ASTRO ANNUAL MEETING 2019

News Briefing

Highlights from ASTRO 2019

Monday, September 16, 2019
10:30-11:30 a.m. CT

News Briefing: Highlights from ASTRO 2019 (Monday)

Moderator: Geraldine M. Jacobson, MD, MPH, FASTRO, West Virginia University Cancer Institute

Final Results of a Phase II Prospective Trial Evaluating the Combination of Stereotactic Body Radiotherapy (SBRT) with Concurrent Pembrolizumab in Patients with Metastatic Non-Small Cell Lung Cancer (NSCLC) (Abstract 74)

Allison Campbell, Yale Cancer Center

Patterns of Disease Progression with Durvalumab in Stage III NSCLC (PACIFIC) (Abstract LBA-6)

Andreas Rimner, Memorial Sloan Kettering Cancer Center

Applying a Machine Learning Approach to Predict Acute Radiation Toxicities for Head and Neck Cancer Patients (Abstract 141)

Jay Reddy, The University of Texas MD Anderson Cancer Center

The Impact of the Closure of Women's Health Clinics on Cervical Cancer in the United States (Abstract 202)

Amar Srivastava, Washington University School of Medicine in St. Louis

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Final Results of a Phase II Prospective Trial Evaluating the Combination of Stereotactic Body Radiotherapy and Pembrolizumab in Metastatic NSCLC

Allison Campbell, MD, PhD

Yale Cancer Center

Disclosures

- Dr. Campbell works for the Yale University School of Medicine
- Dr. Campbell has no conflicts of interest to disclose

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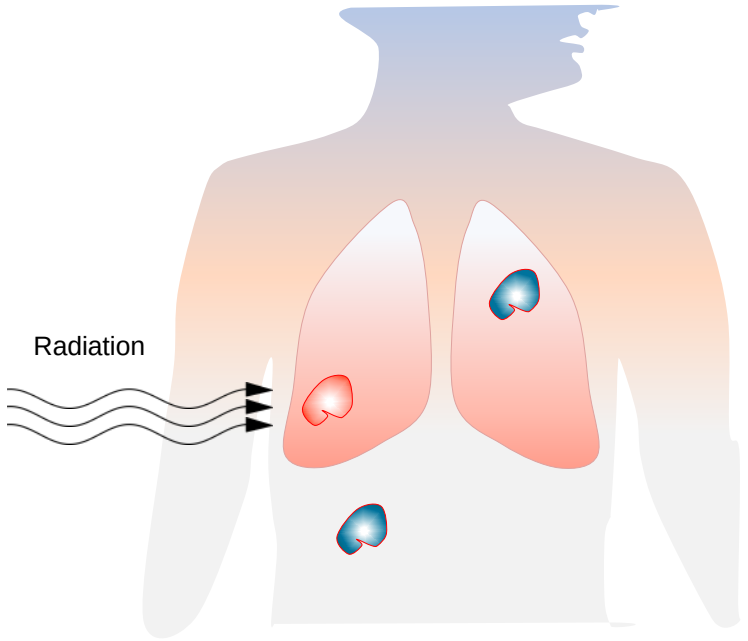
Background

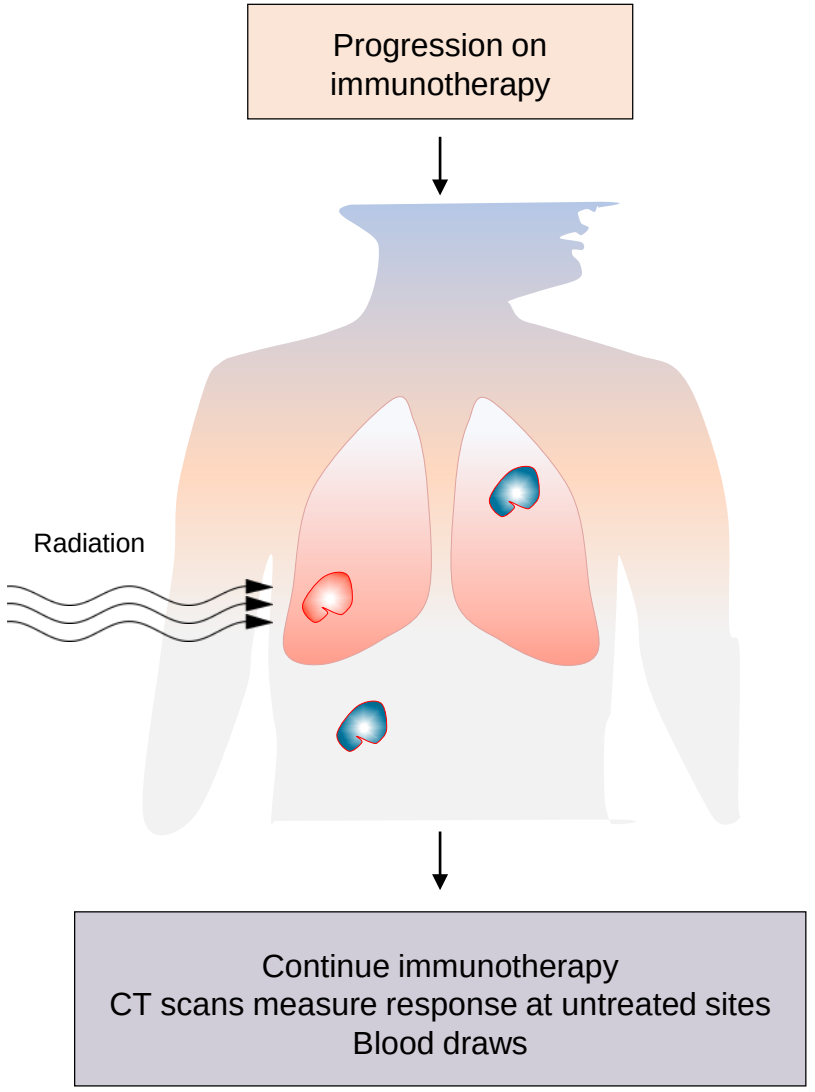
- **Why this trial:**
  - We need more therapies for patients with metastatic lung cancer
  - Immunotherapy activates the immune system to attack cancer
  - Adding radiation to immunotherapy has been shown to result in therapeutic synergy
    - When high dose radiation is given to patients on immunotherapy, tumors that weren't targeted by the radiation can shrink
    - This is called the "abscopal effect"

- **Trial Question:**
  - Can the addition of high dose radiation given in a few fractions to a single site of disease reinvigorate an immune response in patients who have progressed on anti-PD-1 therapy?



