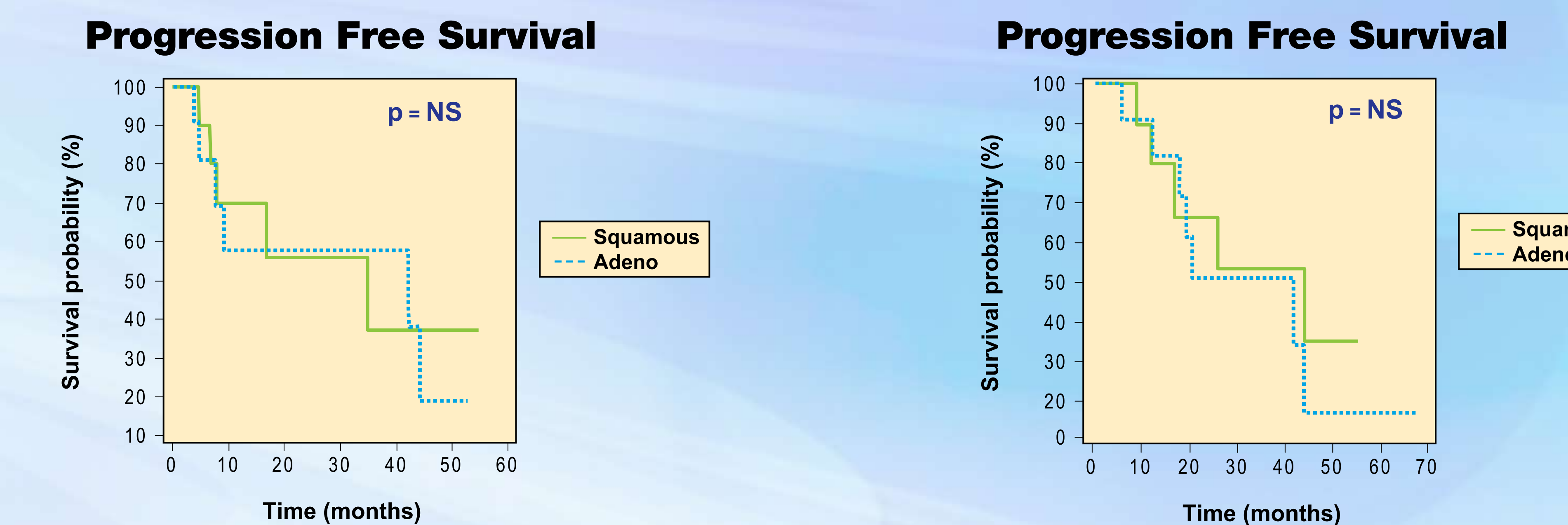
Survival Data

	All Patients (n=22)	"Fibrosis" (n=11)	"Viable" (n=11)
Progression free survival	14.5 months	42 months	9 months
Overall survival	19.5 months	44 months	19 months
Alive NED	7	5	2
Distal relapse (systemic)	7	1	6
Distal relapse (CNS)	3	1	2
Local relapse	3	3	0
Died (unrelated cause)	2	1	1
Mediastinal LN positive at surgery	5	1	4

Viable vs. Fibrosis



Adenocarcinoma vs. Squamous Cell Carcinoma



Conclusions:

- Trimodality therapy is feasible and safe in carefully selected patients with stage III NSCLC
- The presence of residual active tumor bodes poorly and these patients may not benefit from definitive resection.
- Utilization of PET-CT after neoadjuvant therapy may identify "fibrosis" vs. "viable"
- Pathological staging of mediastinum (mediastinoscopy or EBUS) prior to and after neoadjuvant therapy should be employed