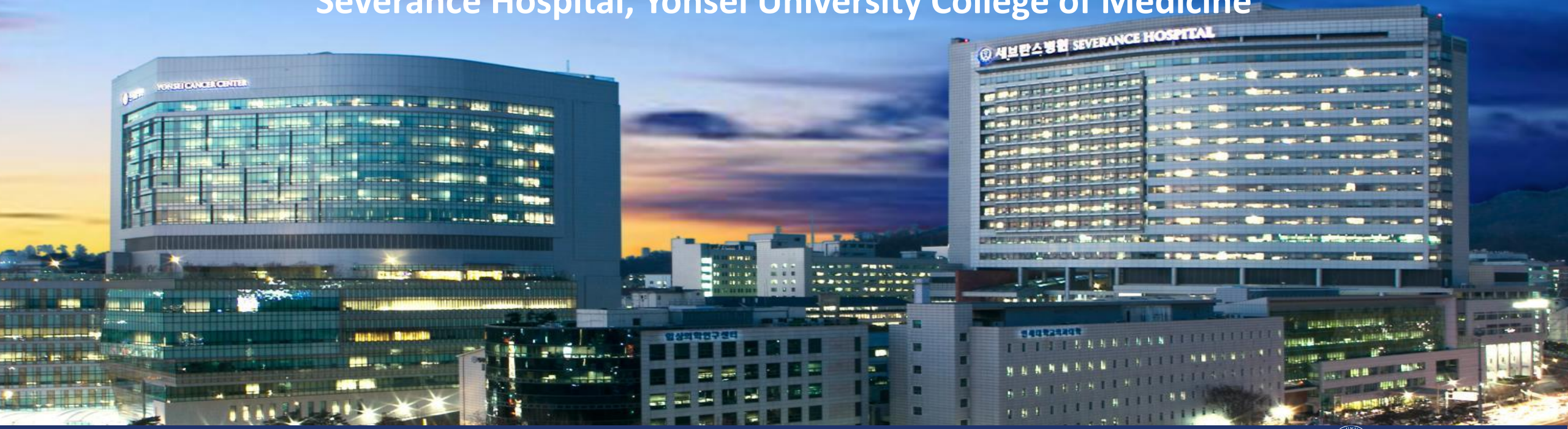
선행 Osimertinib 치료의 수술적 관점 : 절제 가능성과 수술 전략에 미치는 영향

Byung Jo Park

Department of Thoracic and Cardiovascular Surgery

Severance Hospital, Yonsei University College of Medicine



Rationale for Neoadjuvant Therapy in EGFR-Mutant NSCLC

- **Adjuvant Osimertinib** is the **current standard of care after the ADAURA trial**.

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 OCTOBER 29, 2020 VOL. 383 NO. 18

Osimertinib in Resected *EGFR*-Mutated Non–Small-Cell Lung Cancer

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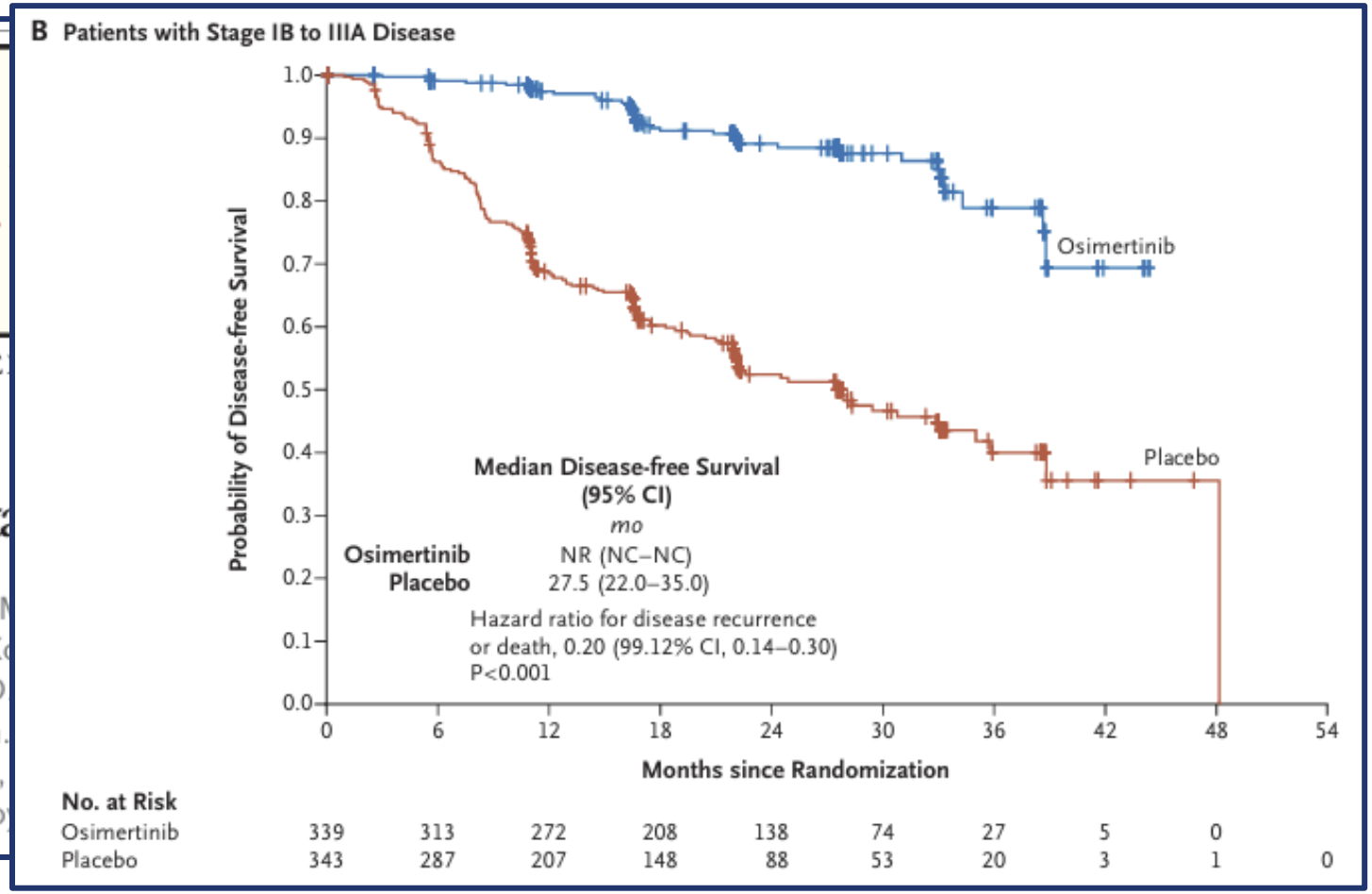

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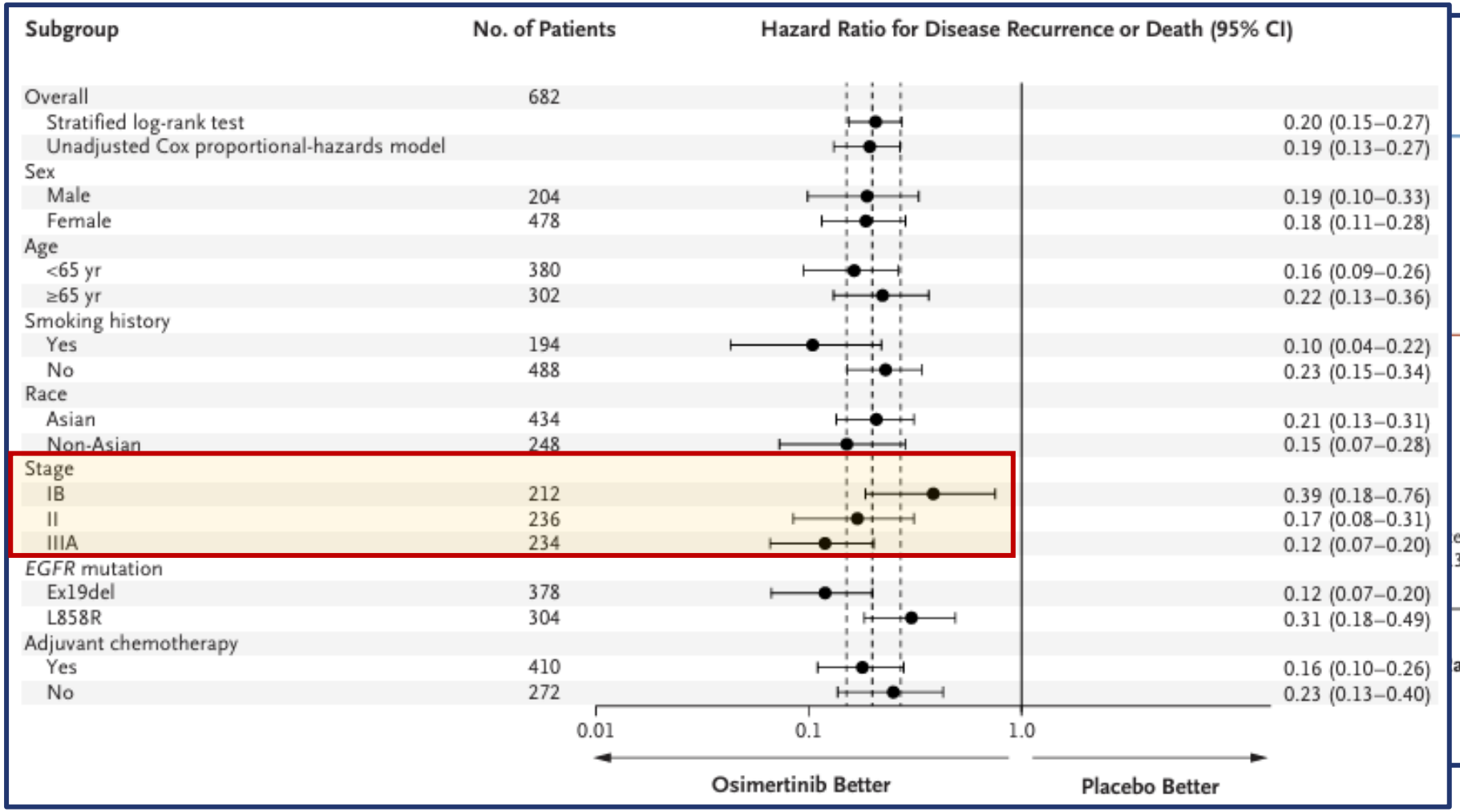

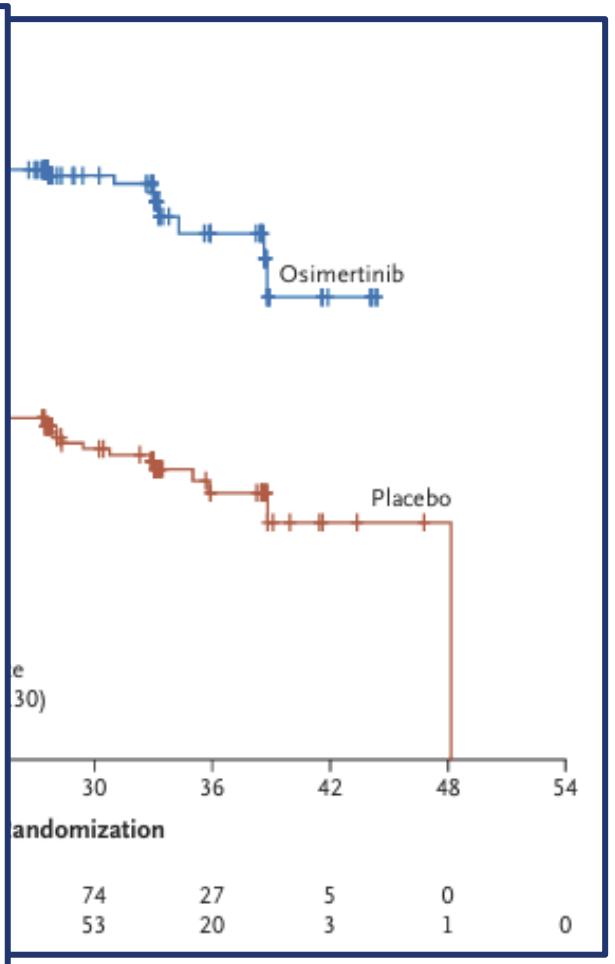

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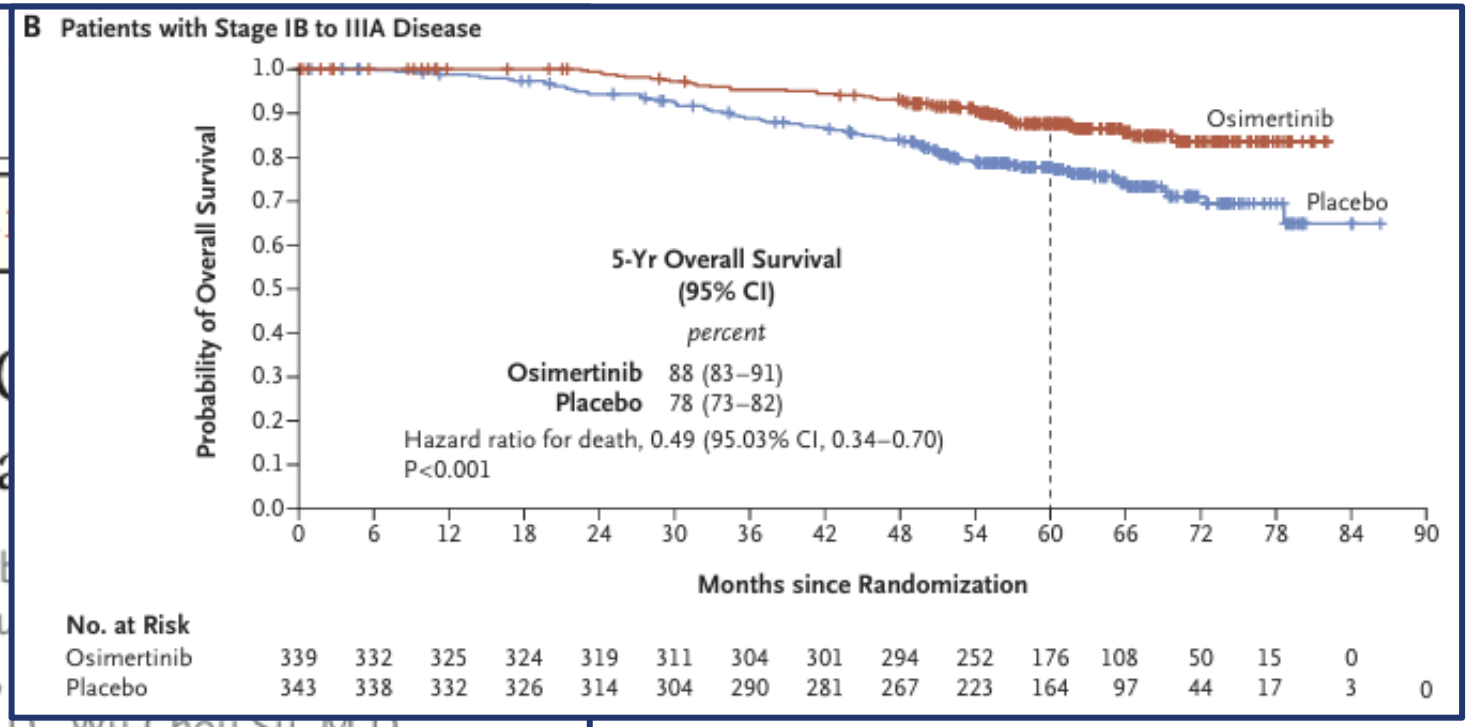