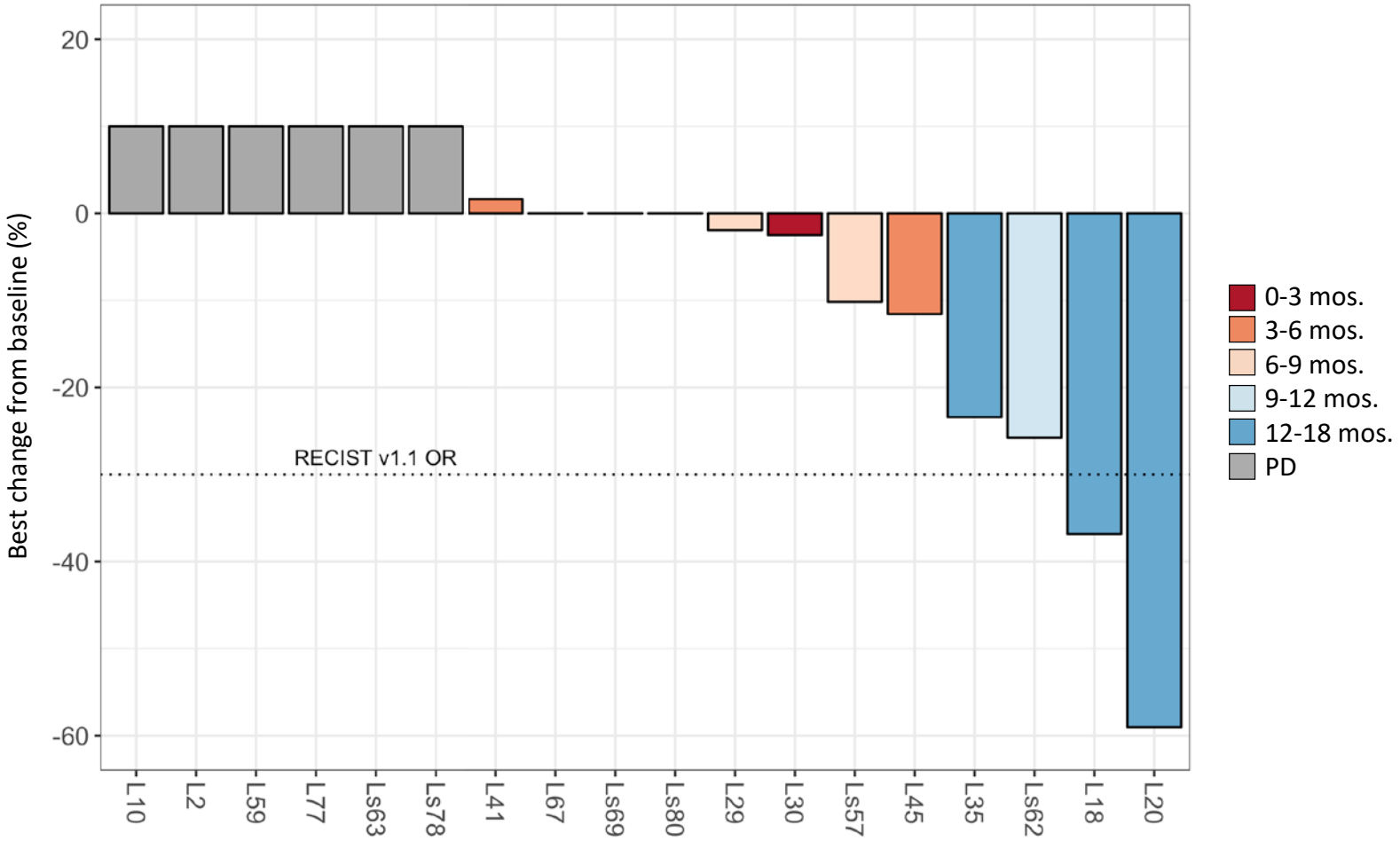
Trial Design

- **Patient eligibility**
  - Metastatic NSCLC
  - ≥ 2 measurable sites of disease (one for treatment, others for measurement)
  - PD-L1+ histology was NOT required
- **Methods**
  - After patients progressed on immunotherapy, we gave high dose radiation in 3 or 5 fractions
  - Only one site of disease was treated with radiation
  - Other sites of disease were measured and tracked over time
  - Blood was drawn so circulating immune cells could be characterized



Results: Responses occurred outside the radiation field

- Waterfall plot representing best change in OVERALL RECIST v1.1 score after SBRT
  - All patients had progressed on anti-PD-1 therapy at the time of SBRT
- Responses are abscopal and represent DISTANT DISEASE
  - The SBRT-target lesion is NOT reflected in this waterfall plot
- 3 patients achieved either a PR or SD that lasted for one year or more
  - Better responses trended toward lasting longer



Results: 10% of patients had a partial response that lasted > 1 year

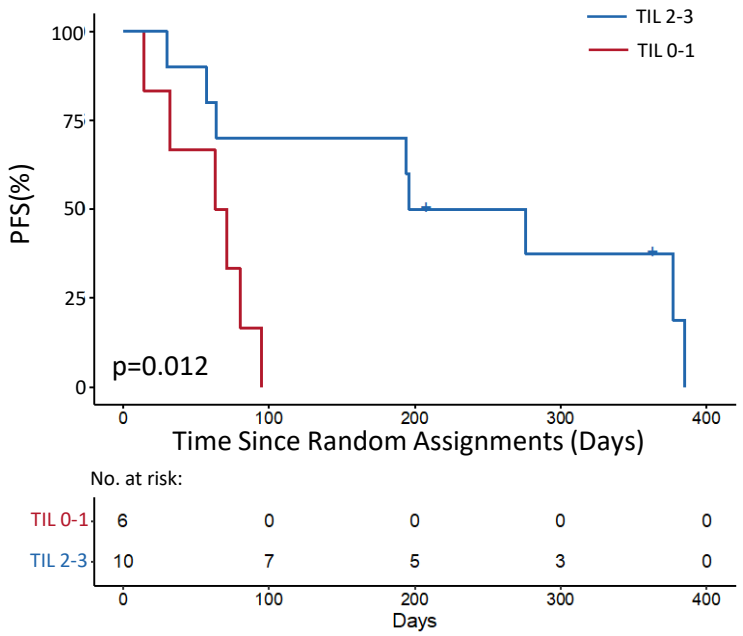
- Disease control rate: 57%
- 2 patients (10%) achieved a partial response sustained for longer than one year
- 10 patients (48%) achieved stable disease after SBRT
- PD-L1+ status trended toward increased PFS, but this did not achieve statistical significance

