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Radiation Therapy *IS* Effective for the Management of Oligometastatic NSCLC

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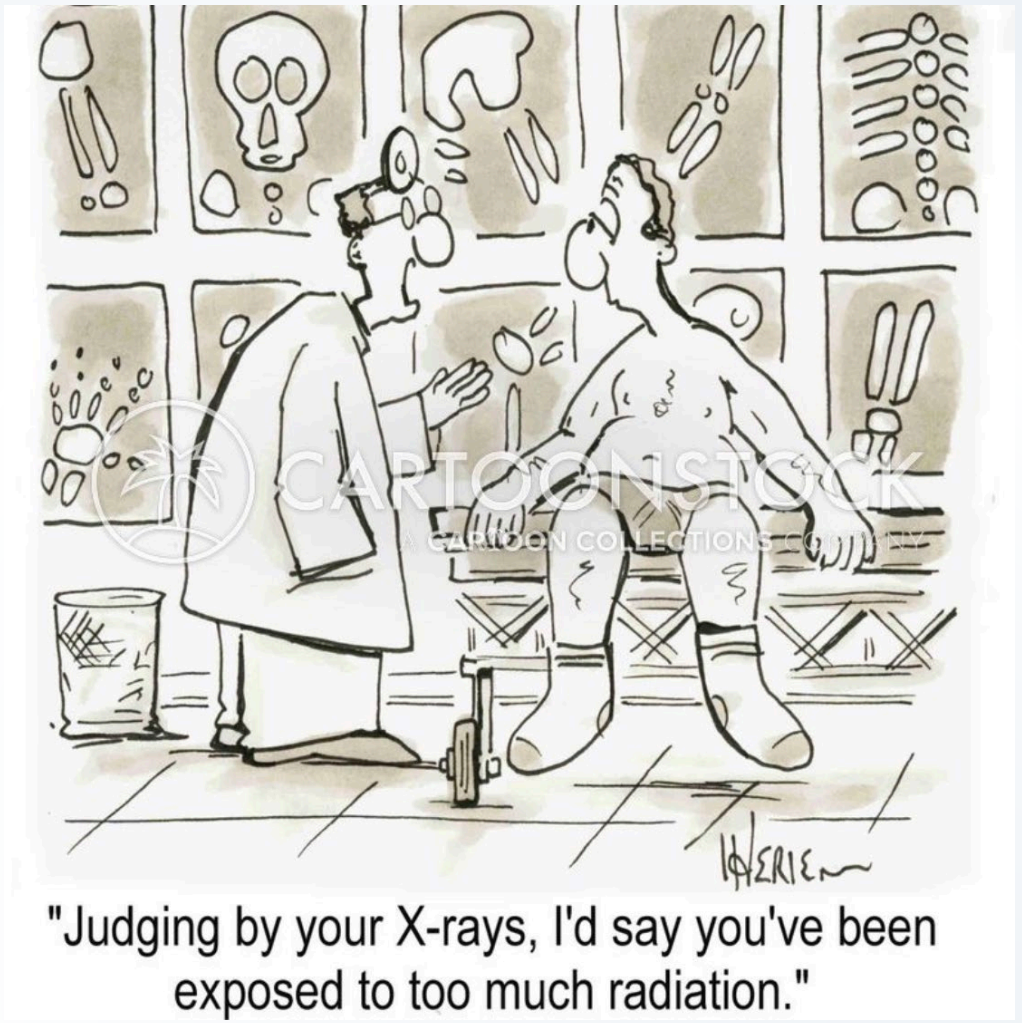
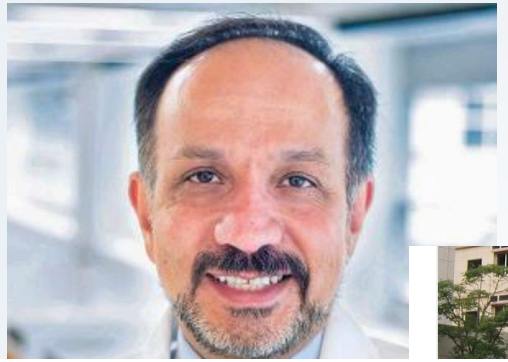
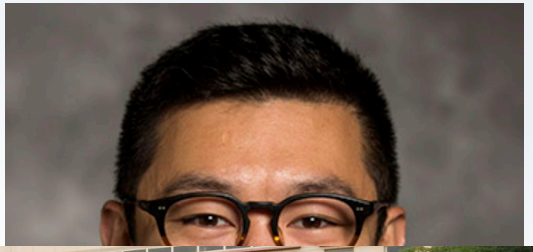
Disclosures