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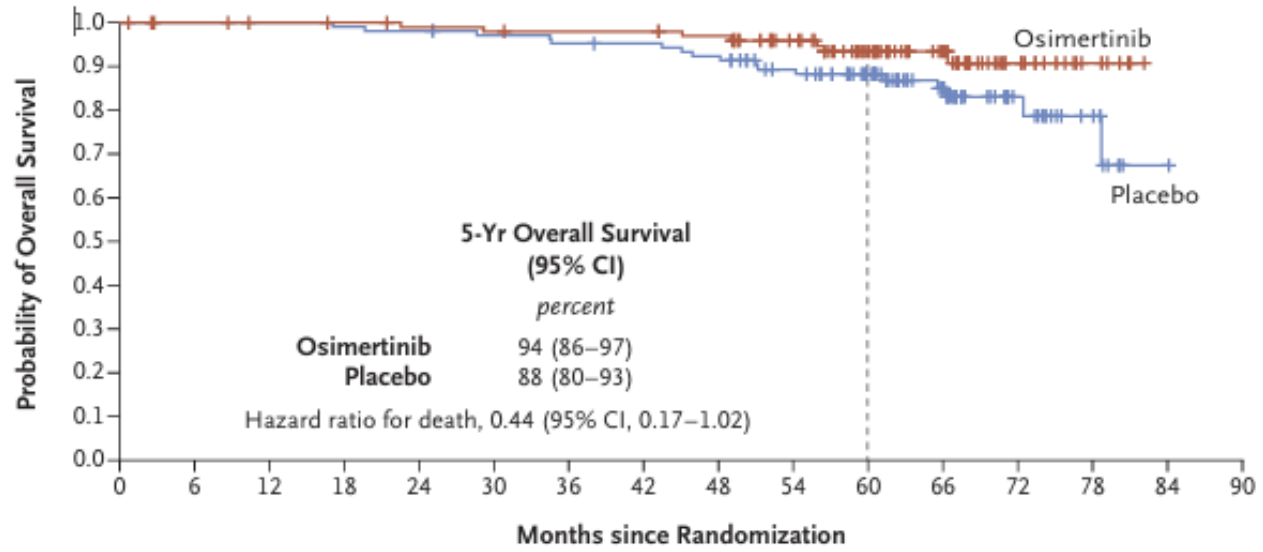
B Patients with Stage IB to IIIA Disease

A Patients with Stage IB Disease



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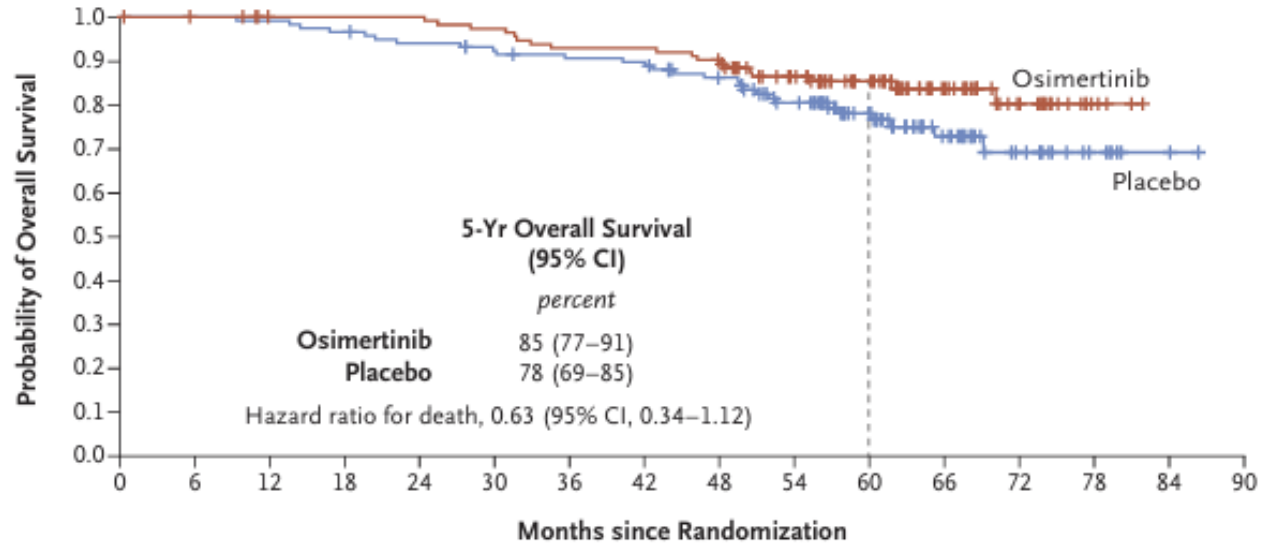
B Patients with Stage II Disease



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B Patients with Stage IB to IIIA Disease

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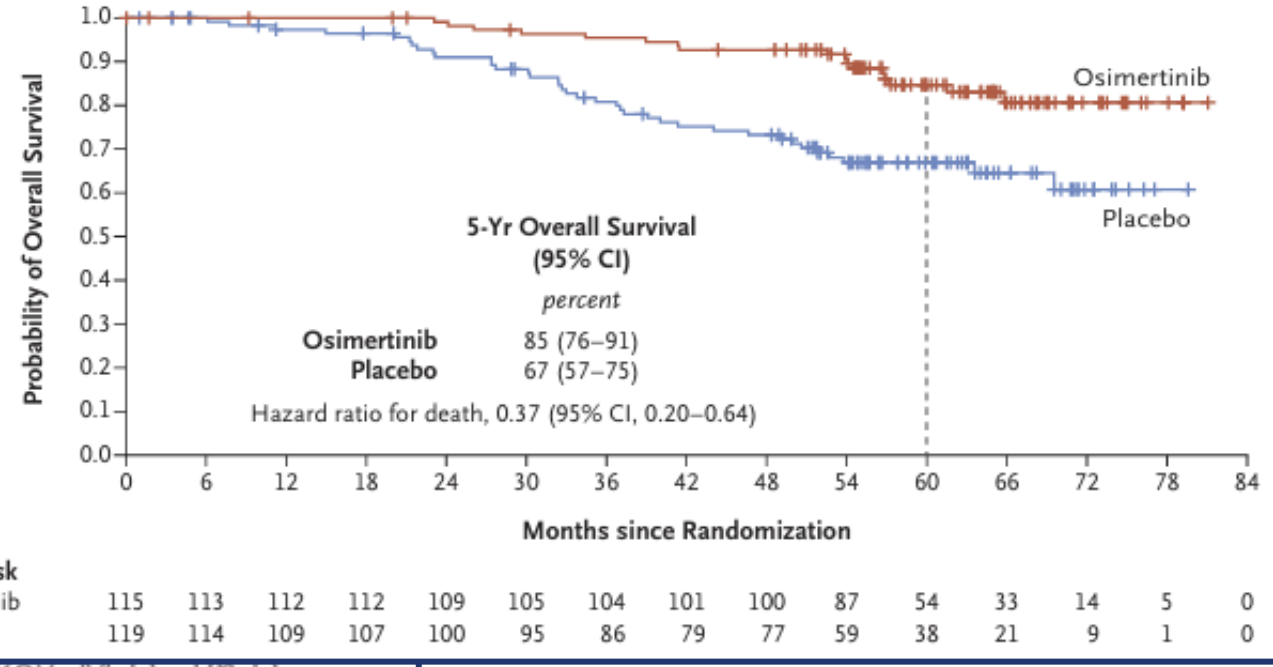
B Patients with Stage II Disease

C Patients with Stage IIIA Disease



Rationale for Neoadjuvant Therapy in EGFR-Mutant NSCLC

- **Adjuvant Osimertinib** is the **current standard of care after the ADAURA trial**.
- However, **recurrence still occurs after surgery**.
- **Neoadjuvant** therapy may:
  - Provide **early systemic disease control**
  - **Downstage** nodal disease
  - Allow in vivo **assessment of treatment response**
- Does **neoadjuvant EGFR-TKI change surgical outcomes**?

NORA: Pilot Study / single arm / single center (Yonsei)

- **8 weeks** of **neoadjuvant Osimertinib** + **3years** of **adjuvant Osimertinib**
- Clinical response: **PR 44% / SD 56%**
- **No patient** lost the opportunity for surgery due to **disease progression**
- R0 resection: 100%
- **MPR: 24% / pCR: 0%**
- **No grade ≥3 adverse events** during neoadjuvant
- Neoadjuvant EGFR-TKI was **Feasible / Well tolerated / Did not compromise surgical candidacy**

NORA: Pilot Study / single arm / single center (Yonsei)

ORIGINAL ARTICLE

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Neoadjuvant and Adjuvant Osimertinib in Stage IA to IIIA, *EGFR*-Mutant NSCLC (NORA)

Jii Bum Lee, MD, PhD,[a] Su-Jin Choi, MS,[a] Hyo Sup Shim, MD, PhD,[b] Byung Jo Park, MD, PhD,[c] Chang Young Lee, MD,[c] Sumedha Sudhaman, PhD,[d] Sharlene Velichko, PhD,[d] Min Hee Hong, MD,[a] Byoung Chul Cho, MD, PhD,[a] Sun Min Lim, MD, PhD[a,*]

[a]*Division of Medical Oncology, Yonsei Cancer Center, Yonsei University College of Medicine, Seoul, Republic of Korea*
[b]*Department of Pathology, Yonsei University College of Medicine, Seoul, Republic of Korea*
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[d]*Natera, Inc., Austin, Texas*

Received 20 November 2024; revised 17 December 2024; accepted 20 December 2024
Available online - 26 December 2024

NORA: Pilot Study / single arm / single center (Yonsei)

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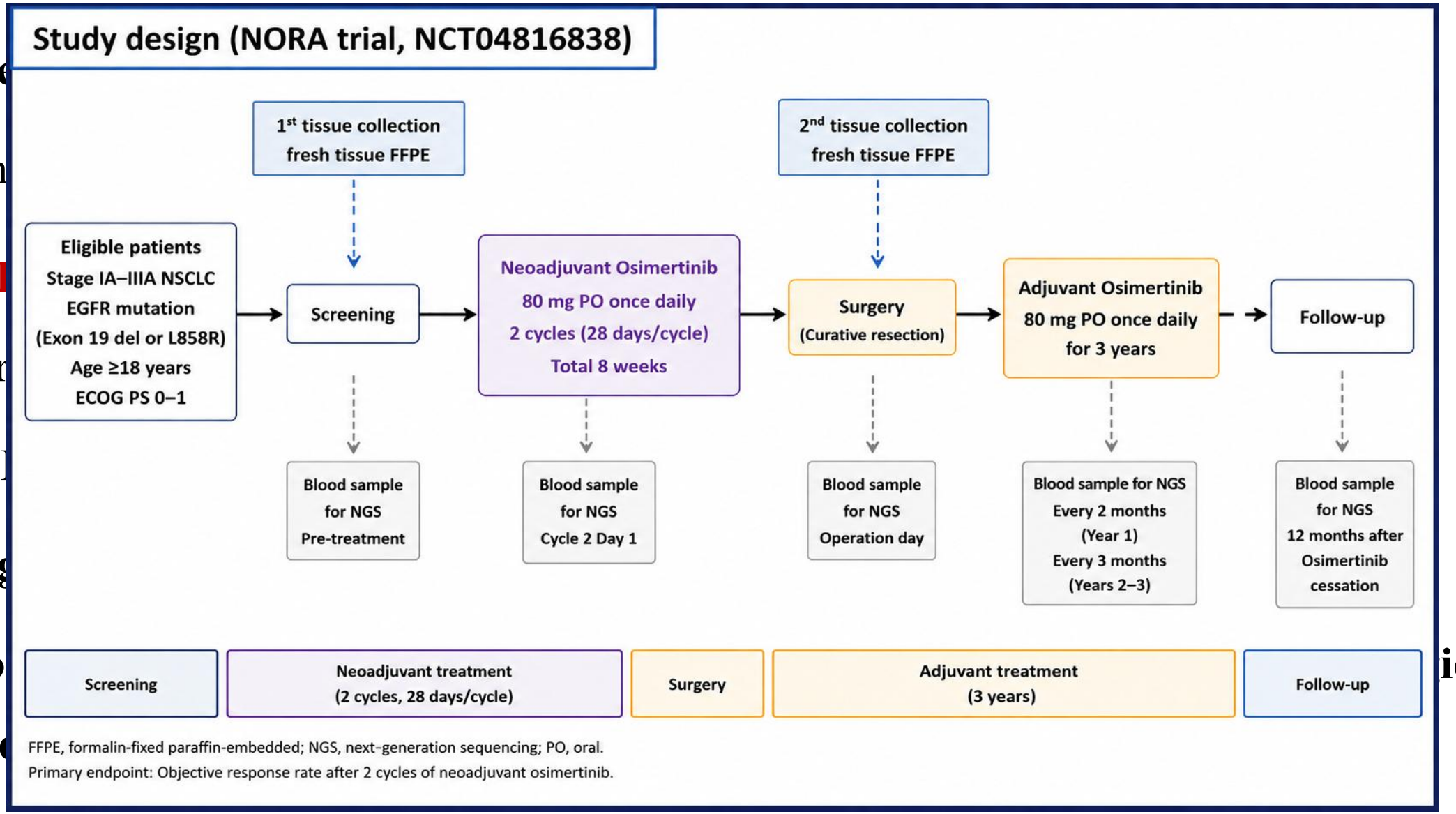

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- **8 weeks** of **neoadjuvant Osimertinib** + **3years** of **adjuvant Osimertinib**
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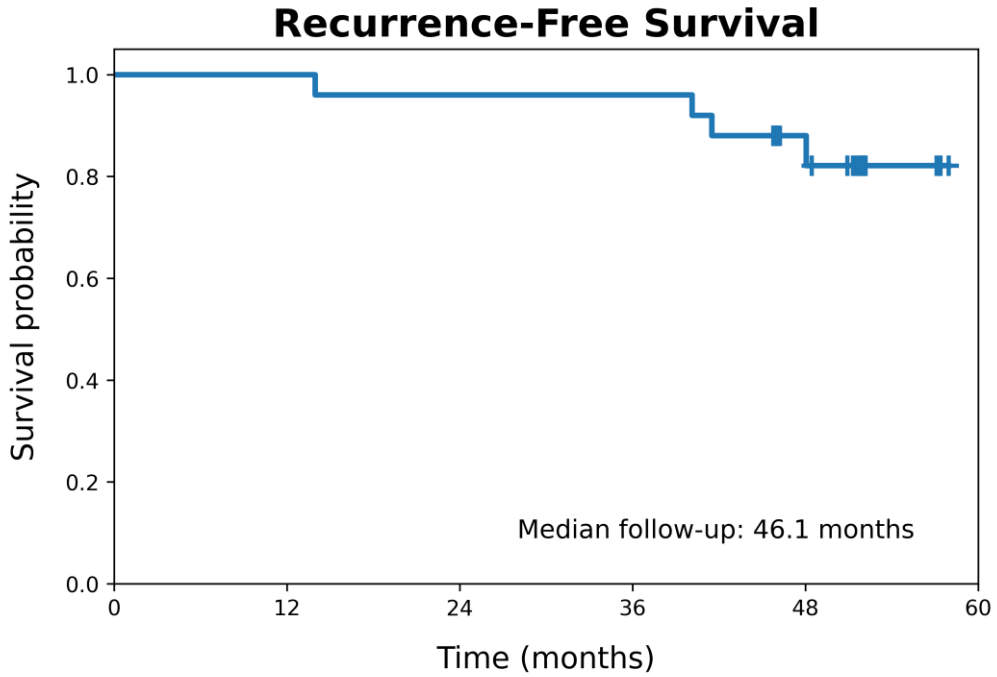
- **No patient** lost the opportunity for surgery due to **disease progression**
- R0 resection: 100% / **VATS: 96%** (Conversion to open: **1 patient** (during LN dissection))
- **MPR: 24% / pCR: 0%**
- **No grade ≥3 adverse events** during neoadjuvant
- Neoadjuvant EGFR-TKI was **Feasible / Well tolerated / Did not compromise surgical candidacy**