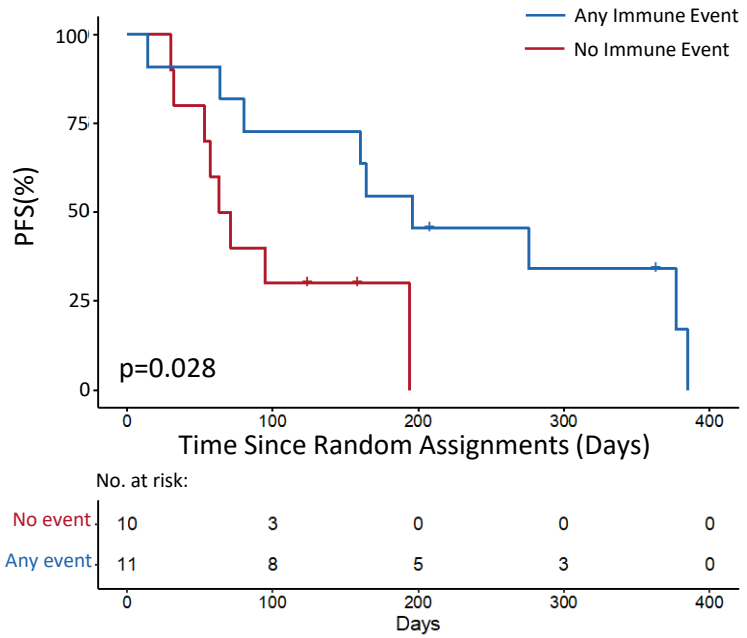
Outcome	
Median Overall Survival after SBRT	7.6 months (5.3-19.3)
Median Follow-up from time of enrollment (whole trial)	15.2 months (10.7-19.3)
Disease control rate after SBRT	57.14%
Patients achieving a PR after SBRT	9.52%
Patients achieving SD after SBRT	47.62%
Patients with PD after SBRT	28.57%
Patients with no scans after SBRT	14.29%
Median PFS after SBRT	4.1 months (2.1-6.5)
Median PFS after SBRT in patients with a PD-L1 status of 0	2.4 months (0.8-6.2)
Median PFS after SBRT in patients with a PD-L1 status > 0	6.5 months (2.1-12.1)
Median PFS after SBRT in patients with TIL scores of 0-1	2.2 months (0.8-2.9)
Median PFS after SBRT in patients with TIL scores of 2-3	6.7 months (2.1-12.1)
Median PFS after SBRT patients with NO immune-related adverse event	2.2 months (1.5-4.2)
Median PFS after SBRT patients with an immune-related adverse event	6.5 months (2.7-12.1)

Results: T cells in the tumor biopsy were associated with longer PFS

- Patients with TIL scores of 2-3 had a median of 6.7 months before disease progression; patients with TIL scores of 0-1 had a median PFS of 2.2 months

- Patients with ANY immune-related adverse event had a median of 6.5 months prior to disease progression; patients with NO immune-related adverse event had a median PFS of 2.2 months

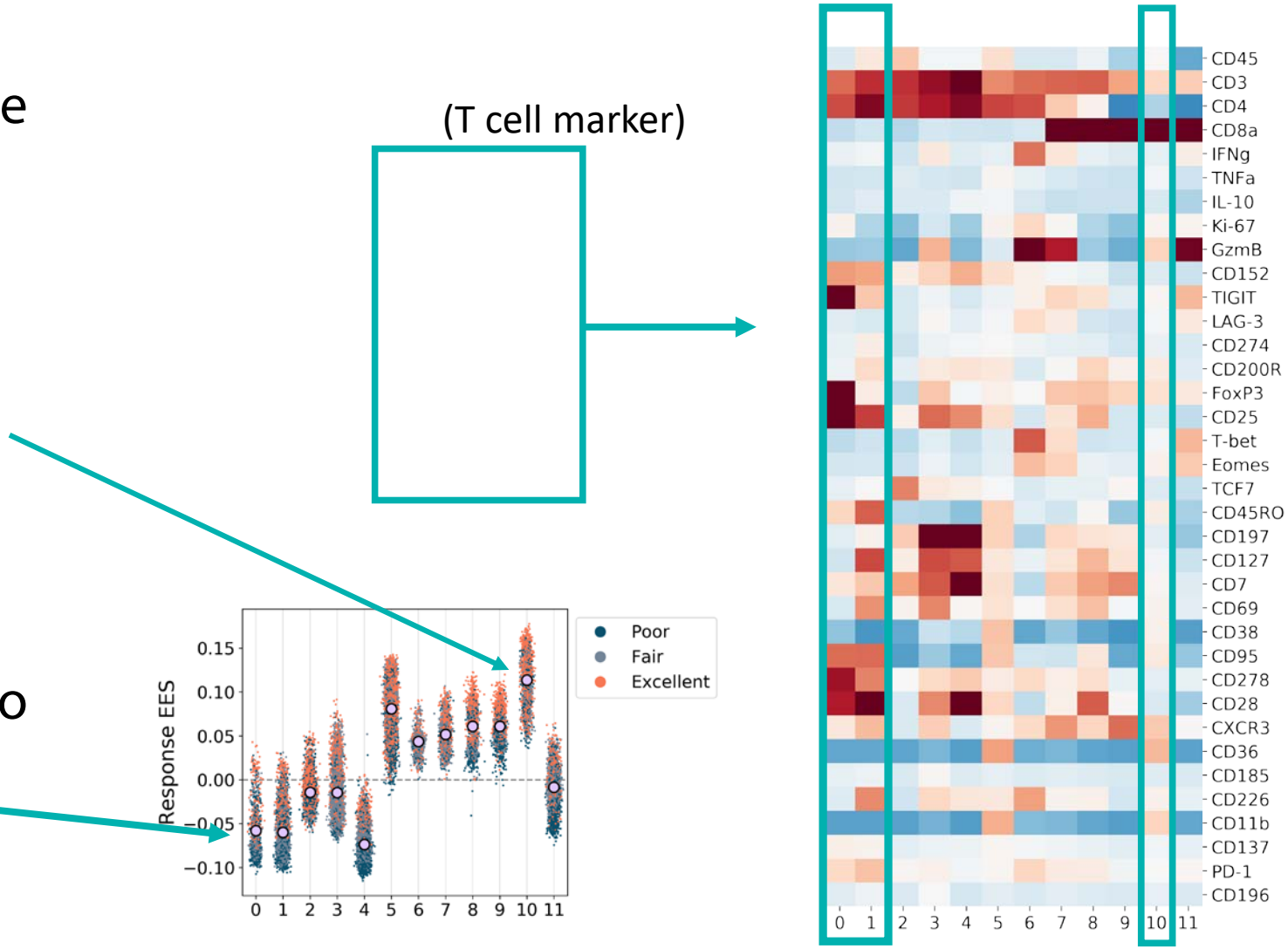




Outcome	
Median PFS after SBRT in patients with TIL scores of 0-1	2.2 months
Median PFS after SBRT in patients with TIL scores of 2-3	6.7 months
Median PFS after SBRT patients with NO immune-related adverse event	2.2 months
Median PFS after SBRT patients with an immune-related adverse event	6.5 months

Results: Patients who responded well had more CD8+ "killer" T cells in their blood