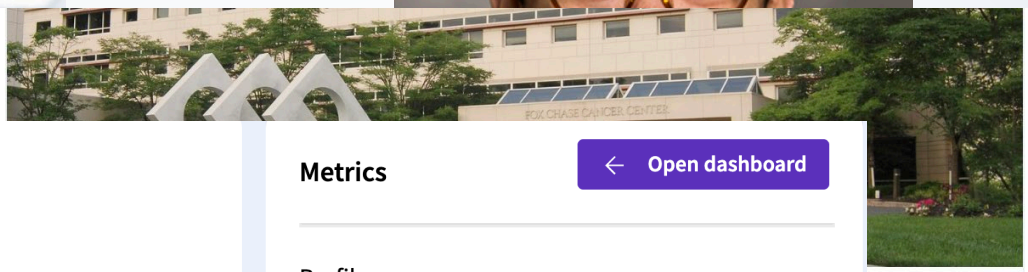
Company Name	*Honoraria/ Expenses*	*Consulting/ Advisory Board*	*Funded Research*	*Employee*	*Other (please specify)*
Emory University				x	
Varian/Siemens Healthineers			x		
Genentech		x			
Merck via RTOG Foundation	x	x			
RefleXion Medical			x		
BioAscend	x				


SCHWADRON
"THE GOOD NEWS IS YOUR BRAIN SCAN, LUNG SCAN, AND BODY SCAN WERE NEGATIVE. THE BAD NEWS IS YOU'VE GOT RADIATION POISONING."


"Judging by your X-rays, I'd say you've been exposed to too much radiation."







HB

Hossein Borghaei

Highly Cited Award Recipient

(Borghaei, Hossein)

Identifiers Web of Science ResearcherID: AFV-1992-2022

Published names Borghaei, Hossein Borghaei, H. Borghaei, H Borghaeit, H.

Organizations
Fox Chase Cancer Center
Temple University
Fox Chase Canc Ctr Main Campus
Fox Chase Canc Ctr Temple Hlth
Fccc

Subject Categories Oncology; Respiratory System; Hematology; Radiology, Nuclear Medicine & Medical Imaging; General & Internal Medicine

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NRG-LU002

Patients with metastatic NSCLC having completed 4 cycles or courses of first-line/induction systemic therapy Restaging studies reveal no evidence of progression and limited (≤ 3 discrete sites) metastatic disease, all of which must be amenable to SBRT +/- Surgery A minimum of one disease site (metastasis or primary) needs to be present after first-line/induction systemic therapy and treatable with local consolidative therapy	STRATIFY	Histology: Squamous vs. Non-squamous Systemic Therapy: Immunotherapy vs Cytotoxic Chemotherapy	RANDOMIZE	Arm 1: Maintenance systemic therapy alone Arm 2: SBRT or SBRT and Surgery to all sites of metastases (≤ 3 discrete sites) plus irradiation (SBRT or hypofractionated RT) of the primary site followed by maintenance systemic therapy. All Arm 2 patients, even if treated with Surgery, must have one site of disease (metastasis or primary) treated with radiation.

- N = **218** accrued (phase II)
- 11/12/21 - Closed
- ~90% rcvd IO
- Synchronous oligometastatic dz
  - Induced oligopersistence
  - Metachronous oligorecurrence