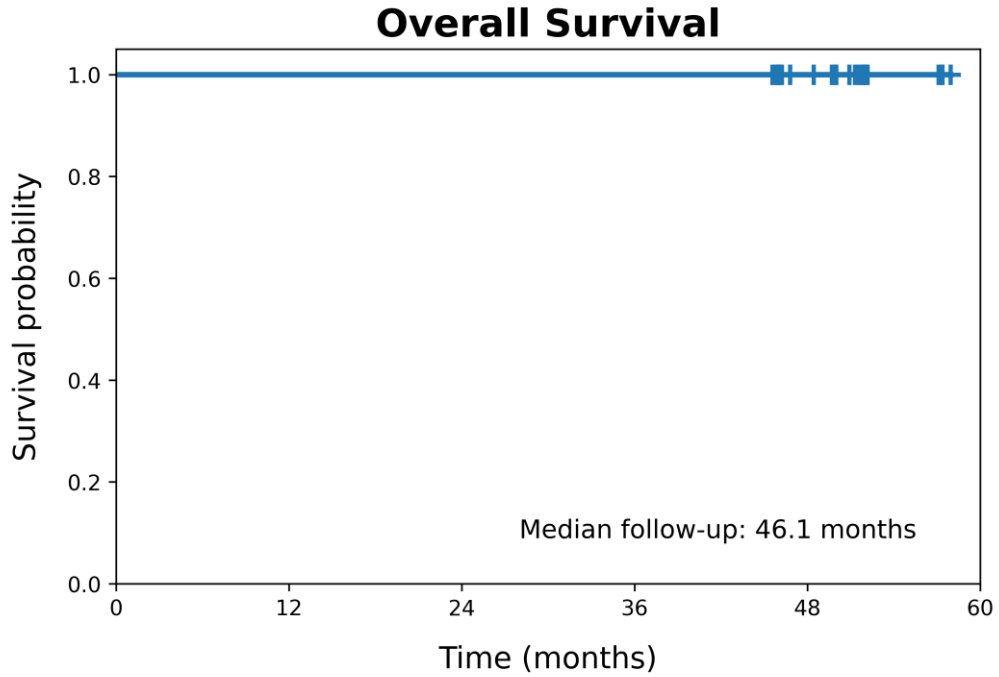
NORA: Pilot Study / single arm / single center (Yonsei)

- **Midterm oncologic outcome**



No. at risk

25	25	24	24	15	0

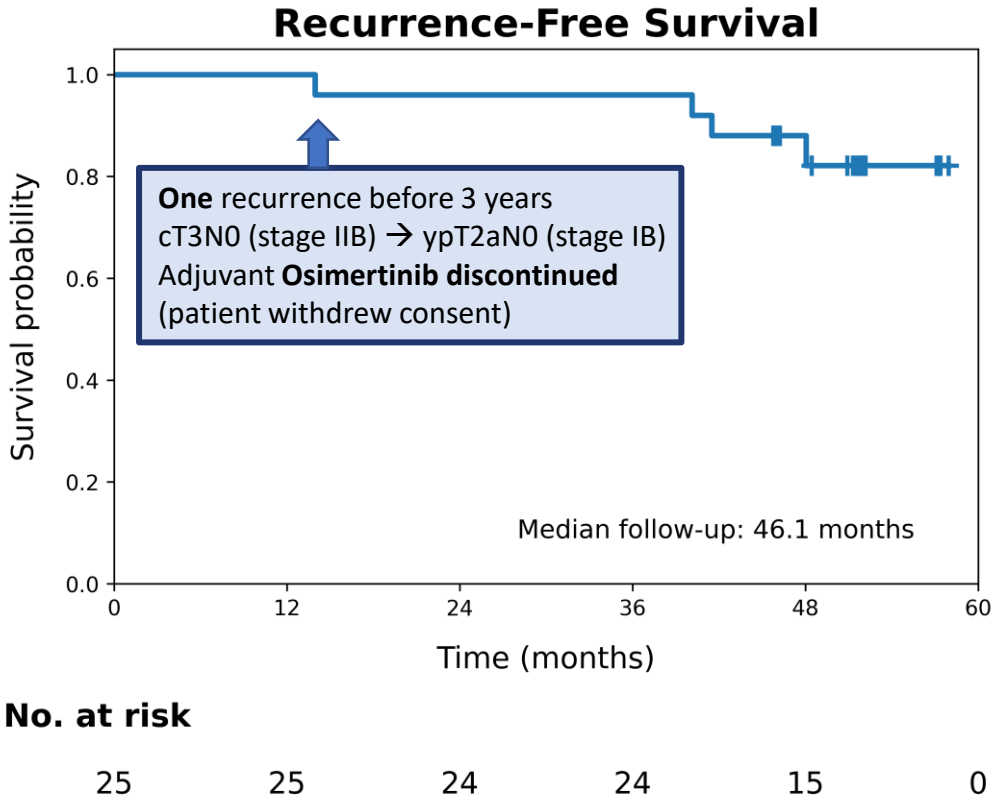


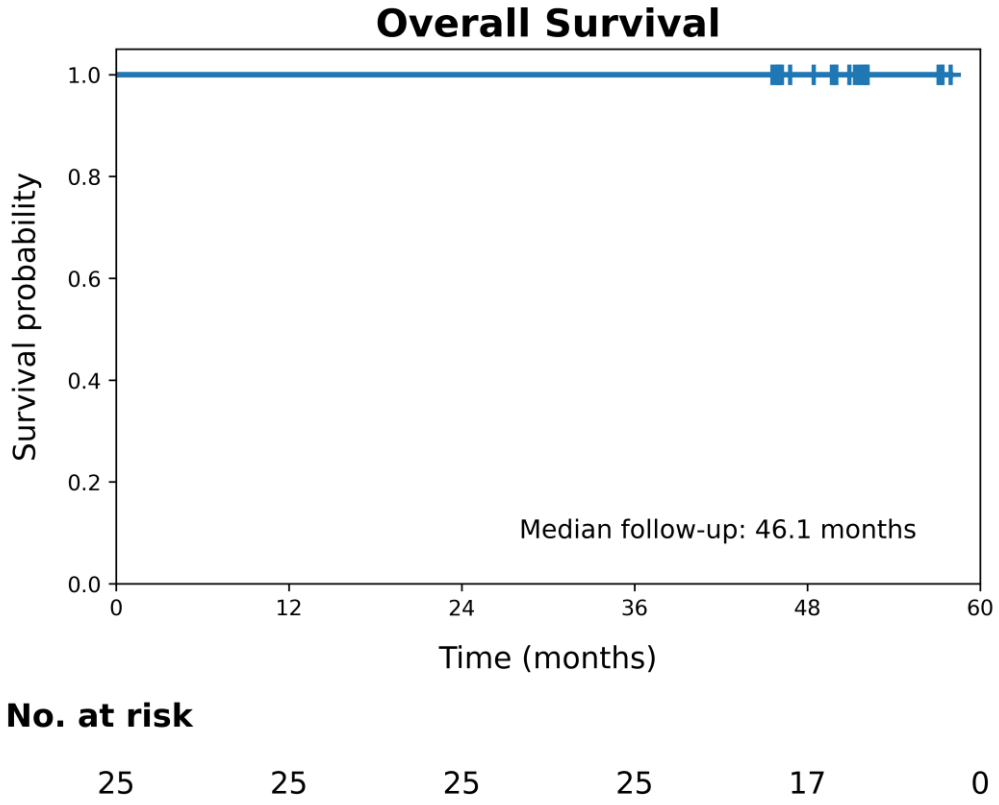
No. at risk

25	25	25	25	17	0

NORA: Pilot Study / single arm / single center (Yonsei)

- **Midterm oncologic outcome**





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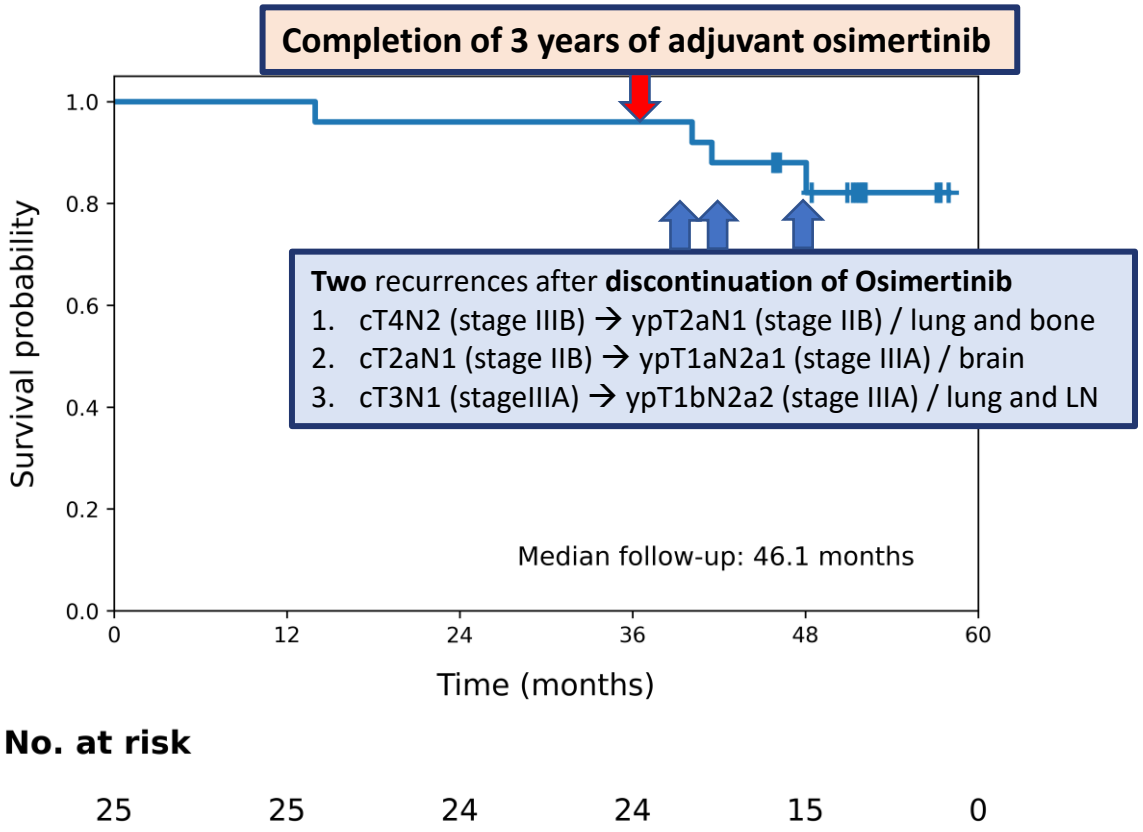
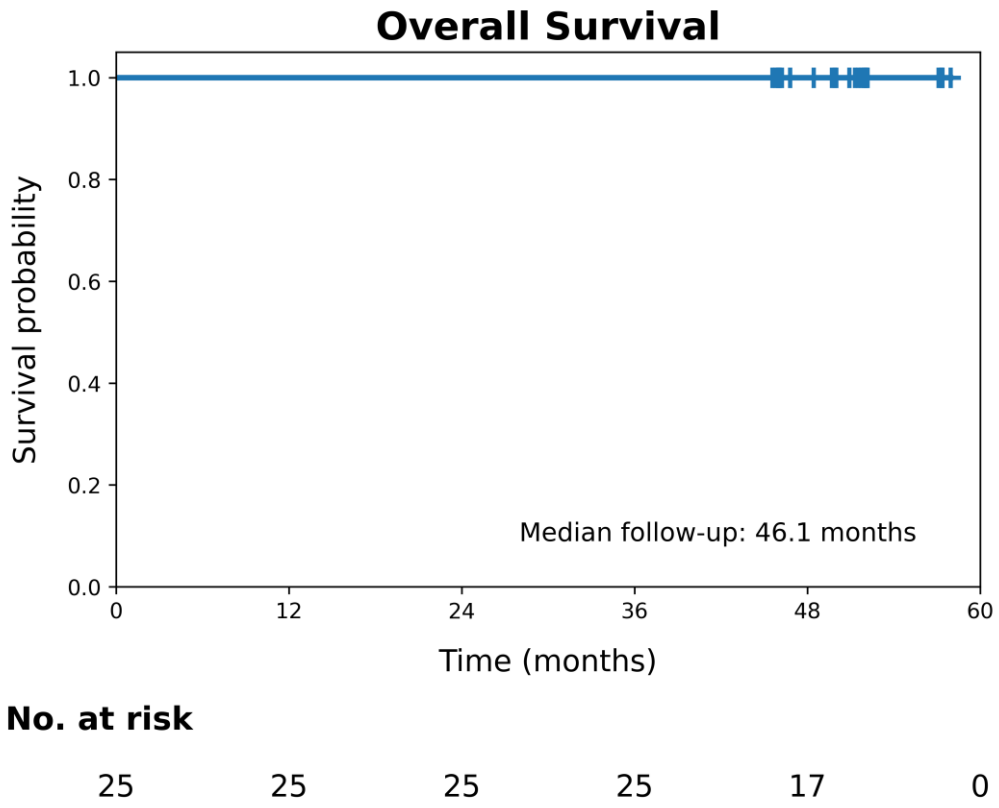


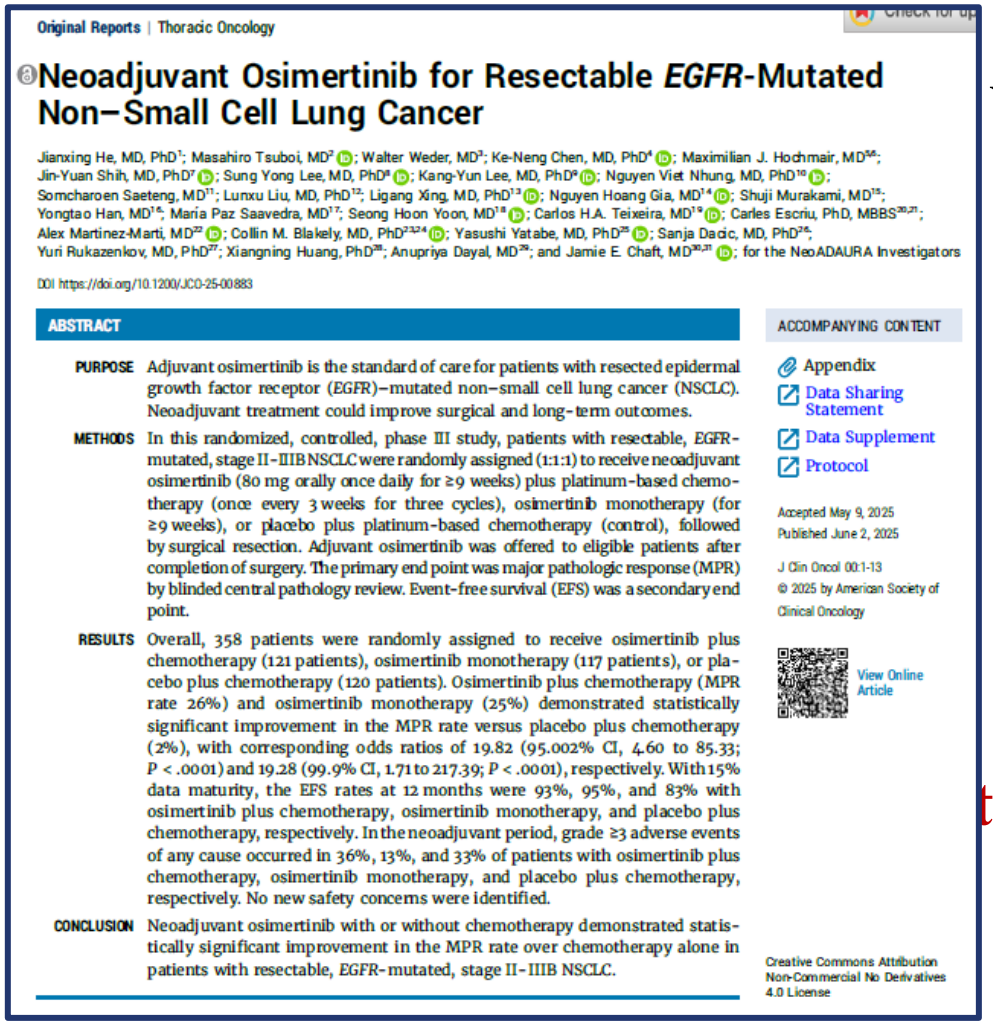


NeoADAURA (Phase III)