- CD8+ effector memory cells in the peripheral blood are enriched in patients with a partial response that lasted one year or more (cluster 10)
  - These cells can kill tumors
- CD4+ "regulatory" cells are enriched the peripheral blood in patients who responded poorly to SBRT (clusters 0 and 1)
  - These cells inhibit immune responses



Conclusions

- 10% of patients had a partial response that lasted > 1 year
  - These patients had already progressed on immunotherapy when they got SBRT
  - These patients had many sites of disease, but only got radiation at a single site
- Some responses were abscopal (occurred outside the radiation field)
- T cells in the tumor biopsy were associated with longer progression free survival
- Patients with an immune-mediated adverse event had longer progression free survival
- Patients who responded well to SBRT had more CD8+ "killer" T cells in their blood
- Patients who responded poorly to SBRT had more CD4+ "regulatory" T cells in their blood

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Patterns of Disease Progression with Durvalumab in Stage III NSCLC (PACIFIC)

Andreas Rimner, MD

Memorial Sloan Kettering Cancer Center

Disclosures

- Andreas Rimner has received consulting fees and research grants from AstraZeneca
- This study was sponsored by AstraZeneca
- The author affiliated with MSKCC confirms that, in accordance with GPP3, he did not receive any payment from AstraZeneca related to this publication; additionally, MSKCC did not receive any funding from the study sponsor, AstraZeneca, for this study and its resulting publications. The author affiliated with MSKCC is acting in his individual capacity.

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Background

- In the phase 3 PACIFIC trial, durvalumab significantly prolonged PFS (HR, 0.52; P <0.0001) and OS (HR, 0.68; P = 0.00251) versus placebo in patients with unresectable, Stage III NSCLC who did not progress after concurrent chemoradiotherapy (cCRT)[1,2,3]
- Time to death or distant metastasis (TTDM) was longer with durvalumab versus placebo (28.3 vs. 16.2 months; HR, 0.53), and the frequency of new lesions was 22.5% and 33.8%, respectively[2]
- Durvalumab was associated with manageable safety and did not detrimentally impact patient-reported outcomes compared to placebo[1,2,4]
- Durvalumab has received global approvals,[3,5] and the 'PACIFIC regimen' (durvalumab after cCRT) has become SoC[6]
- Here, we report exploratory analyses to characterize patterns of disease progression, including the sites of first progression, in patients from PACIFIC

HR, hazard ratio; NSCLC, non-small cell lung cancer; OS, overall survival; PFS, progression-free survival; SoC, standard of care;

1. Antonia SJ, et al. N Engl J Med 2017;377:1919–29; 2. Antonia SJ, et al. N Engl J Med. 2018;379:2342–505; 3. European Medicines Agency. Durvalumab (Imfinzi). Summary of product characteristics 2018 [Last accessed 25 July 2019]. Available from: https://www.ema.europa.eu/en/documents/product-information/imfizi-epar-product-information_en.pdf;
4. Hui R, et al. 2019; *In Press*; 5. US Food and Drug Safety Administration. IMFINZI (Durvalumab) Label 2018 [Last accessed 25 July 2019]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761069s002lbl.pdf; 6. National Comprehensive Cancer Network. NCCN Guidelines: Non-small Cell Lung Cancer. 2018

Methods

- Disease progression was assessed by blinded independent central review (BICR; RECIST v1.1)
- Scans were re-evaluated for unequivocal new lesions by a new, independent reviewer*
- New lesions identified within the lung parenchyma or chest wall, including the diaphragm, were categorized as intrathoracic
  - Information on 'in-RT-field' versus 'out-of-RT-field' intrathoracic location was not available
- The proportions of patients with progression (or death), region of first progression, location and number of organs with new lesions, and number of new lesions at progression were descriptively summarized
- Time to progression by region was estimated by Kaplan–Meier method with between-treatment HRs calculated by stratified Log rank test

*A new, separate reviewer to the BICR assessment used for the primary analysis of PFS

First Progression by Location (BICR)*

- Durvalumab reduced first progression versus placebo in all regions (45.4% vs. 64.6%, respectively)
- Overall, intrathoracic progression was the most common (80.6% vs. 74.5% of progressors)

	ITT Population		Subpopulation with Progression	
	Durvalumab (N=476)	Placebo (N=237)	Durvalumab (n=216, 45.4% of ITT)	Placebo (n=153, 64.6% of ITT)
Any RECIST progression, n (%)	216 (45.4)	153 (64.6)	216 (100)	153 (100)
Intrathoracic only	174 (36.6)	114 (48.1)	174 (80.6)	114 (74.5)
Extrathoracic only	33 (6.9)	31 (13.1)	33 (15.3)	31 (20.3)
Intrathoracic and extrathoracic simultaneously	9 (1.9)	8 (3.4)	9 (4.2)	8 (5.2)

*With a data cutoff of March 22, 2018, median duration of follow-up was 25.2 months (range 0.2–43.1)

Time to Progression or Death per BICR (ITT)*

- Durvalumab improved the times to intrathoracic progression only, extrathoracic progression only and simultaneous intrathoracic and extrathoracic progression

	Median time (95% CI) months		**HR (95% CI)**
	Durvalumab (N=476)	Placebo (N=237)	
Type of progression (or death)			
Intrathoracic only	25.2 (19.2–NR)	9.2 (5.6–13.6)	0.55 (0.43–0.70)
Extrathoracic only	NR (NR–NR)	NR (29.3–NR)	0.41 (0.27–0.63)
Intrathoracic and extrathoracic simultaneously	NR (NR–NR)	NR (NR–NR)	0.48 (0.28–0.82)

NR, not reached
*With a data cutoff of March 22, 2018, median duration of follow-up was 25.2 months (range 0.2–43.1)

New Extrathoracic Lesions at First Progression (BICR)*

- Durvalumab reduced new extrathoracic lesions at first progression versus placebo (8.8% vs. 16.5%, respectively)
- Approximately 2/3 of patients had 1 or 2 extrathoracic lesions at first progression

	ITT Population		Subpopulation with Progression and New Extrathoracic Lesions	
	Durvalumab (N=476)	Placebo (N=237)	Durvalumab (n=42, 8.8% of ITT)	Placebo (n=39, 16.5% of ITT)
Any new extrathoracic lesion, n (%)	42 (8.8)	39 (16.5)	42 (100)	39 (100)
1 lesion	19 (4.0)	15 (6.3)	19 (45.2)	15 (38.5)
2 lesions	9 (1.9)	13 (5.5)	9 (21.4)	13 (33.3)
3–5 lesions	9 (1.9)	8 (3.4)	9 (21.4)	8 (20.5)
>5 lesions	5 (1.1)	3 (1.3)	5 (11.9)	3 (7.7)

*With a data cutoff of March 22, 2018, median duration of follow-up was 25.2 months (range 0.2–43.1)