Iyengar et al. Abstract 8506 ASCO 2024

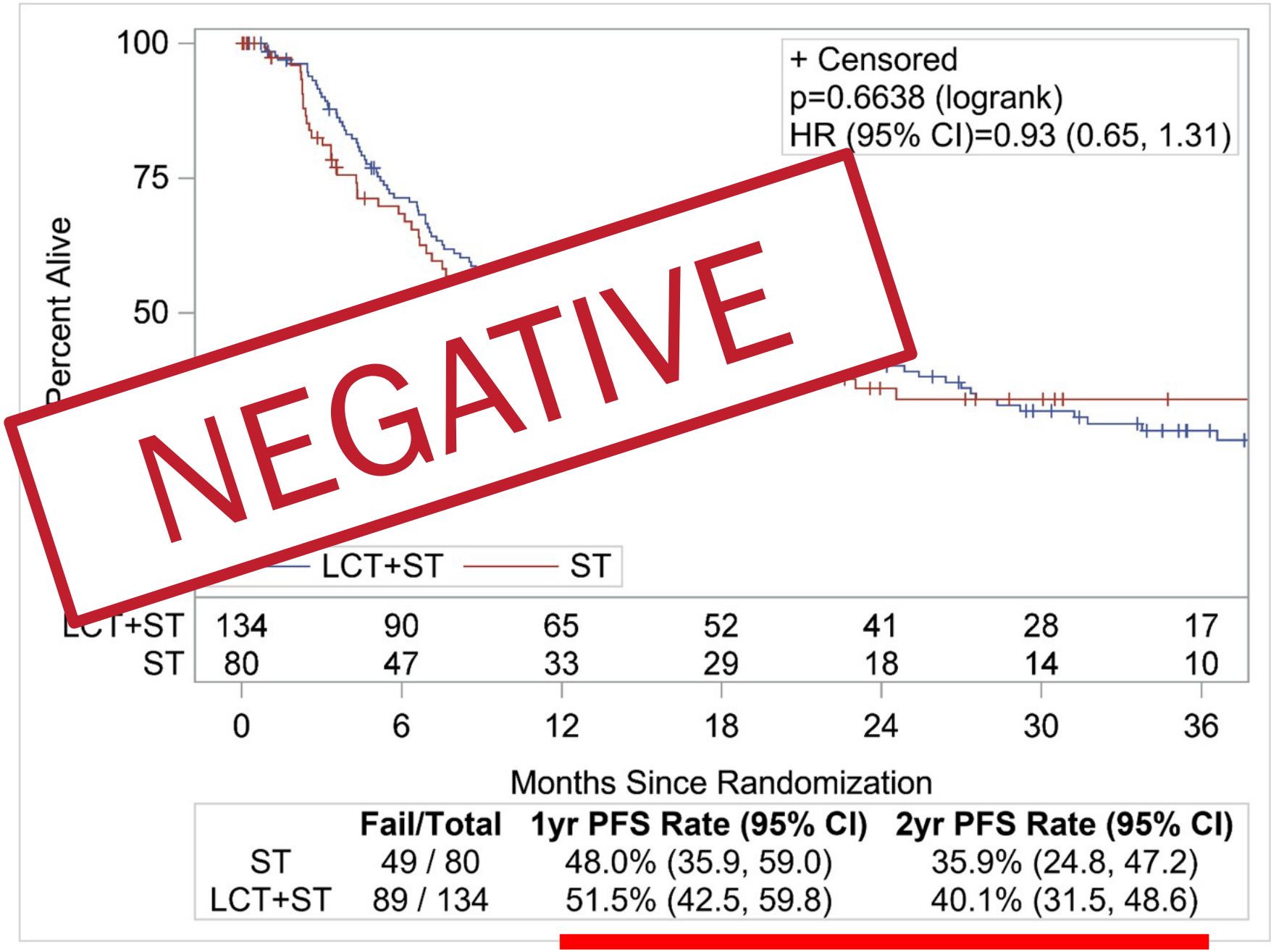
Results – PFS

Median Follow-up:

All patients – 21.9 mo

Surviving patients – 29.4 mo

Of 185/215 patients treated with IO-containing systemic therapy regimens, the PFS HR was 0.90 (95% CI: 0.61, 1.32).