- Resectable **stage II–IIIB**, **EGFR-mutant** NSCLC
- **MPR**: **~25%** with osimertinib vs **2%** with chemotherapy
- Pathologic complete response: low
- **90~95%** underwent surgery
- **High R0** resection rate: **91~95%**
- **N2 downstaging** observed
- **Neoadjuvant osimertinib significantly improves pathologic response without compromising surgical feasibility.**

NeoADAURA (Phase III)

- Resectable **stage II–IIIB**, **EGFR-mutant** NSCLC
- with chemotherapy
- tly improves pathologic response without



Original Reports | Thoracic Oncology

Neoadjuvant Osimertinib for Resectable *EGFR*-Mutated Non–Small Cell Lung Cancer

Jianxing He, MD, PhD[1]; Masahiro Tsuboi, MD[2]; Walter Weder, MD[3]; Ke-Neng Chen, MD, PhD[4]; Maximilian J. Hochmair, MD[5,6]; Jin-Yuan Shih, MD, PhD[7]; Sung Yong Lee, MD, PhD[8]; Kang-Yun Lee, MD, PhD[9]; Nguyen Viet Nhung, MD, PhD[10]; Somcharoen Saeteng, MD[11]; Lunxu Liu, MD, PhD[12]; Ligang Xing, MD, PhD[13]; Nguyen Hoang Gia, MD[14]; Shuji Murakami, MD[15]; Yongtao Han, MD[16]; María Paz Saavedra, MD[17]; Seong Hoon Yoon, MD[18]; Carlos H.A. Teixeira, MD[19]; Carles Escriu, PhD, MBBS[20,21]; Alex Martinez-Marti, MD[22]; Collin M. Blakely, MD, PhD[23,24]; Yasushi Yatabe, MD, PhD[25]; Sanja Dacic, MD, PhD[26]; Yuri Rukazenkov, MD, PhD[27]; Xiangning Huang, PhD[28]; Anupriya Dayal, MD[29]; and Jamie E. Chaft, MD[30,31]; for the NeoADAURA Investigators

DOI https://doi.org/10.1200/JCO-25-00883

ABSTRACT

PURPOSE Adjuvant osimertinib is the standard of care for patients with resected epidermal growth factor receptor (*EGFR*)–mutated non–small cell lung cancer (NSCLC). Neoadjuvant treatment could improve surgical and long-term outcomes.

METHODS In this randomized, controlled, phase III study, patients with resectable, *EGFR*-mutated, stage II-IIIB NSCLC were randomly assigned (1:1:1) to receive neoadjuvant osimertinib (80 mg orally once daily for ≥9 weeks) plus platinum-based chemotherapy (once every 3 weeks for three cycles), osimertinib monotherapy (for ≥9 weeks), or placebo plus platinum-based chemotherapy (control), followed by surgical resection. Adjuvant osimertinib was offered to eligible patients after completion of surgery. The primary end point was major pathologic response (MPR) by blinded central pathology review. Event-free survival (EFS) was a secondary end point.

RESULTS Overall, 358 patients were randomly assigned to receive osimertinib plus chemotherapy (121 patients), osimertinib monotherapy (117 patients), or placebo plus chemotherapy (120 patients). Osimertinib plus chemotherapy (MPR rate 26%) and osimertinib monotherapy (25%) demonstrated statistically significant improvement in the MPR rate versus placebo plus chemotherapy (2%), with corresponding odds ratios of 19.82 (95.002% CI, 4.60 to 85.33; $P < .0001$) and 19.28 (99.9% CI, 1.71 to 217.39; $P < .0001$), respectively. With 15% data maturity, the EFS rates at 12 months were 93%, 95%, and 83% with osimertinib plus chemotherapy, osimertinib monotherapy, and placebo plus chemotherapy, respectively. In the neoadjuvant period, grade ≥3 adverse events of any cause occurred in 36%, 13%, and 33% of patients with osimertinib plus chemotherapy, osimertinib monotherapy, and placebo plus chemotherapy, respectively. No new safety concerns were identified.

CONCLUSION Neoadjuvant osimertinib with or without chemotherapy demonstrated statistically significant improvement in the MPR rate over chemotherapy alone in patients with resectable, *EGFR*-mutated, stage II-IIIB NSCLC.

ACCOMPANYING CONTENT

Appendix
Data Sharing Statement
Data Supplement
Protocol

Accepted May 9, 2025
Published June 2, 2025

J Clin Oncol 00:1-13

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Skip

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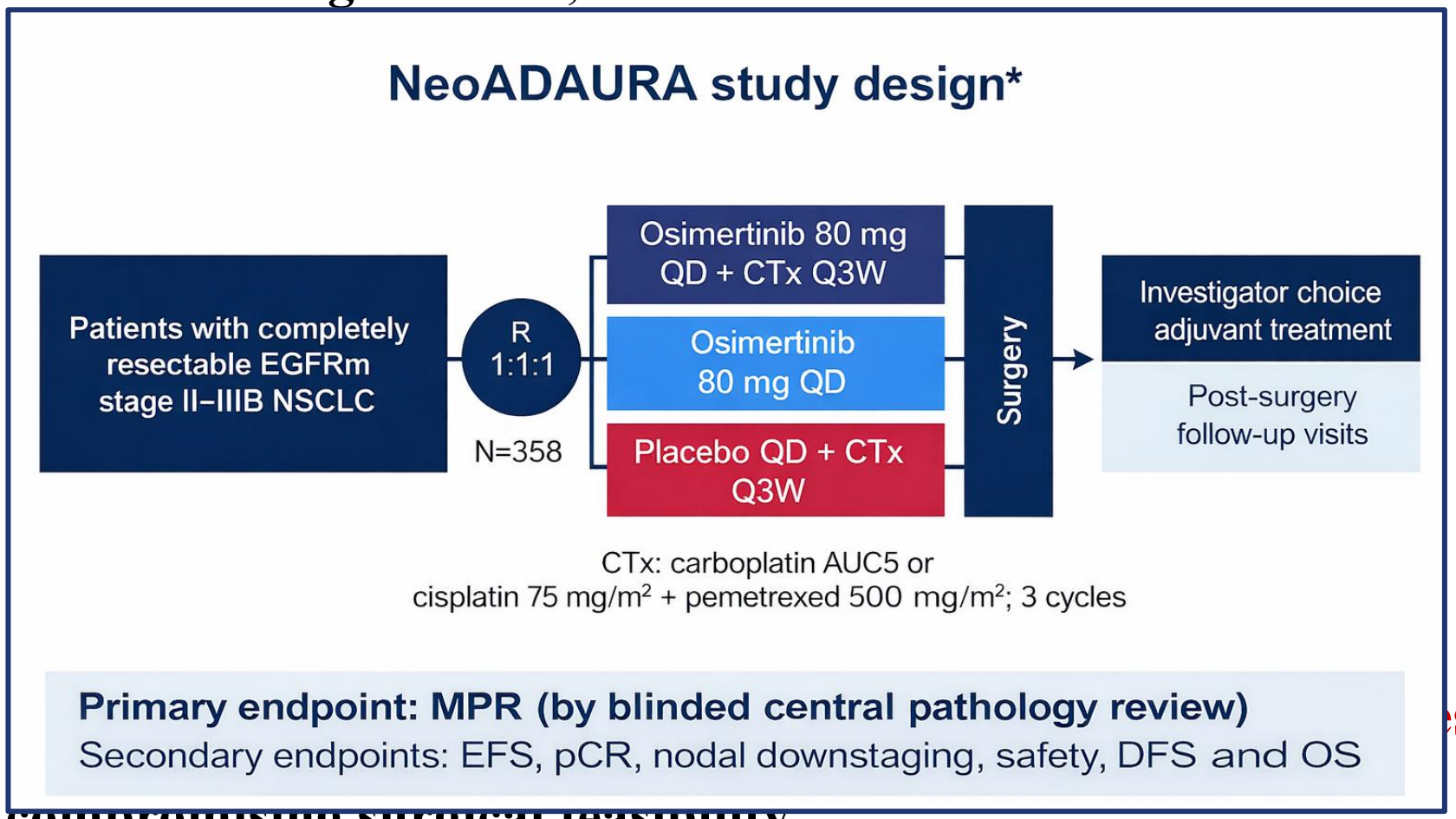

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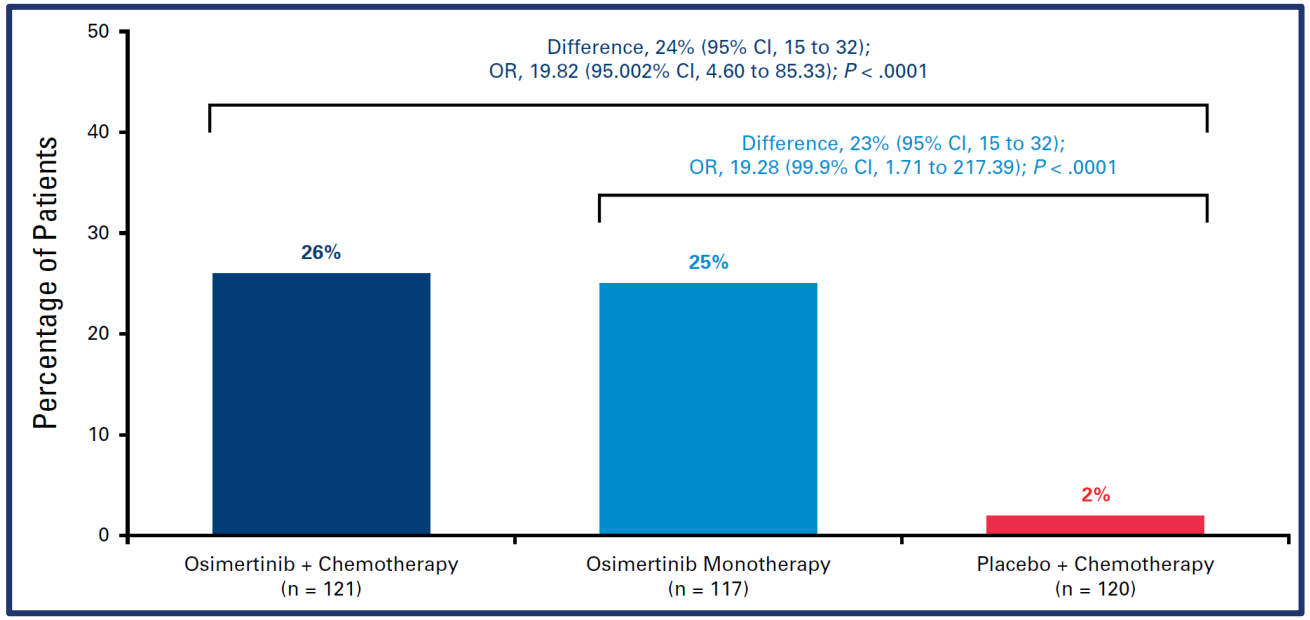

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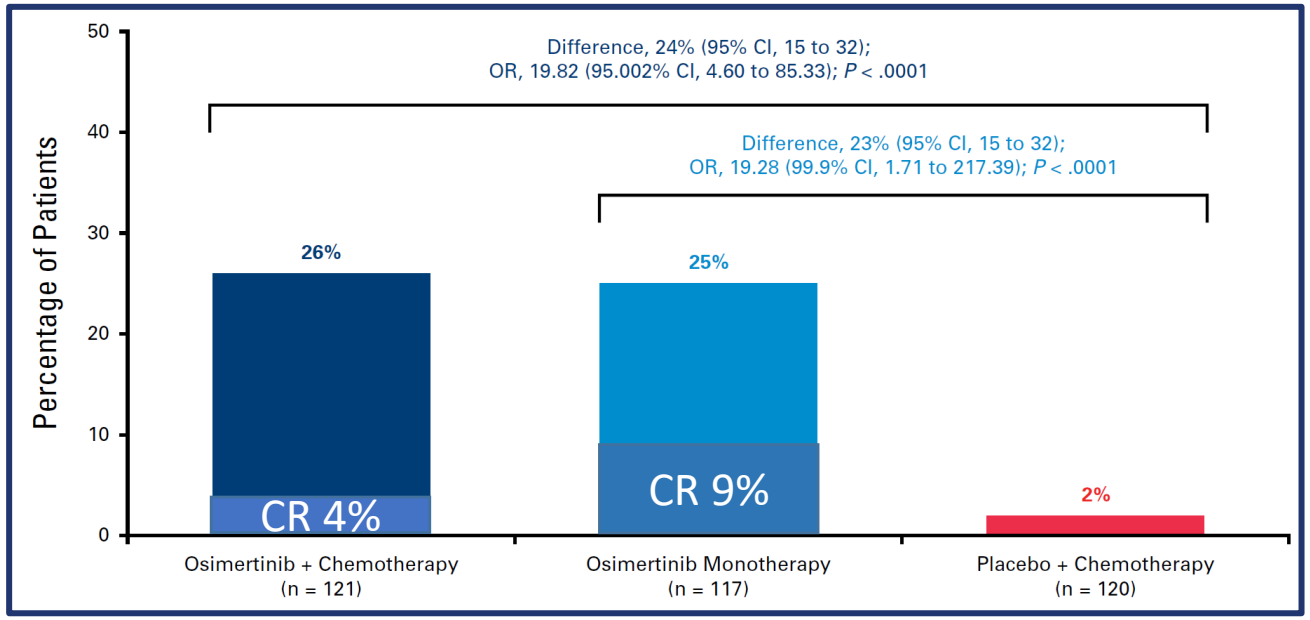