New Extrathoracic Lesions at First Progression by Site (BICR)*

- Most new extrathoracic lesions occurred in a single organ, most commonly in the brain
- The distribution of extrathoracic lesions across organs was similar regardless of treatment

	Subpopulation with Progression and New Extrathoracic Lesions	
	Durvalumab (n=42, 8.8% of ITT)	Placebo (n=39, 16.5% of ITT)
No. of organ locations, n (%)		
1	40 (95.2)	37 (94.9)
2	2 (4.8)	2 (5.1)
Organ location, n (%)		
Brain	26 (61.9)	26 (66.7)
Bone	6 (14.3)	3 (7.7)
Liver	6 (14.3)	5 (12.8)
Lymph nodes	3 (7.1)	3 (7.7)
Other (adrenal gland, myelum, spleen)	3 (7.1)	4 (10.3)

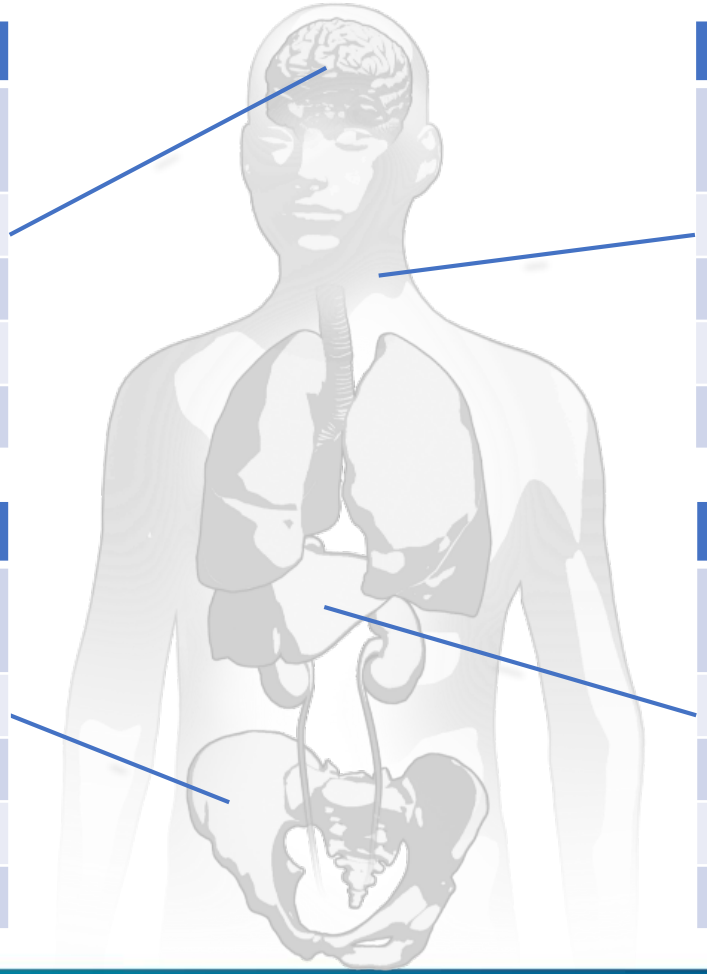
*With a data cutoff of March 22, 2018, median duration of follow-up was 25.2 months (range 0.2–43.1)

New Extrathoracic Lesions at First Progression per Site (BICR)*

- The patterns of extrathoracic lesion numbers per organ were similar regardless of treatment

BRAIN	No. of patients (%)	
No. of new brain lesions	Durvalumab (n=26)	Placebo (n=26)
1	12 (46.2)	9 (34.6)
2	8 (30.8)	9 (34.6)
3–5	6 (23.1)	5 (19.2)
>5	0	3 (11.5)

BONE	No. of patients (%)	
No. of new bone lesions	Durvalumab (n=6)	Placebo (n=3)
1	6 (100)	2 (66.7)
2	0	0
3–5	0	1 (33.3)
>5	0	0



LYMPH NODES	No. of patients (%)	
No. of new lymph node lesions	Durvalumab (n=3)	Placebo (n=3)
1	1 (33.3)	1 (33.3)
2	1 (33.3)	1 (33.3)
3–5	0	1 (33.3)
>5	1 (33.3)	0

LIVER	No. of patients (%)	
No. of new liver lesions	Durvalumab (n=6)	Placebo (n=5)
1	0	3 (60.0)
2	0	2 (40.0)
3–5	2 (33.3)	0
>5	4 (66.7)	0

*With a data cutoff of March 22, 2018, median duration of follow-up was 25.2 months (range 0.2–43.1)

Conclusions

- The addition of durvalumab after cCRT (PACIFIC regimen) reduced rates of progression versus placebo at both intrathoracic and extrathoracic sites
- Durvalumab improved the time to progression versus placebo, regardless of location
  - Most patients experienced an intrathoracic recurrence at first progression, regardless of treatment
- The extrathoracic recurrence patterns at first progression were similar with both treatments
- Most patients who progressed had 1 or 2 extrathoracic lesions, making them potentially amenable to local ablative therapies

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Expert Perspective

Benjamin Movsas, MD, FASTRO

ASTRO Board of Directors
Chair of Radiation Oncology, Henry Ford Cancer Institute

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Q & A

Use the "Question" tab in GoToWebinar to submit your questions.

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Applying a Machine Learning Approach to Predict Acute Radiation Toxicities for Head and Neck Cancer Patients

Jay Reddy, MD, PhD

University of Texas MD Anderson Cancer Center

Disclosures for Dr. Reddy

- I am employed by MD Anderson Cancer Center.
- I have previously received travel expenses from VisionRT.