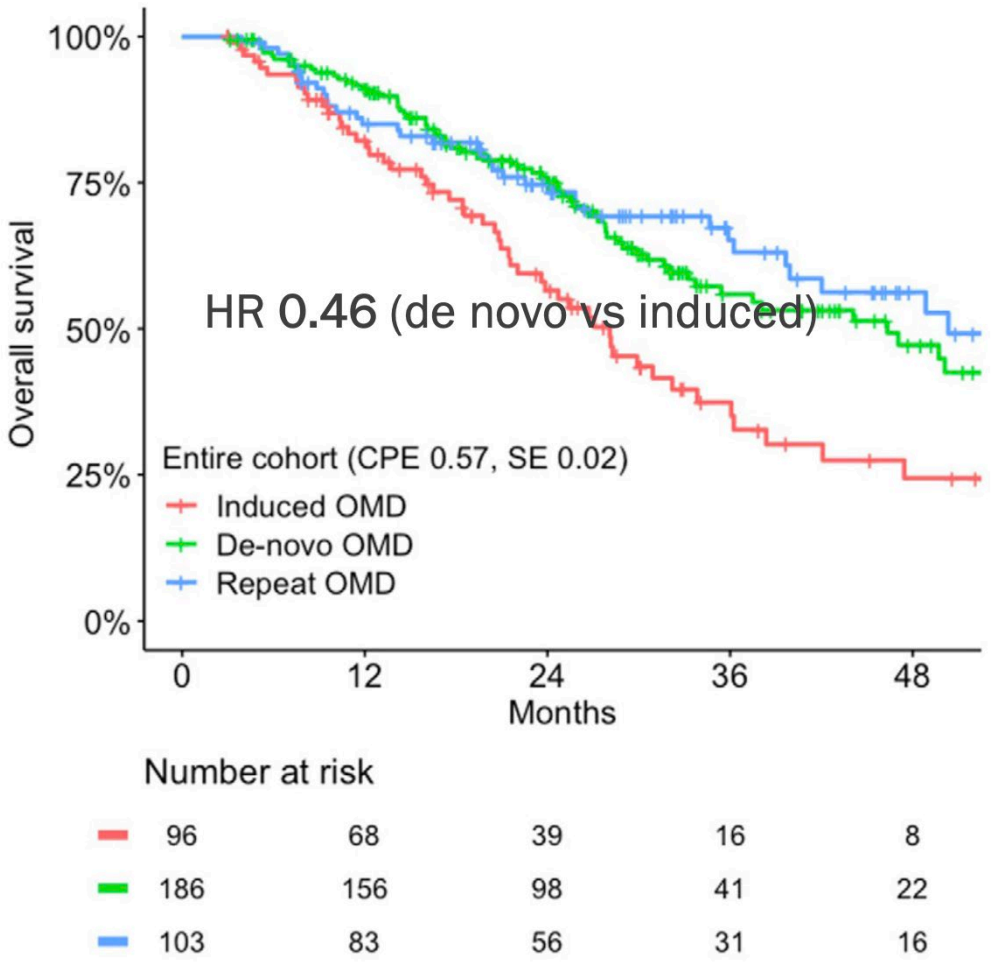


	Fail/Total	1yr PFS Rate (95% CI)	2yr PFS Rate (95% CI)
ST	49 / 80	48.0% (35.9, 59.0)	35.9% (24.8, 47.2)
LCT+ST	89 / 134	51.5% (42.5, 59.8)	40.1% (31.5, 48.6)

Limitations of Trial

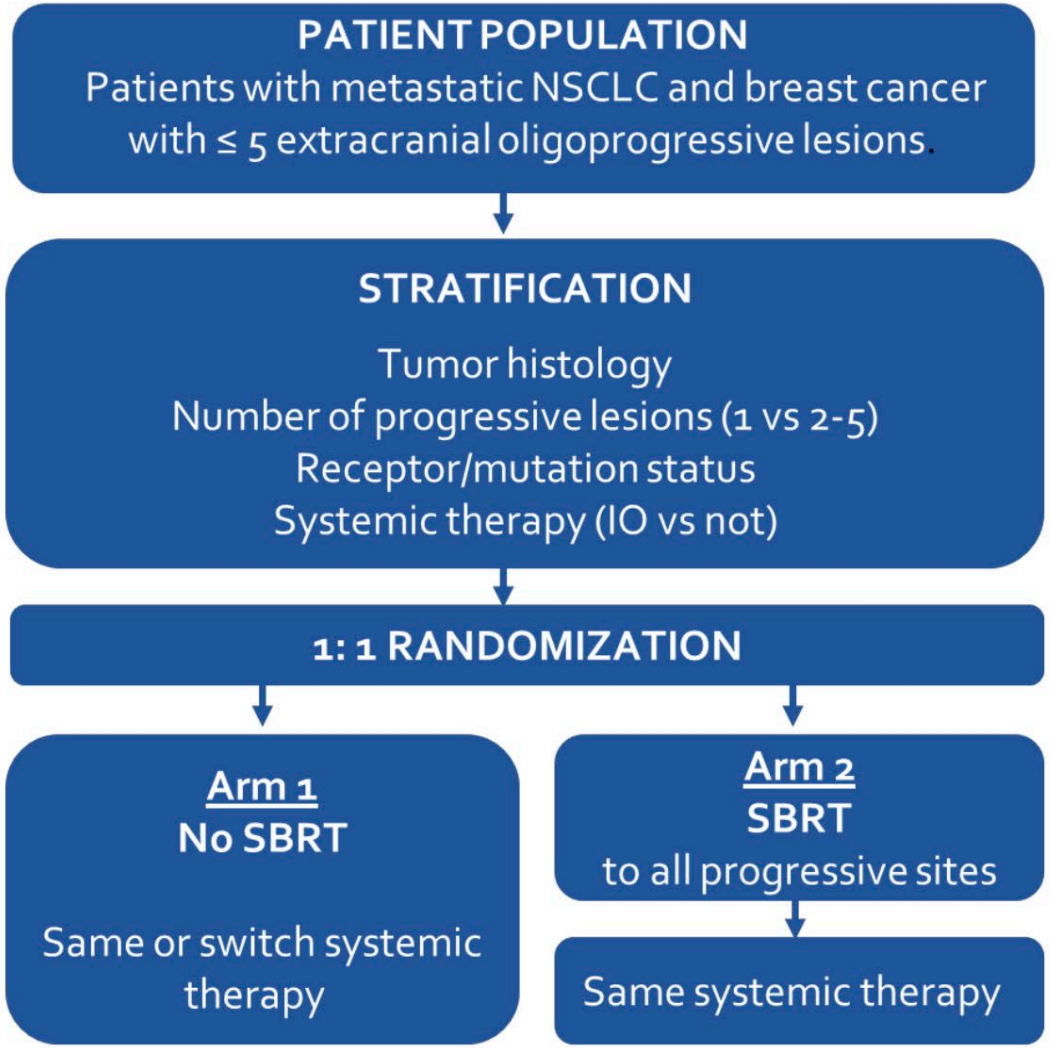
- Agnostic to systemic therapy, no single regimen was used in the study.
- Oligometastatic disease was determined by one cross-sectional imaging evaluation and somewhat arbitrary cut-off of 3 or fewer extracranial metastases.
- N[illegible]t for tr[illegible]nt p[illegible]t heterogeneity.
- N[illegible] Incidence of in-field failure HR 0.65 disease trajectories.
- Previous studies had not randomized patients in IO era.