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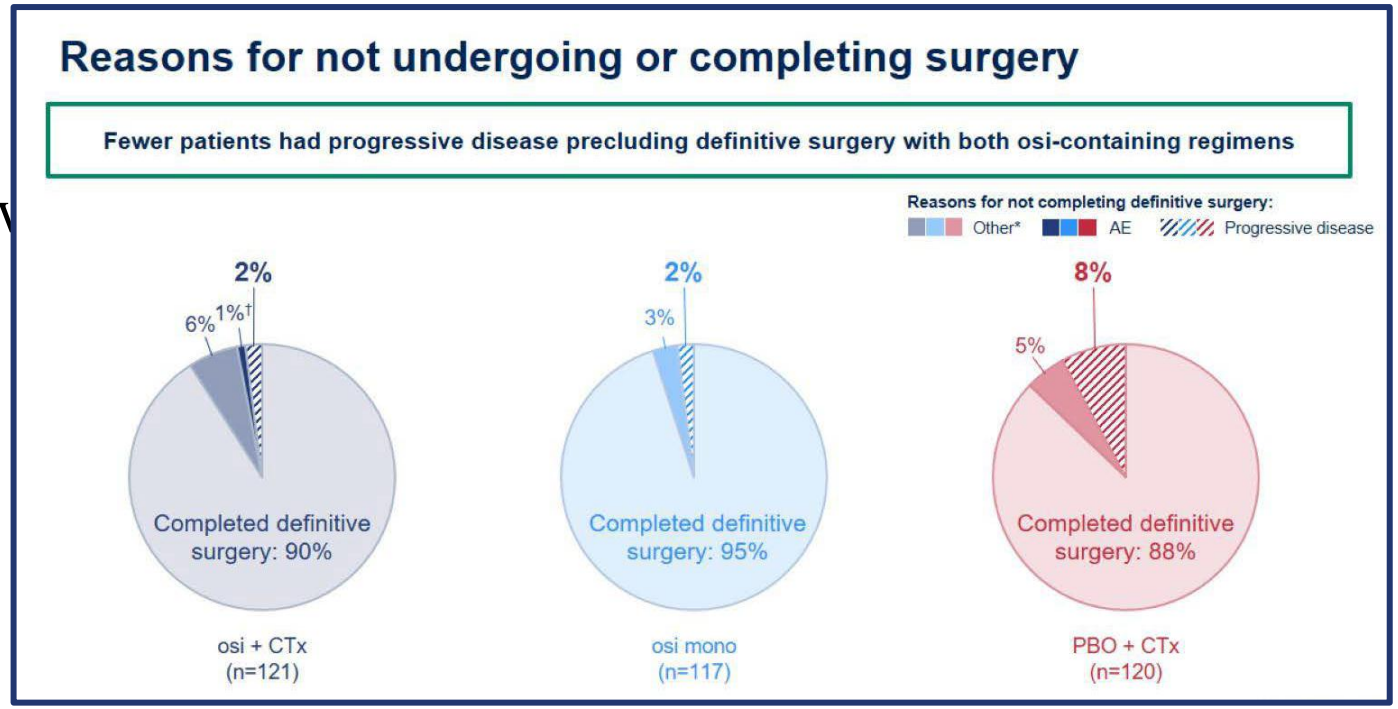

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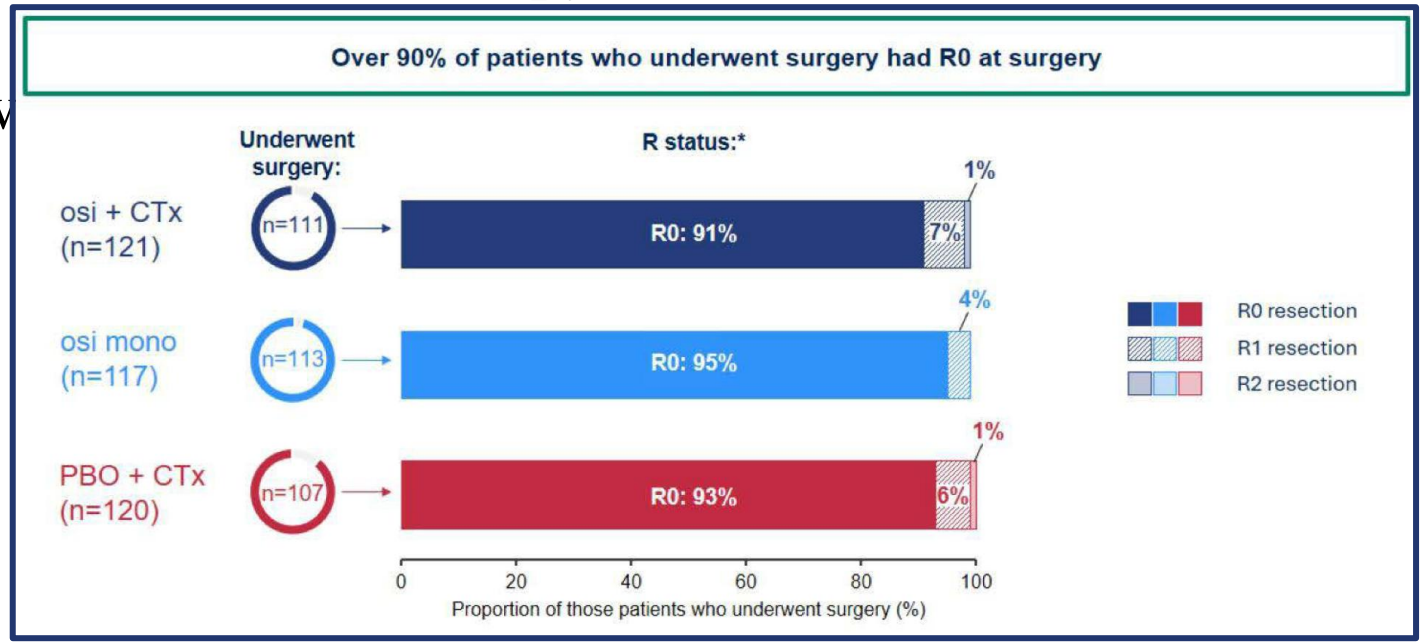

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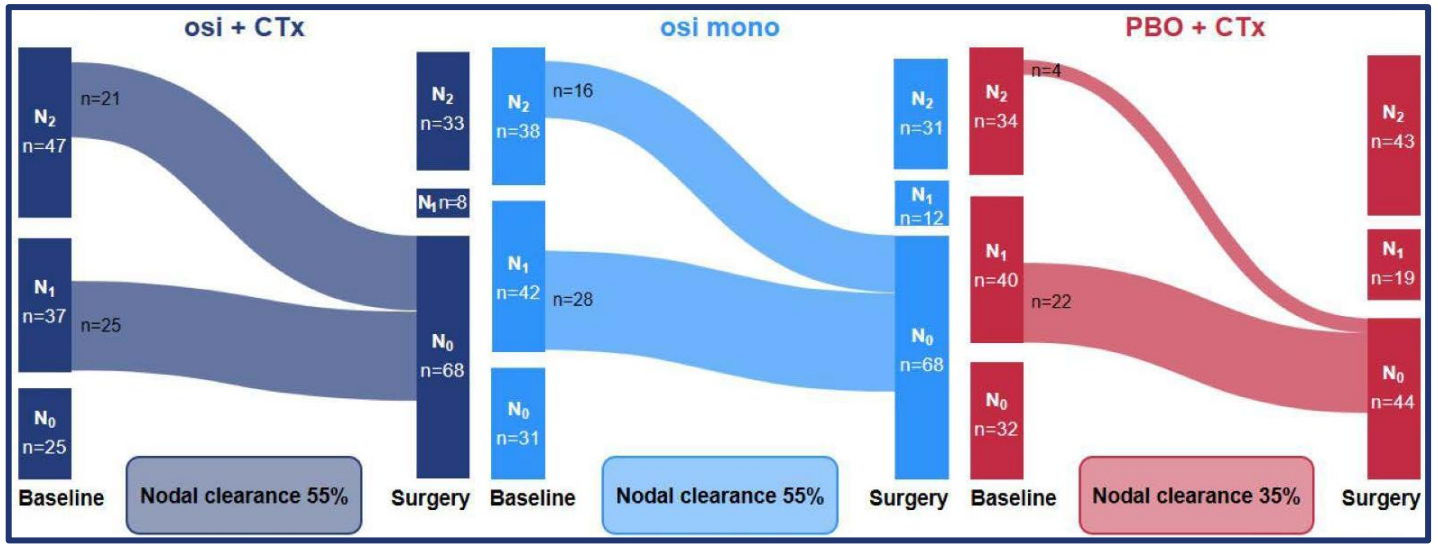

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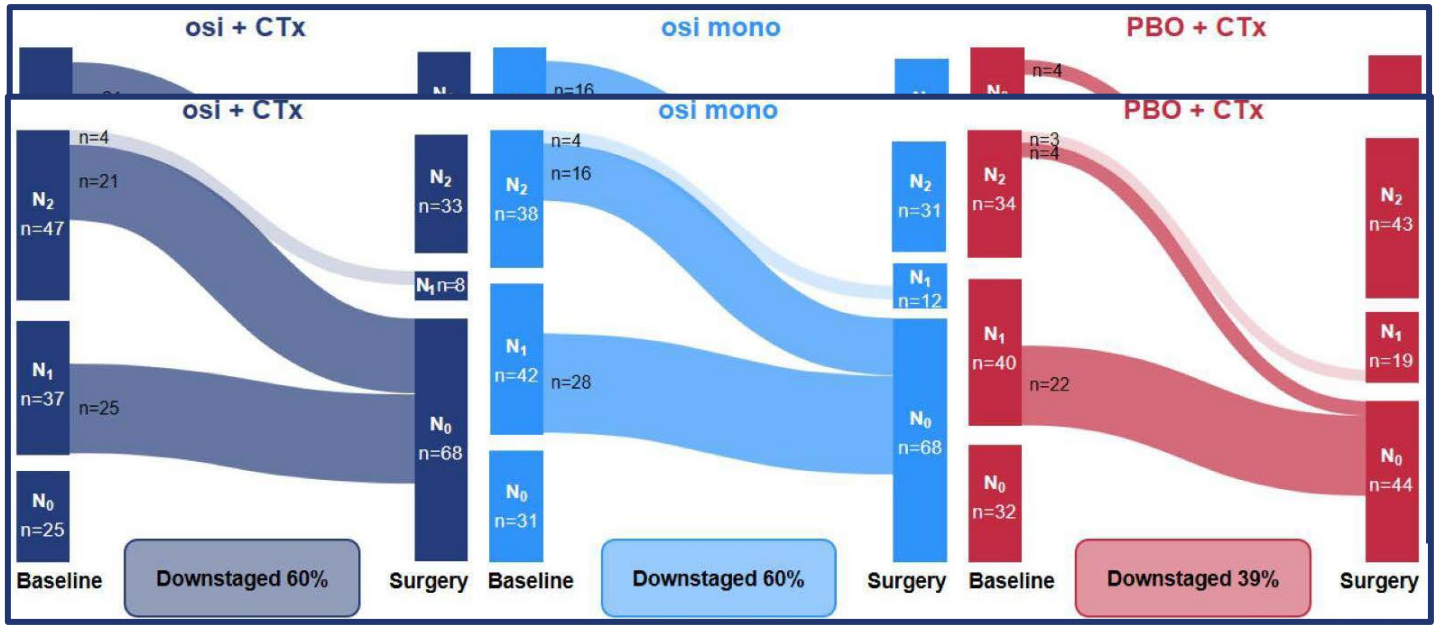

- **Neoadjuvant osimertinib significantly improves pathologic response without compromising surgical feasibility.**

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NeoADAURA (Phase III)

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- **High R0** resection rate: **91~9**
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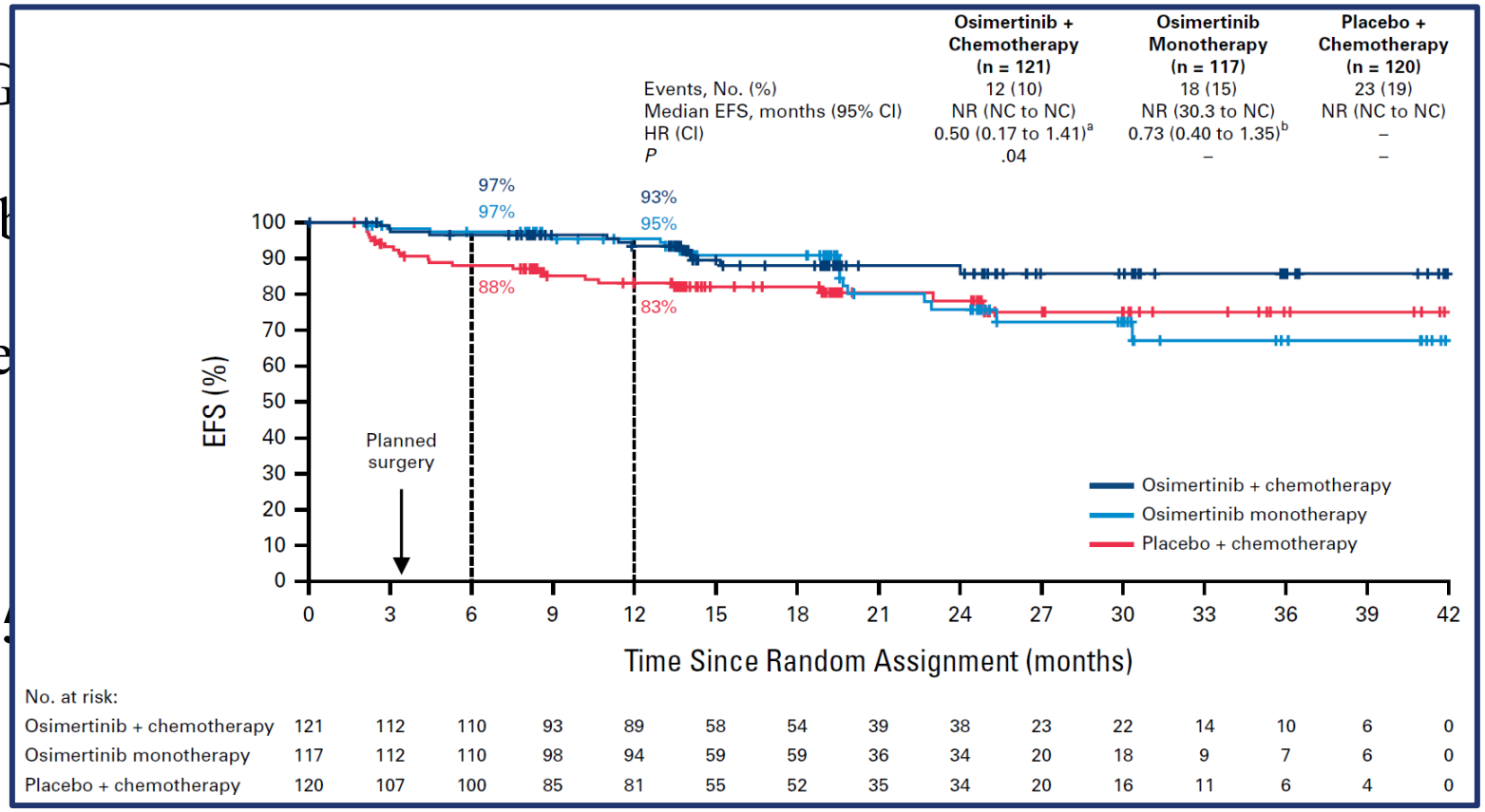