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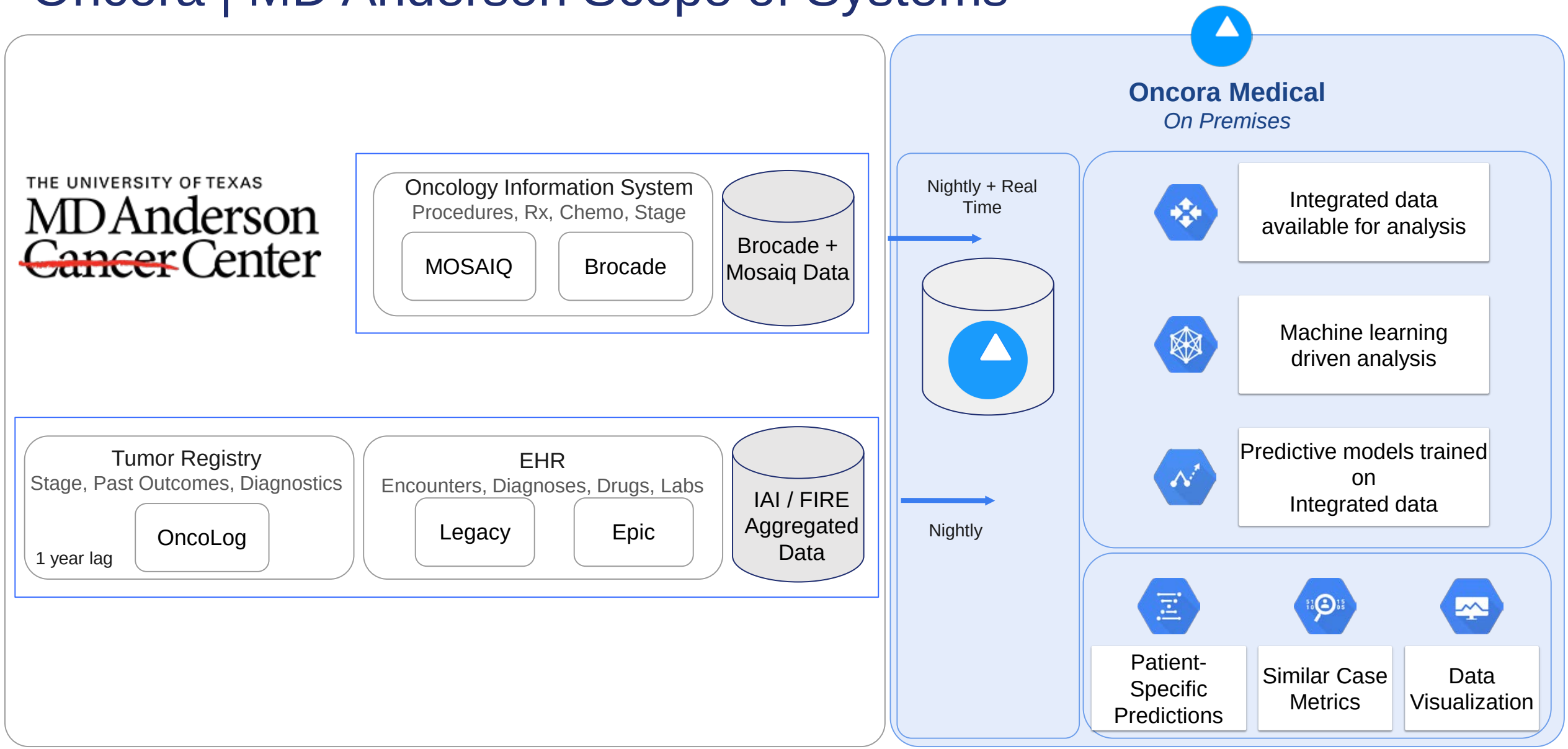
Background

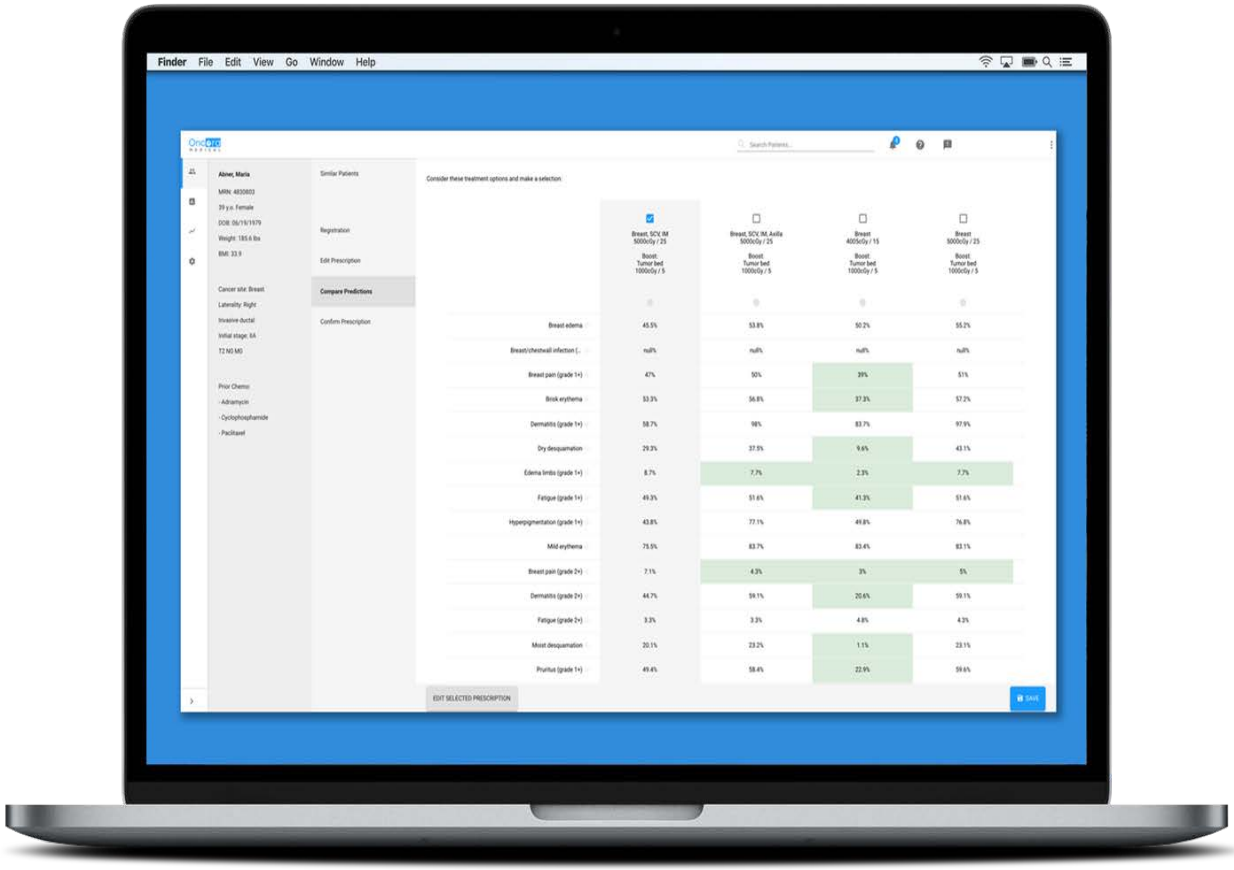
- Radiation therapy (RT) plays an integral role in the management of head and neck cancers.
- Nearly all patients receiving RT will experience some toxicity.
  - Dysphagia weight loss and need for feeding tube
  - Hospitalization for pain management, rehydration, nutritional support
- When and how to intervene represents a common clinical decision in the management of these patients.
- Precision oncology refers to the application of big data and predictive analytics to tailor specific treatments to patients and offer expected outcomes and toxicities
- This approach requires structured data for multiple variables, including clinical and pathologic characteristics, outcome, and acute toxicities

Oncora | MD Anderson Scope of Systems



Oncora Analytics

Oncora Patient Care



Objective

- To develop predictive models of acute toxicity during radiation for HN cancer patients.
  - Unplanned hospitalization ($\leq$ 3 months from RT start)
  - Significant weight loss (>10% during RT)
  - Feeding tube placement