No distinction/stratification for oligometastatic definition



Willmann et al. *Radiother Oncol.* 2022;168:256-264.

CURB Trial Design – Phase 2 RCT



Eligibility criteria:

- ≥ 18 years of age
- NSCLC progressed after 1st-line systemic/targeted therapy
- TNBC or high-risk ER+ MBC progressed after 1st line systemic therapy
- No upper limit of total lesions

Exclusion criteria:

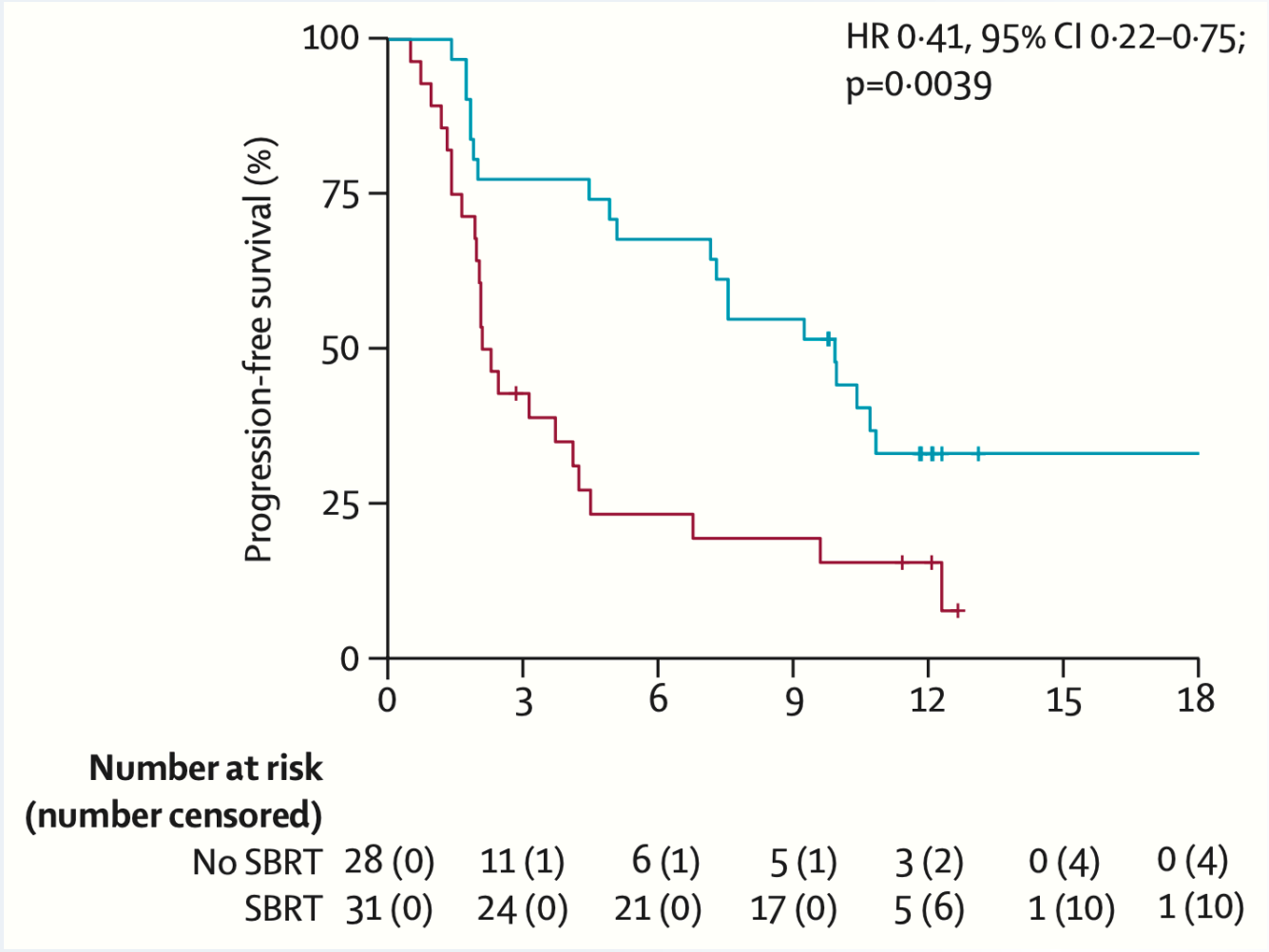
- Leptomeningeal disease

Trial opened: 2019
Accrual goal: 160 (80 each arm)

Closed to accrual at 106/160 by DSMC due to efficacy after interim analysis

Tsai et al. *Lancet* 2024 Jan 13;403(10422):171-182.