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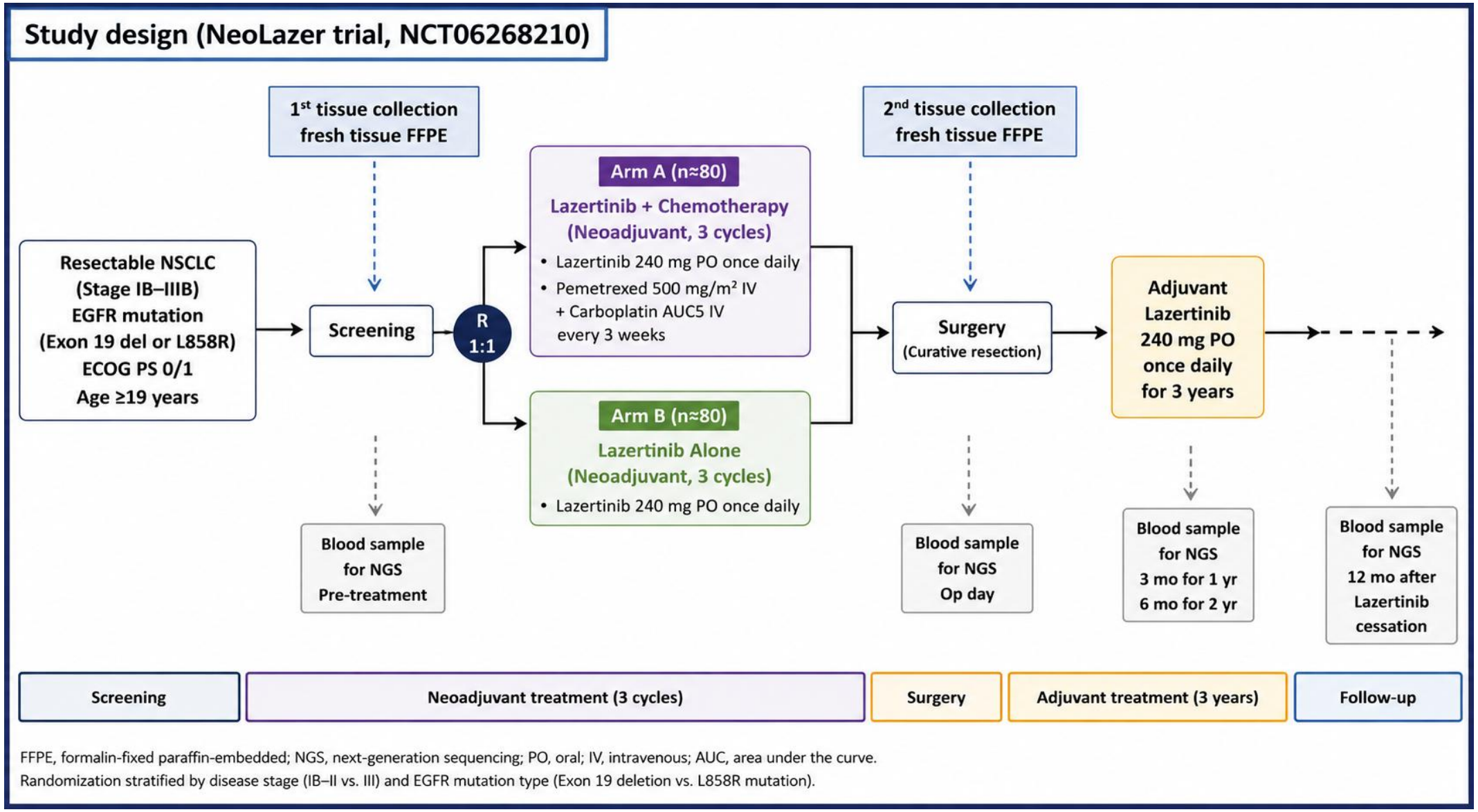
Skip

Neolazer: phase II / randomized / multi-center



FFPE, formalin-fixed paraffin-embedded; NGS, next-generation sequencing; PO, oral; IV, intravenous; AUC, area under the curve.
Randomization stratified by disease stage (IB–II vs. III) and EGFR mutation type (Exon 19 deletion vs. L858R mutation).

Neoadjuvant TKI Case 1

- Lung cancer (RLL, ADC, **cT3N2bM0**) + **E19del** mutation
- **Neoadjuvant Osimertinib** (2022-01-21 ~ 2022-03-16, **8wks**)

Neoadjuvant TKI Case

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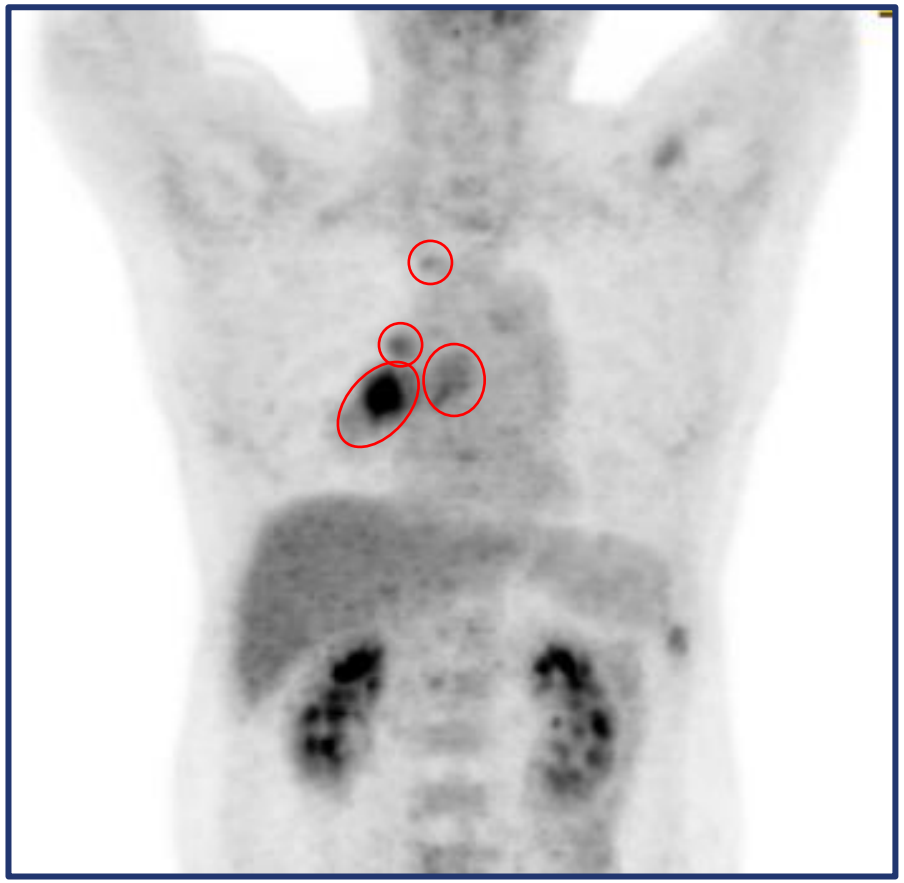
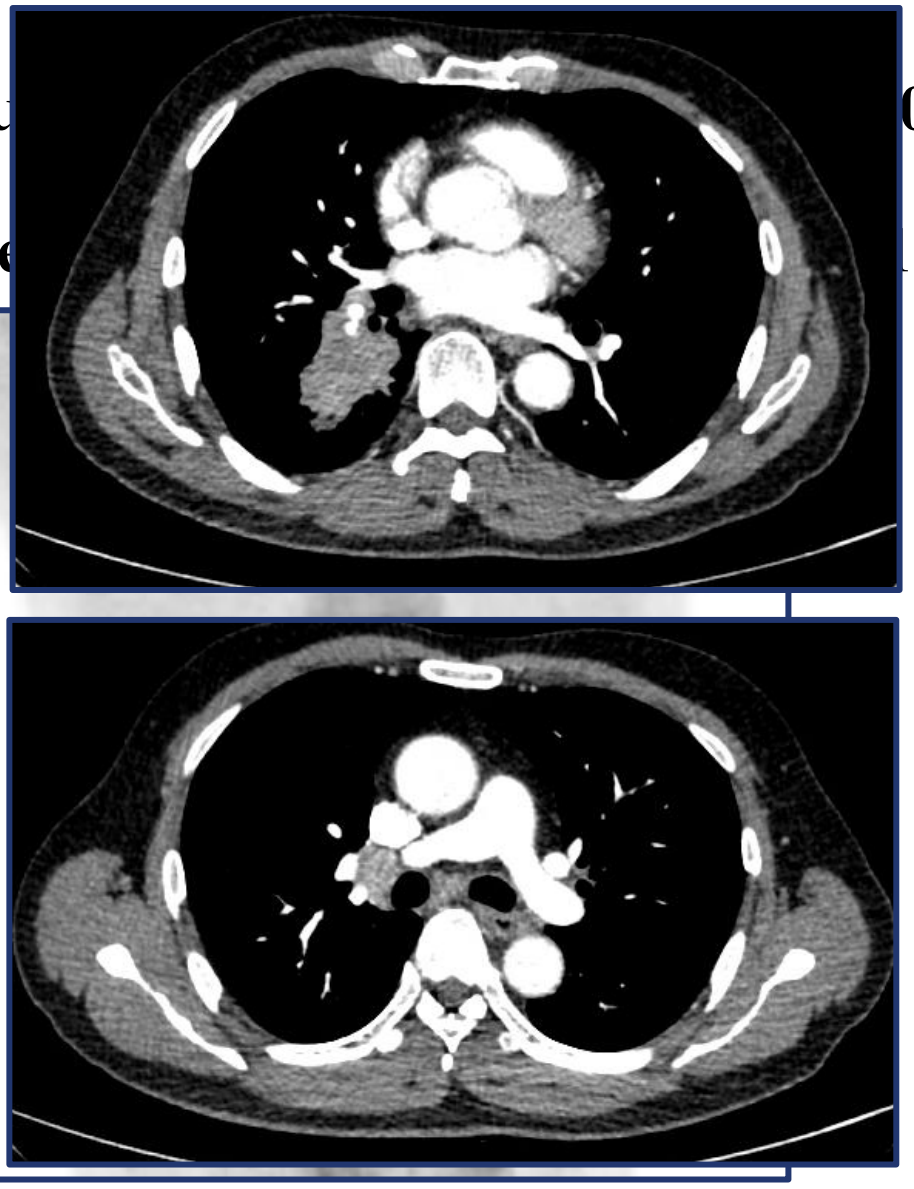


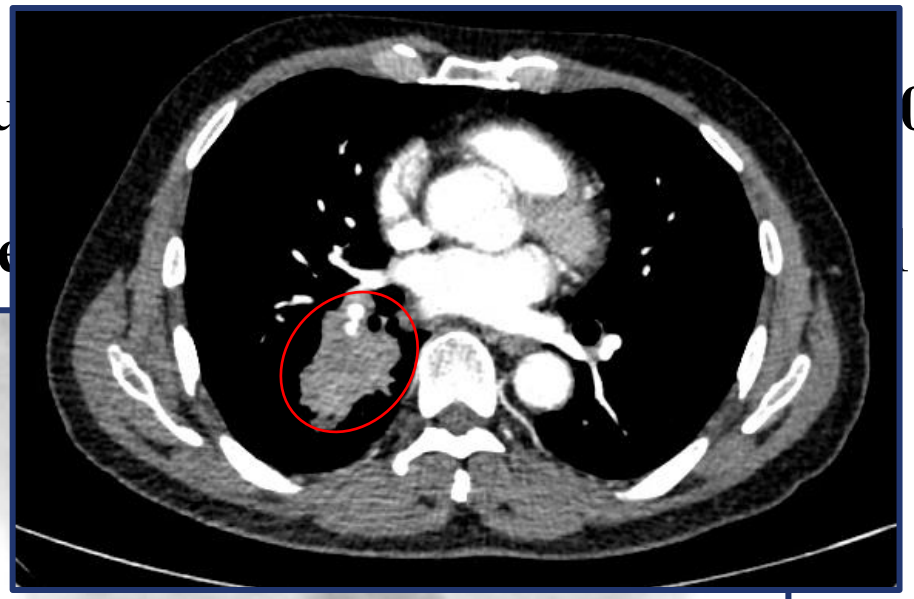
Neoadjuvant TKI Case

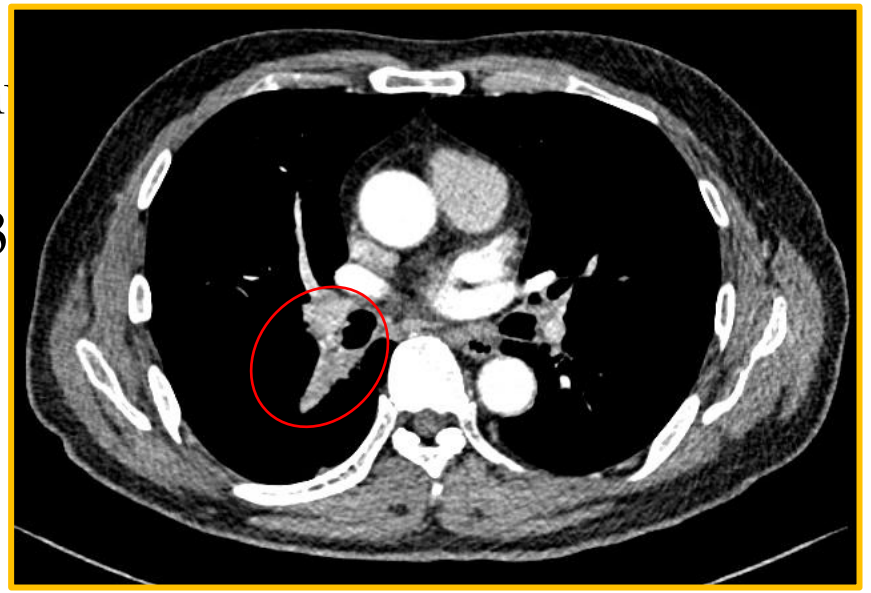
- Lu **0)** + **E19del** mutation
- **Ne** -21 ~ 2022-03-16, **8wks**)