Methods

- 2121 consecutive courses of radiation treatment for HN cancer from May 2016—Aug 2018

- >700 clinical and treatment variables extracted
  - Demographics
  - Clinical and pathological characteristics
  - Treatment variables (RT details)

- Outcomes
  - Unplanned hospitalization ($\leq$ 3 months from RT start)
  - Significant weight loss (>10% during RT)
  - Feeding tube placement

Methods

- **Training set**: first 1896 RT courses for HN cancer
  - Three machine learning models to predict outcome
    - Random forest—100 boosted decision trees
    - Extreme gradient boosted decision tree—100 boosted decision trees
    - Logistic regression with trained L1 regularization

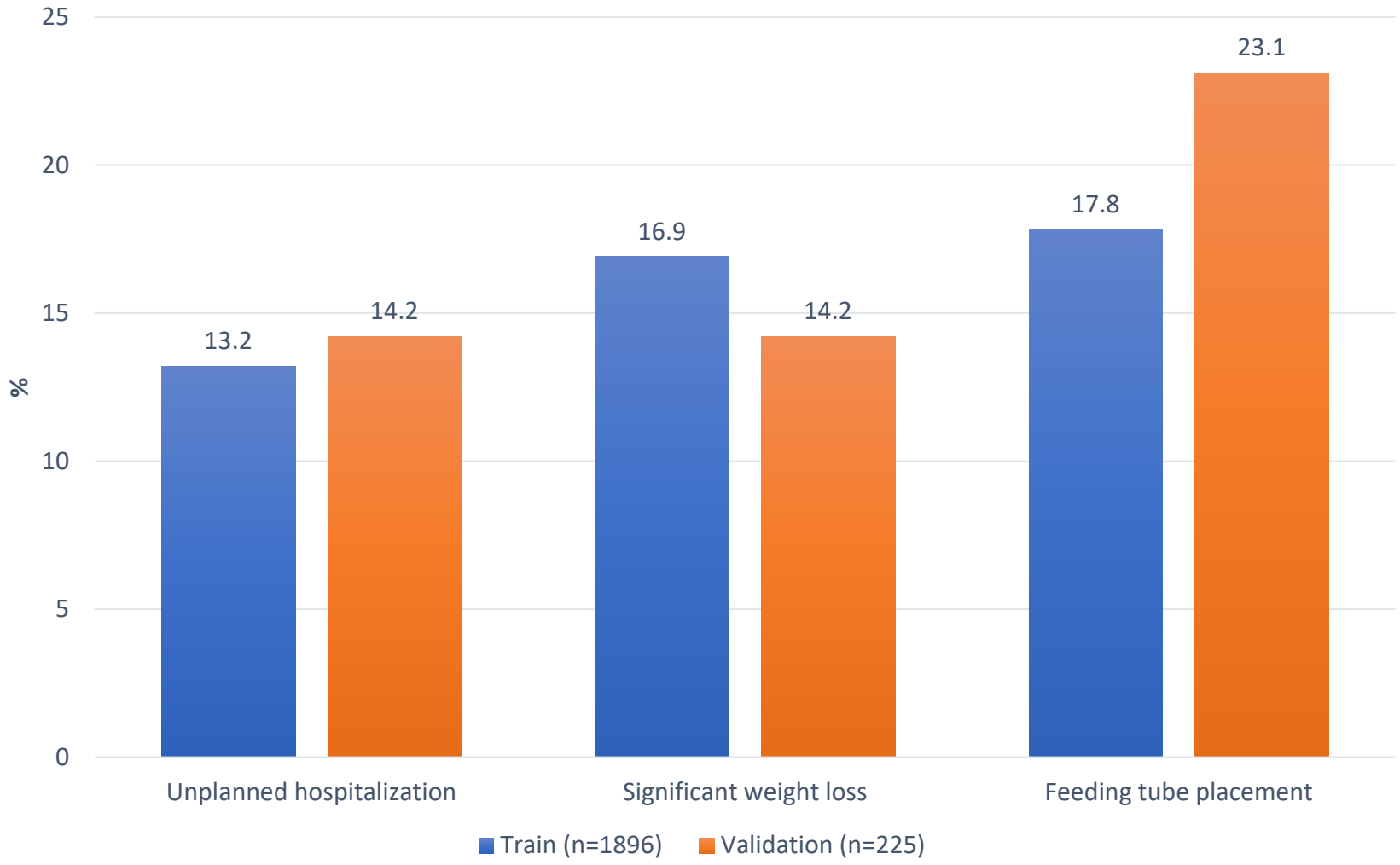
- **Validation set**: subsequent 225 courses of RT
  - Final models for each toxicity were then evaluated
  - AUC > 0.7 considered clinically valid

Descriptive Statistics (n=2121)

Gender, count (%)	
Female	527 (24.8%)
Male	1594 (75.2%)
Age, median (IQR)	63 yrs (55.1—70.3)
RT Dose, median (IQR)	60 Gy (30—69.3)
No. of fractions, median (IQR)	30 (9—33)

Treatment Site	No. (%)
Oropharynx	743 (35.1%)
Oral cavity	314 (14.8%)
Skin	233 (11%)
Larynx	171 (8.1%)
Salivary gland	129 (6.1 %)
Thyroid	106 (5.0 %)
Nasopharynx	87 (4.1 %)
Nasal cavity	62 (2.9 %)
Sinus	48 (2.3 %)

Outcomes


25
20
15
10
5
0
%
13.2
14.2
16.9
14.2
17.8
23.1
Unplanned hospitalization
Significant weight loss
Feeding tube placement
Train (n=1896)
Validation (n=225)

AUC for Training Set Models (n=1896)

	Unplanned hospitalization (13.2%)	Significant weight loss (16.9%)	Feeding tube placement (17.8%)
Random forest	0.676	0.834	0.783
Gradient boosted decision trees	0.672	0.843	0.787
Logistic regression	0.666	0.838	0.779

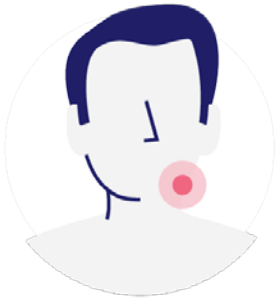
AUC for Validation Set Models (n=225)

	Unplanned hospitalization (14.2%)	Significant weight loss (14.2%)	Feeding tube placement (23.1%)
Random forest	0.640		
Gradient boosted decision trees		0.751	0.755
Logistic regression			

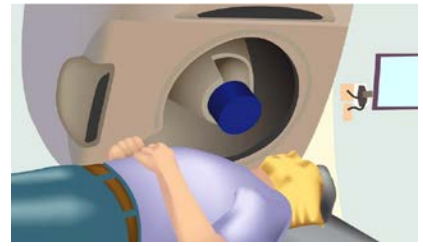
Conclusions

- Application of three machine-learning models to a structured dataset enabled the development of predictive models for acute radiation toxicities for HN cancer patients.
- The models for predicting significant weight loss and feeding tube placement met criteria for clinical validity.
- This study demonstrates the feasibility of employing precision oncology to predict acute radiation toxicities.
- May facilitate the identification of patients for whom early intervention is warranted.