SBRT Is Effective for NSCLC Subgroup



N=59 NSCLC subgroup

PFS 2.2 vs 10 months (HR 0.41)

No local progression in all 111 irradiated lesion (from 55 pts)

Less progression in pre-existing (and un-irradiated) lesions
68 vs 26% (SOC vs SBRT)

Tsai et al. *Lancet* 2024 Jan 13;403(10422):171-182.

Canadian Cancer Trials Group | Groupe canadien des essais sur le cancer

BR.38: CONSOLIDATIVE USE OF RADIOTHERAPY TO BLOCK (CURB2) OLIGOPROGRESSION IN PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER

Study Chair: C. Jillian Tsai

- Phase 3 RCT (NCT06686771)
- Canadian Cancer Trials Group
- PI: Jillian Tsai, MD

Dual 1° Endpoints:
- OS and PFS

Key eligibility criteria:
1. Stage IV NSCLC
2. On 1L ICB ± chemo (≥ 3C)
3. ≤ 5 extracranial asx oligoprogressive lesions amenable to SBRT
4. ECOG 0-2

Stratification
- ICB vs ICB + chemo
- Lesions: 1-2 vs 3-5
- ECOG: 0-1 vs 2

N = 320

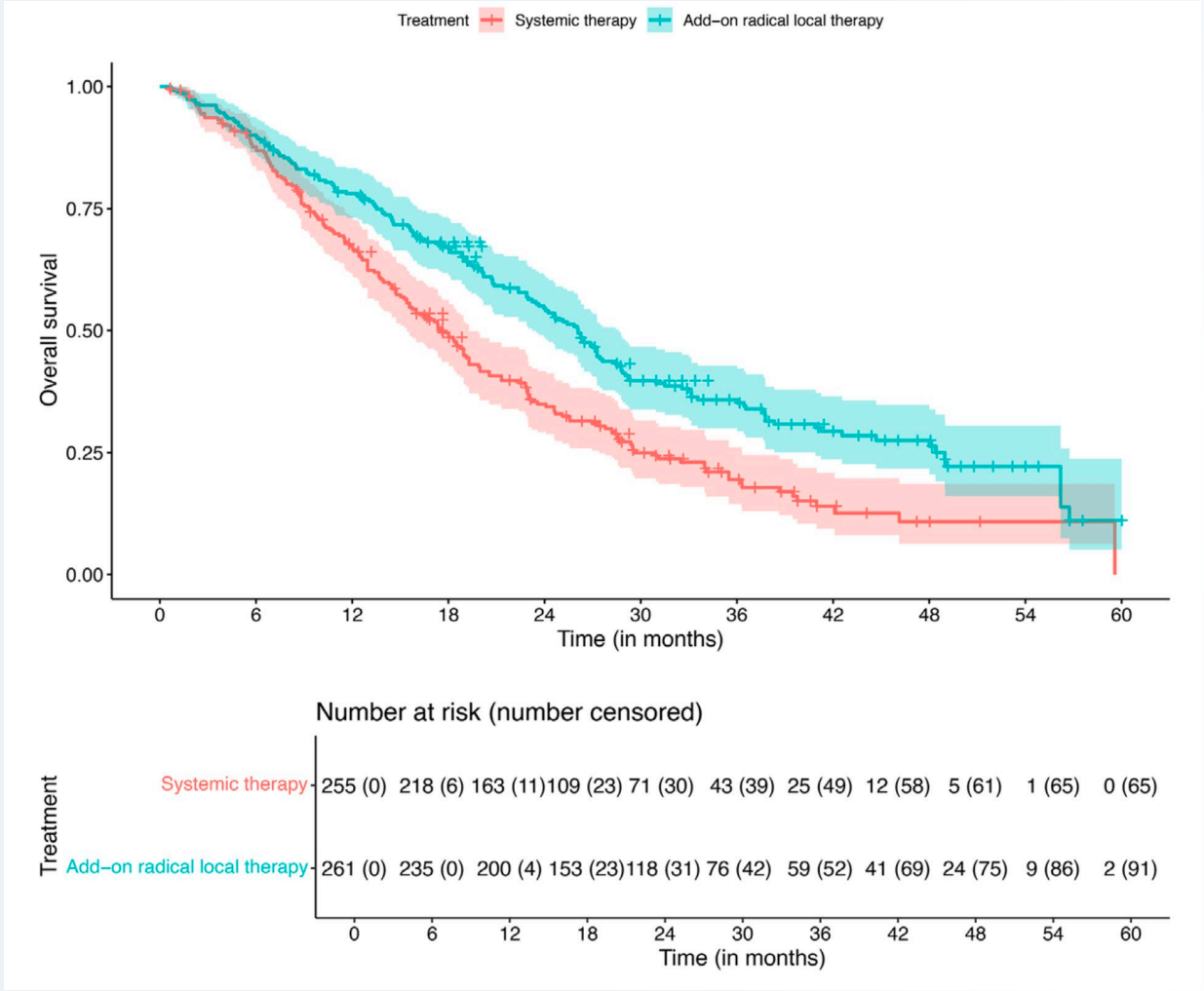
1:1

Same 1L systemic therapy
+
SBRT to all sites of progression

2L systemic therapy alone

Tsai et al. WCLC 2025

Local Therapy Meta-Analysis



N=517 (for OS) from **7** RCTs

- Gomez et al. 2019
- CURB
- PEMBRO-RT
- SINDAS
- STOP
- Peng et al. 2023
- Lim et at. 2015

OS HR **0.62** (95% CI: 0.5 – 0.76)

Between-trial heterogeneity led to median of 3% variation in HR
No concerns over inconsistency
Certainty – 'high' (GRADE framework)

Tewari et al. *BMJ Open Respir Res* 2025;12:e003276.

SBRT is Safe for Oligometastatic Cancers

- N=1,422 from 17 NHS centers in UK
- Prospective registry study
- SABR for 1-3 extracranial oligomets
- Most common G3 AE – fatigue (2%)
- No treatment-related deaths

- N=943 from 21 prospective studies
- SBRT (≤8fx) treating up to 5 mets
- Acute G3-5 AE rate 1.2%
- Late G3-5 AE rate **1.7%**
- Weighted random-effects model

Stereotactic ablative body radiotherapy in patients with oligometastatic cancers: a prospective, registry-based, single-arm, observational, evaluation study

Anastasia Chalkidou, Thomas Macmillan, Mariusz T Grzeda, Janet Peacock, Jennifer Summers, Saskia Eddy, Bola Coker, Hannah Patrick, Helen Powell, Lee Berry, Gareth Webster, Peter Ostler, Peter D Dickinson, Matthew Q Hatton, Ann Henry, Stephen Keevil, Maria A Hawkins, Nick Slevin, Nicholas van As

JAMA Oncology | **Original Investigation**

Safety and Survival Rates Associated With Ablative Stereotactic Radiotherapy for Patients With Oligometastatic Cancer
A Systematic Review and Meta-analysis

Eric J. Lehrer, MD, MS; Raj Singh, MD; Ming Wang, MS, PhD; Vernon M. Chinchilli, PhD; Daniel M. Trifiletti, MD; Piet Ost, MD, PhD; Shankar Siva, PhD, MBBS; Mao-bin Meng, MD, PhD; Leila Tchelebi, MD; Nicholas G. Zaorsky, MD, MS