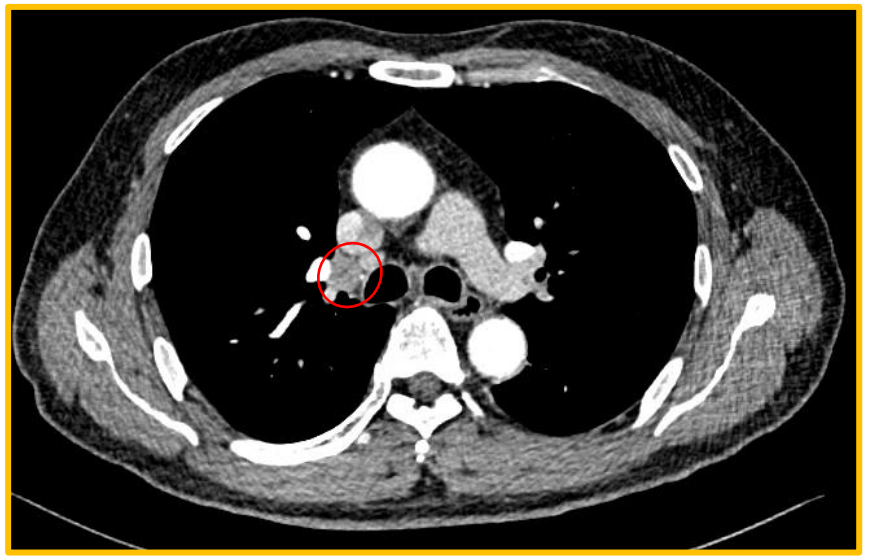


Neoadjuvant TKI Case

- Lu 0) + **E19del** m
- **Ne** -21 ~ 2022-03







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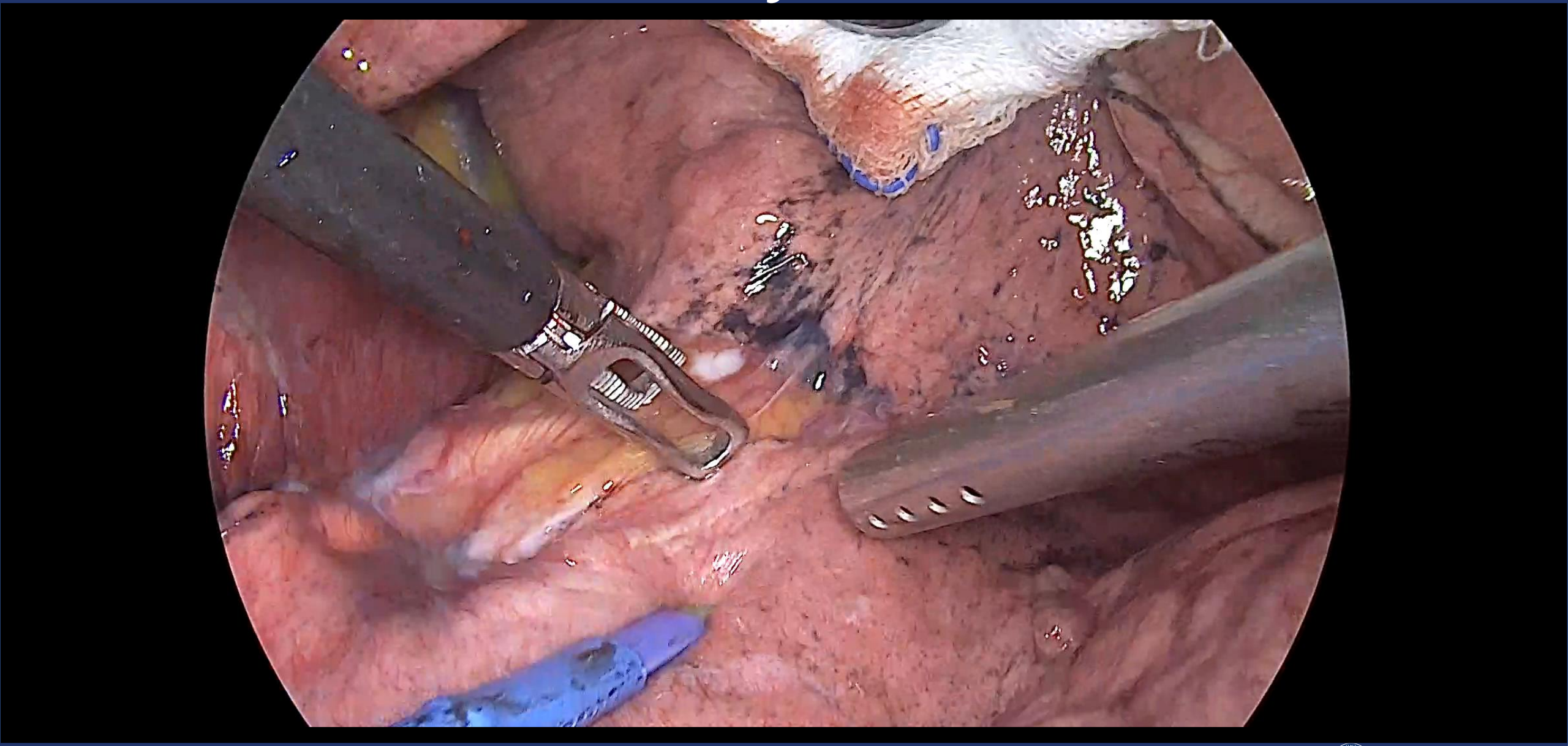
- **Neoadjuvant Osimertinib** (2022-01-21 ~ 2022-03-16, **8wks**)
- VATS RLLobectomy with MLND + En-bloc wedge resection of RML (2022-03-28)

N1 LN dissection after neoadjuvant Osimertinib



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- **cT3N2bM0 → ypT3N1a(2mm)**

Neoadjuvant TKI Case 2

- Lung cancer (RLL, ADC, **cT2aN2a2M0**) + **L858R** mutation
- **Neoadjuvant Lazertinib** + chemoTx (2026-03-11 ~ 2026-05-17, **10wks + A/C #3/3**)

Neoadjuvant TKI Case 2

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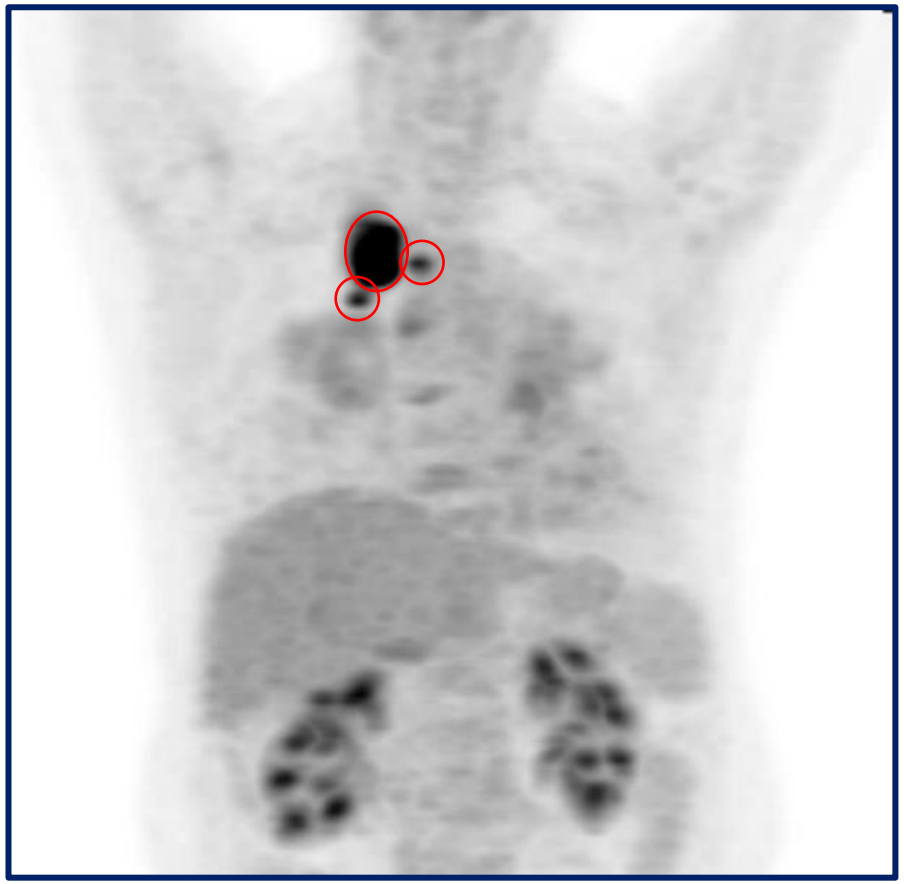
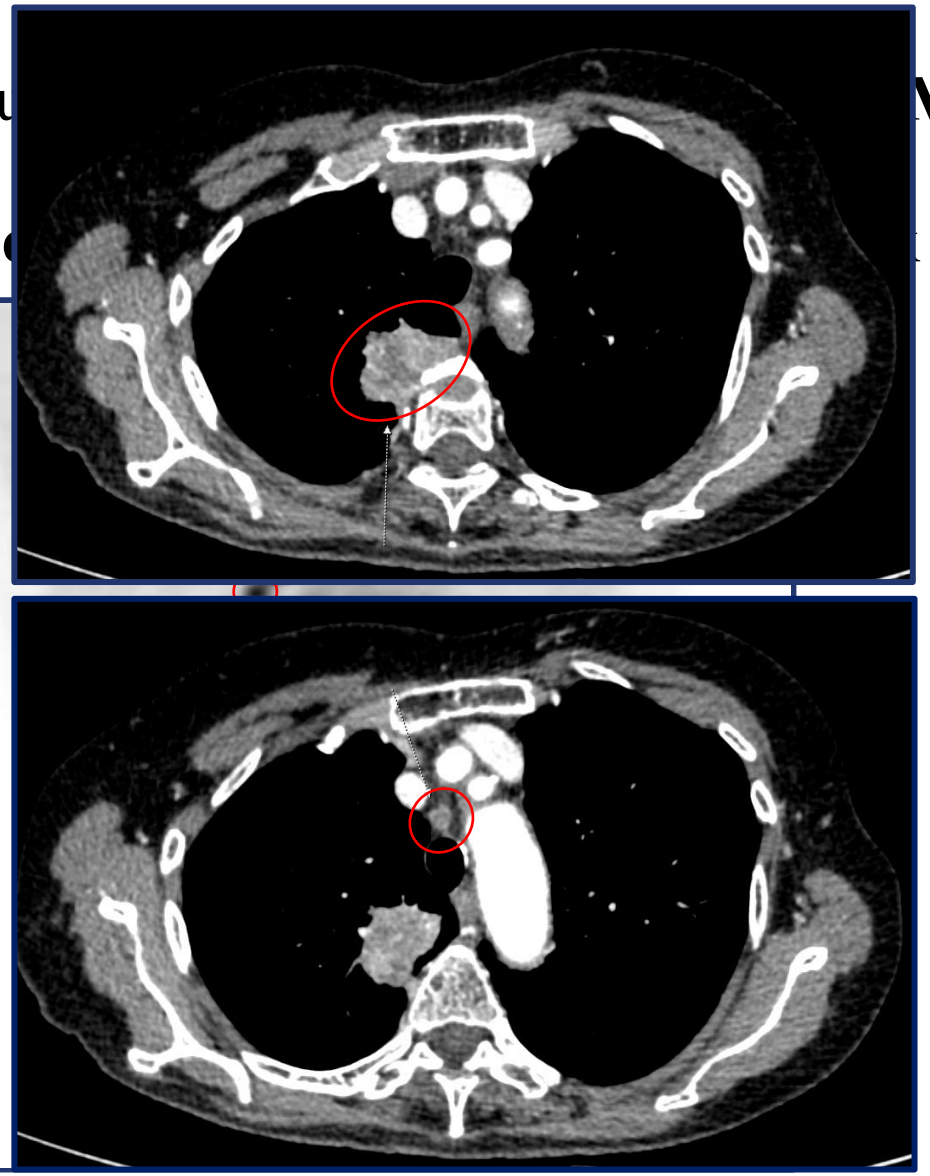
- **Neoadjuvant Lazertinib** + chemoTx (2026-03-11 ~ 2026-05-17, **10wks + A/C #3/3**)



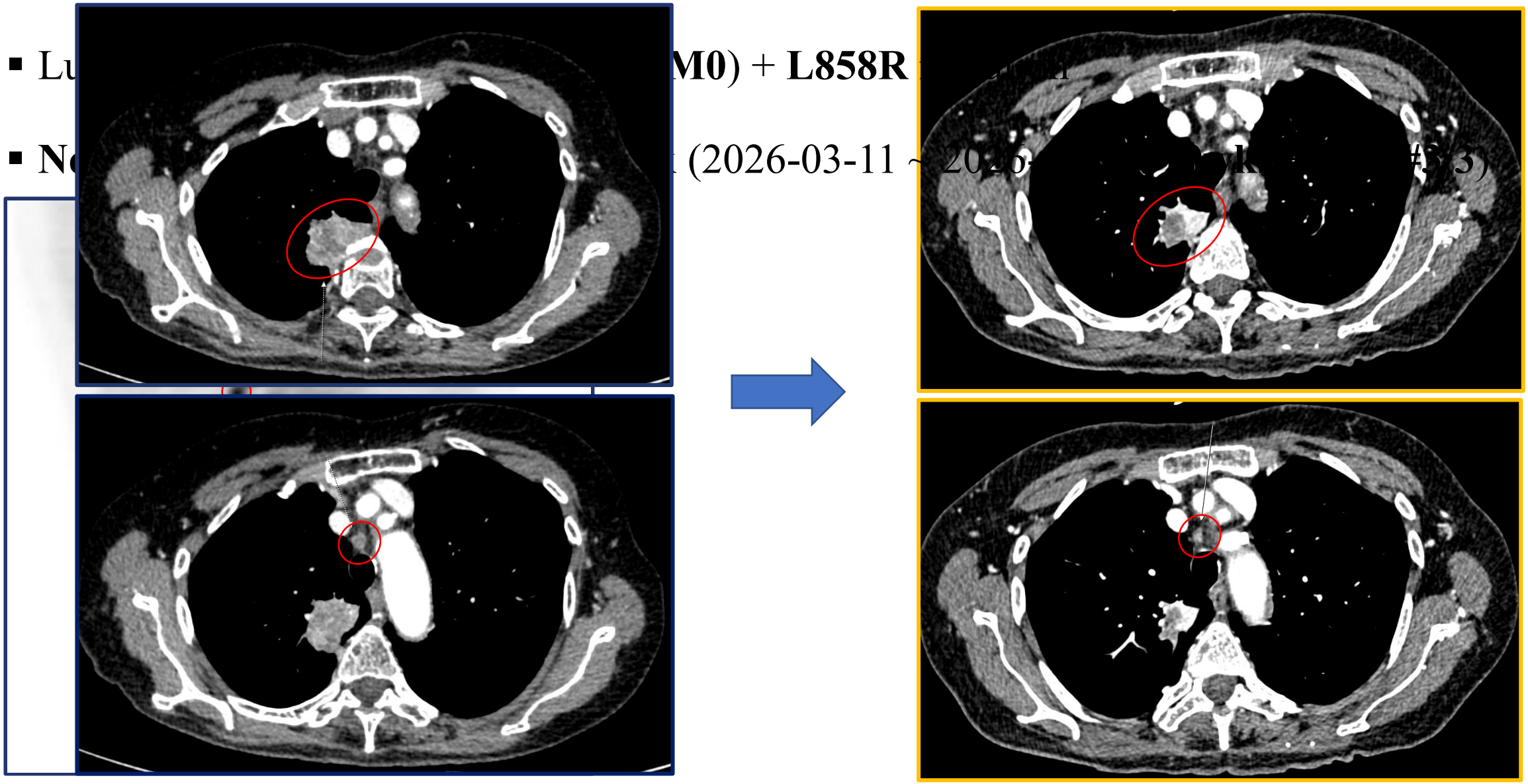
Neoadjuvant TKI Case 2

- Lu[illegible]M0) + **L858R** mutation
- Ne[illegible] (2026-03-11 ~ 2026-05-17, **10wks + A/C #3/3**)