Chalkidou et al. *Lancet Oncol* 2021 PMID 33387498

Lehrer et al. *JAMA Oncol* 2021 PMID 33237270

SBRT Is Cost Effective

5-fraction SBRT

- $10,000 – 15,000

Systemic Therapy*

Pembrolizumab - $4

Pembro + chemo ~

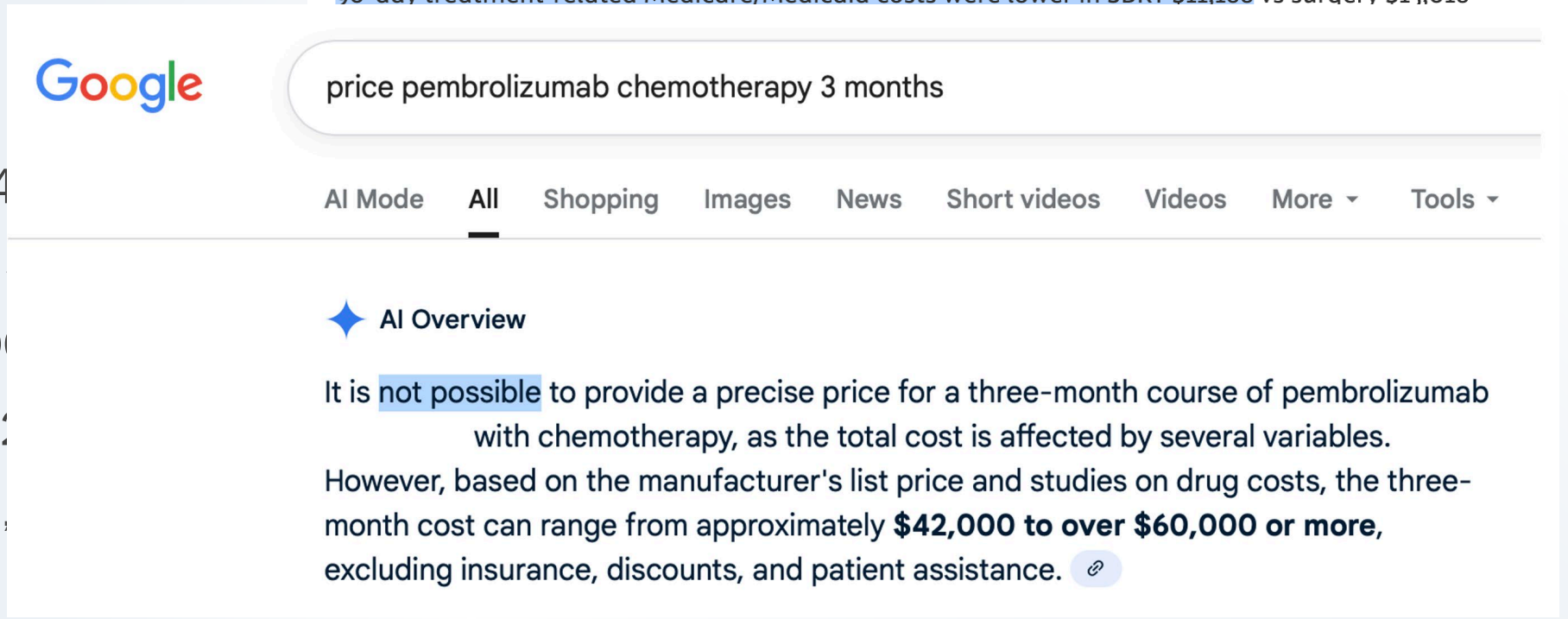
Osimertinib - $54,0

Lorlatinib – $55,45

*Cost not including infusion,

Results

The median potential follow-up for all patients was 36.0 months. According to Medicare reimbursement, the cost for 4 or 5 SBRT fractions was $8,679 or $9,676. The cost for 33 fractions of EBRT was $15,649. The cost for 33 fx of IMRT was $18,801 vs. $12,496 for 3D-CRT. Based on a median number of change from baseline in QOL measures with SBRT. At two-years the change in QOL measure was similar between the cohorts, except change in role functioning was significantly lower in SBRT patients. Median 90-day treatment-related Medicare/Medicaid costs were lower in SBRT $11,188 vs surgery $15,018

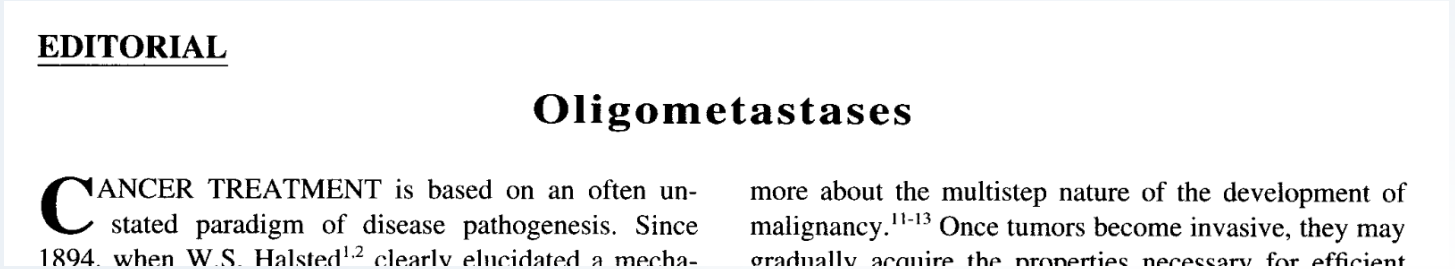


Radiation Therapy for the Management of Oligometastatic NSCLC Is

Safe ✓

Effective ✓

Cost-Efficient ✓



EDITORIAL

Oligometastases

CANCER TREATMENT is based on an often unstated paradigm of disease pathogenesis. Since 1894, when W.S. Halsted[1,2] clearly elucidated a mecha-

more about the multistep nature of the development of malignancy.[11-13] Once tumors become invasive, they may gradually acquire the properties necessary for efficient

"An attractive consequence of the presence of a clinically significant oligometastatic state is that ***some*** patients so affected should be amenable to a curative therapeutic strategy."

"This must be distinguished from the circumstance in which the identified metastases are the most evident of a much larger number of widespread deposits"

- No consensus definition for oligometastatic state
  - Maximum of 3-5 metastases in 3 organs proposed
- Candidate biomarkers
  - Tumor based – genomic alterations, PD-L1, TMB, TILs, miRNA
  - Circulating – liquid biopsy, **ctDNA**, cytokines
  - Image based – radiomics, metabolic tumor burden, tumor velocity

Hellman and Weichselbaum. *J Clin Oncol.* 1995;13(1):8-10.

Dingemans et al. *J Thorac Oncol.* 2019;14(12):2109-2119.

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