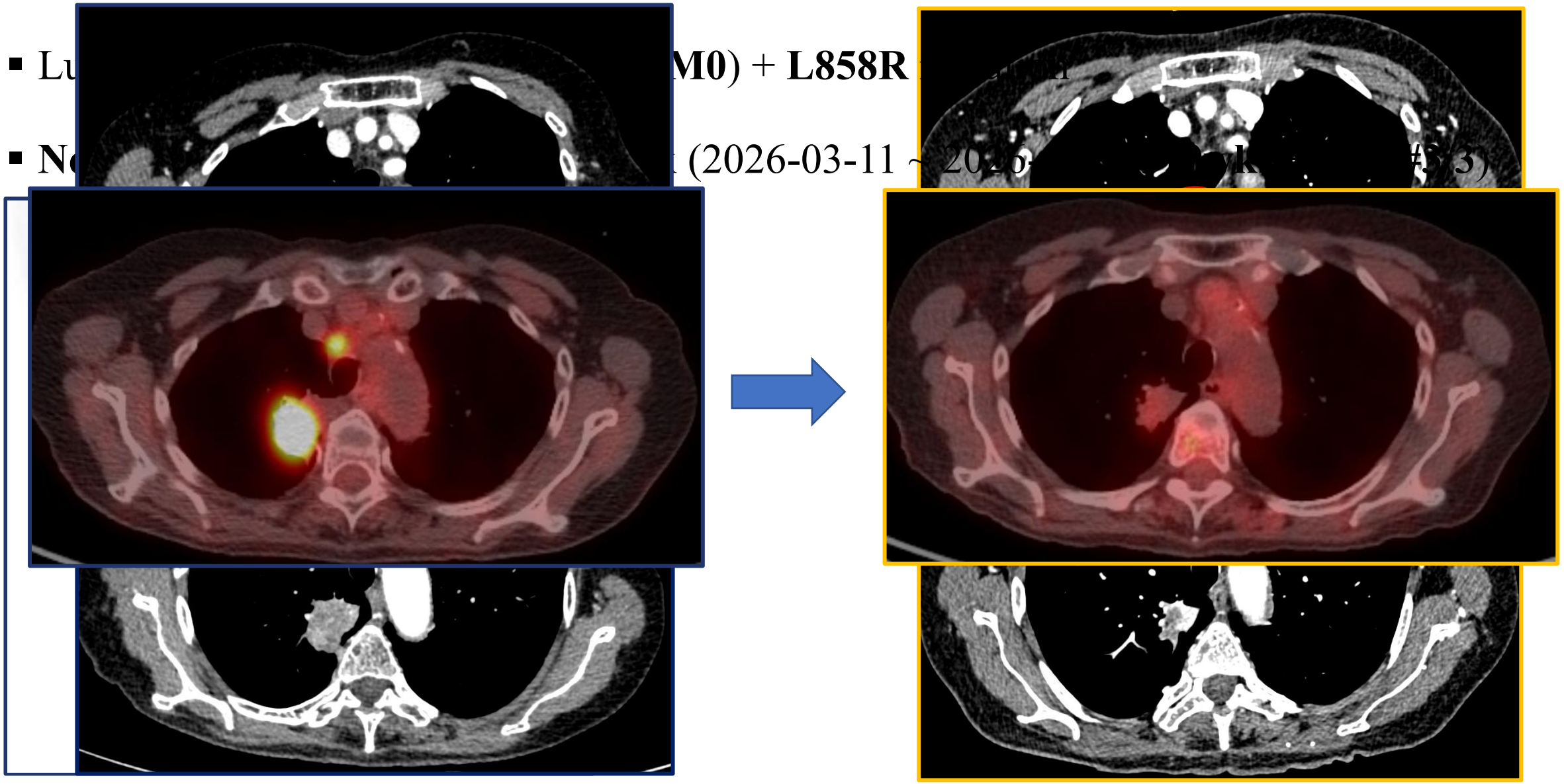
Neoadjuvant TKI Case 2

- Lu… M0) + **L858R** …
- Ne… (2026-03-11 ~ 202…)



Neoadjuvant TKI Case 2

- Lu… M0) + **L858R** …
- Ne… (2026-03-11 ~ 2026-… #3/3)



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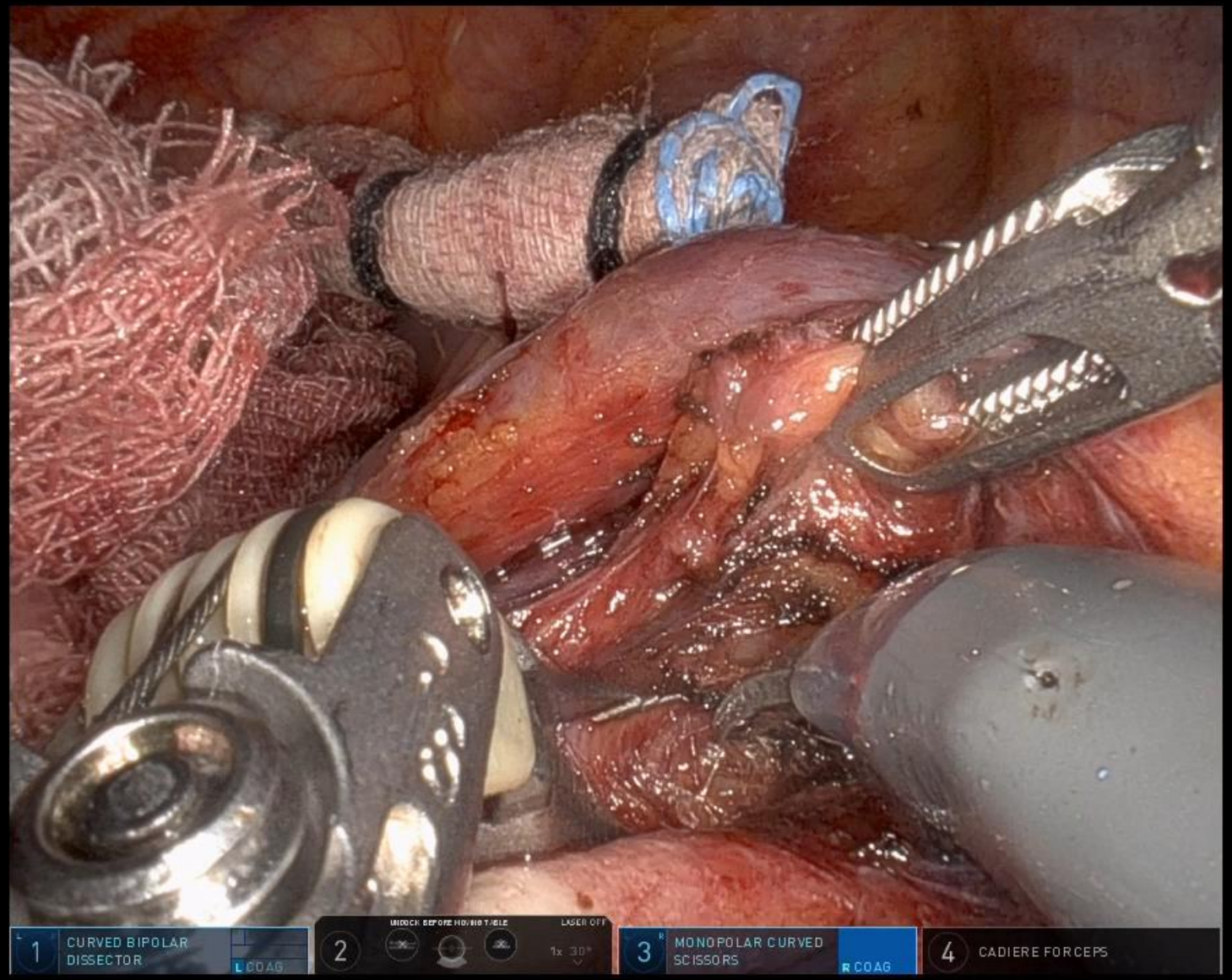
- RATS RULobectomy with MLND (2026-05-21)

Rt. paratracheal LN dissection after neoadjuvant Lazertinib



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- RATS RULobectomy with MLND (2026-05-21)
- **cT2aN2a2M0 → ypT2aN0**

Surgical Considerations After EGFR-TKI

- **Limited inflammatory reaction**
- **Preserved tissue planes**
- **Hilar dissection** is generally **feasible**
- **Anatomy often remains recognizable.**
- **No** clear **increase** in perioperative **morbidity** reported

Surgical Considerations After EGFR-TKI

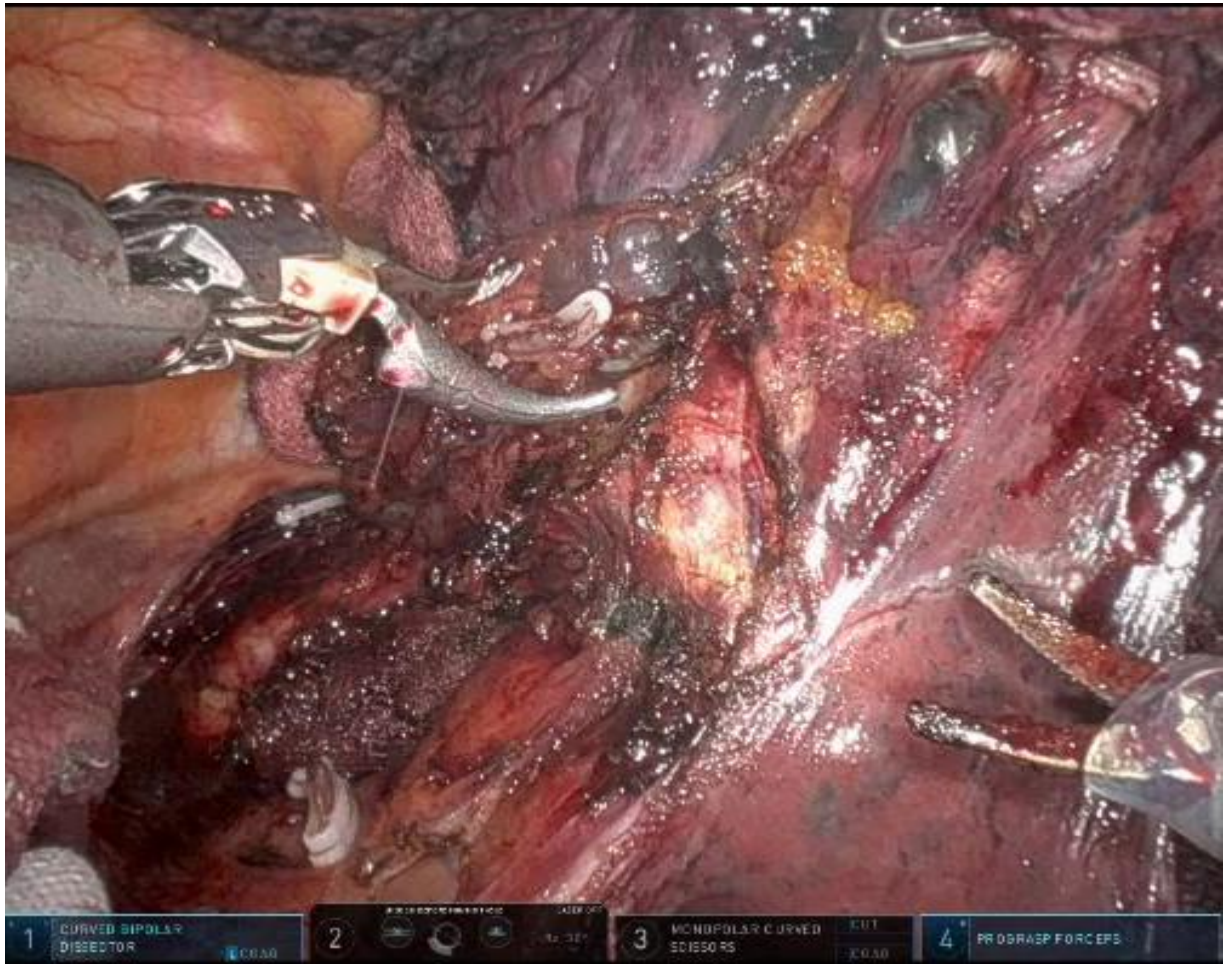
- **Limited inflammatory reaction**
- **Preserved tissue planes**
- **Hilar dissection** is generally **feasible**
- **Anatomy often remains recognizable.**

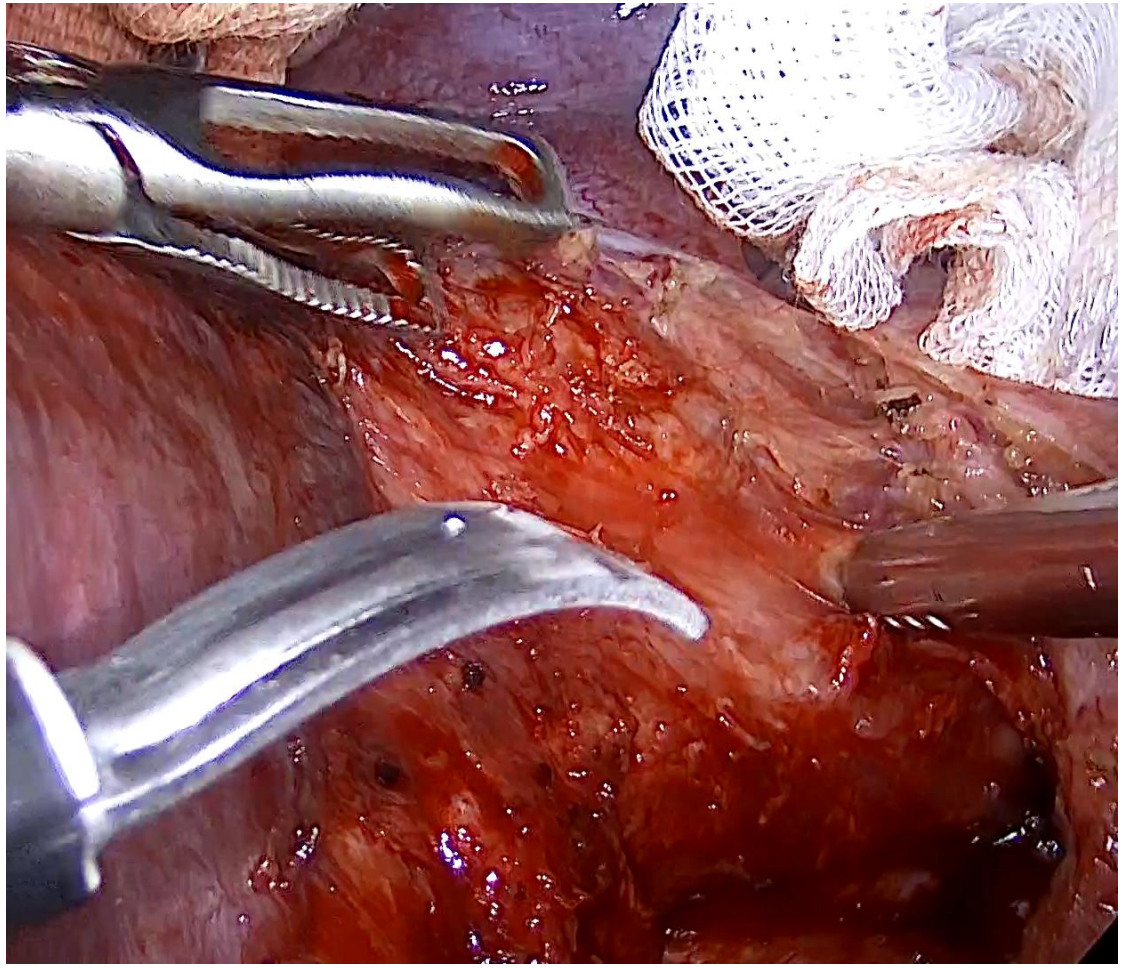
→ **Comparable to upfront surgery**

- **No** clear **increase** in perioperative **morbidity** reported

→ **without compromising surgical feasibility**

Compare to Neoadjuvant IO and CCRT case





Neoadjuvant TKI vs IO vs CCRT: A Surgical Perspective

	EGFR-TKI	Immunotherapy	CCRT
Dominant Effect	**Targeted tumor apoptosis**	Immune-mediated **inflammation**	Radiation-induced **fibrosis** + cytotoxic necrosis
Fibrosis	Usually **mild**	**Variable**, sometimes dense	Often **significant**
Identification of previously metastatic LN	Mild capsular thickening	Diffuse nodal enlargement d/t reactive hyperplasia	Frequently embedded in fibrotic tissue
LN dissection	**Comparable to upfront surgery** in most cases	May require **wider clearance**	**Technically demanding** due to fibrosis
Preservation of **surgical planes**	Usually **preserved**	**Variable**, inflammatory changes	Frequently **distorted**
Overall technical feasibility	**Comparable to upfront surgery in most cases**	**Generally feasible, but less predictable**	**Technically demanding, especially in minimally invasive approaches**

Take home message

- **Neoadjuvant Osimertinib improves pathologic response while preserving surgical feasibility.**
  - **Neoadjuvant Osimertinib significantly improves MPR**
- **Neoadjuvant Osimertinib shows favorable early event-free survival signals, pending longer-term follow-up.**
- **Given the low risk of preoperative progression and recent availability in Korea, neoadjuvant EGFR-TKI is becoming an increasingly important treatment option.**


Severance
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