Future Use Case



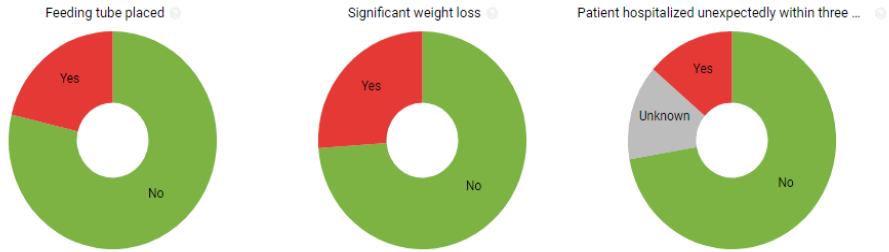
Work-up/Staging



Age
BMI
Stage
Biomarker
Risk Factors
Vitals
Treatment Plan

ML Model

Personalized Predictions



Unplanned hospitalization: **23%**
Significant weight loss: **47%**
Feeding tube placement: **40%**

Decision Support

- Place feeding tube up front
- Nutritional supplementation
- Wait and monitor

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Expert Perspective

Sanjay Aneja, MD

Assistant Professor of Therapeutic Radiology
Yale Cancer Center

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The Impact of the Closure of Women's Health Clinics on Cervical Cancer in the United States

Amar J. Srivastava, MD, MPH

Washington University School of Medicine in St. Louis

Disclosure

I have no conflicts of interest to disclose… except that I consider myself an epidemiologist, of sorts

PREVENT DETECT REDUCE

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Background

- Cervical cancer is a highly-preventable and screening-detectable, cancer and if diagnosed at an early stage is very curable with low mortality
- Women are generally diagnosed through Pap smears, which can be obtained at low-cost women's health clinics (WHCs)
- Between 2010-13, ~100 WHCs in the U.S. closed due to funding and new laws
- In this study, we evaluated the association between clinic closures and screening for cervical cancer, stage at diagnosis, and mortality associated with this disease

PREVENT DETECT REDUCE

The New York Times

Planned Parenthood Refuses Federal Funds Over Abortion Restrictions

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NBCNews.com

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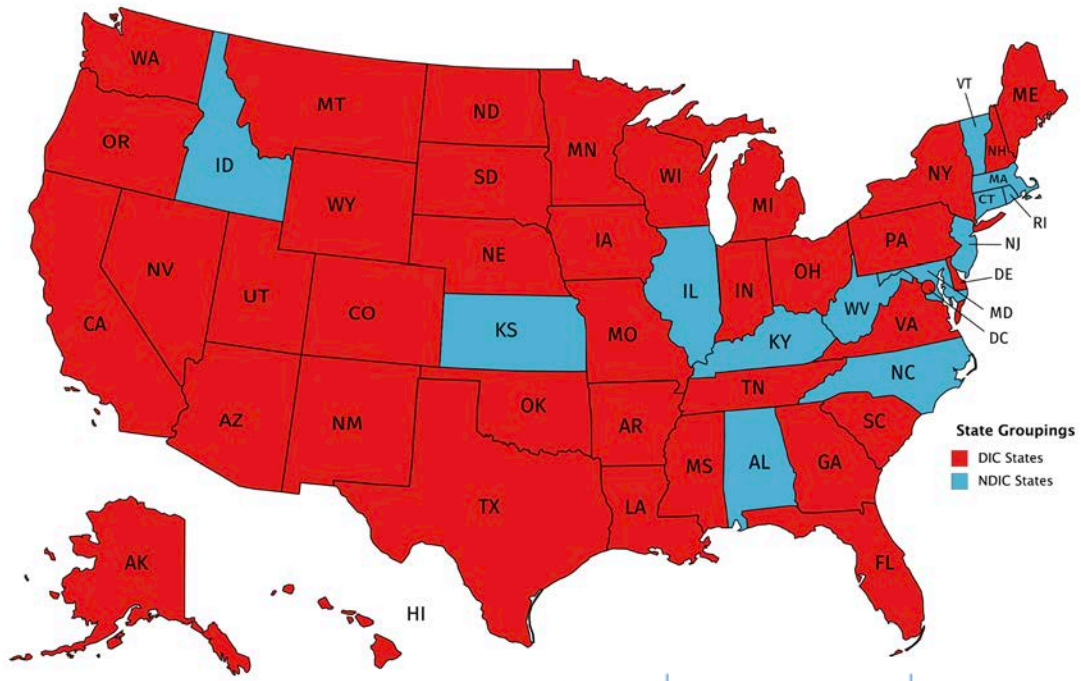
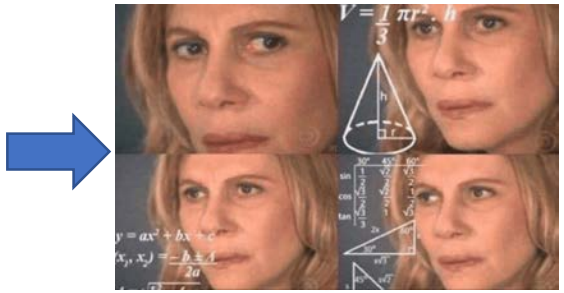
2 weeks ago

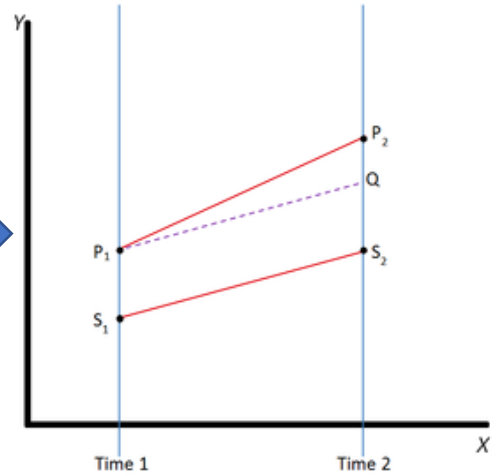
Methods

- States were divided into two cohorts– DIC (decrease in clinics) and NDIC (no decrease in clinics) based on changes in the number of facilities providing comprehensive reproductive services between 2010-13 using national survey data

- We used the BRFSS database to compare changes in screening and SEER to compare changes in stage at diagnosis and mortality using a *difference-in-differences* analysis







Courtesy of Wikipedia

Results

PREVENT

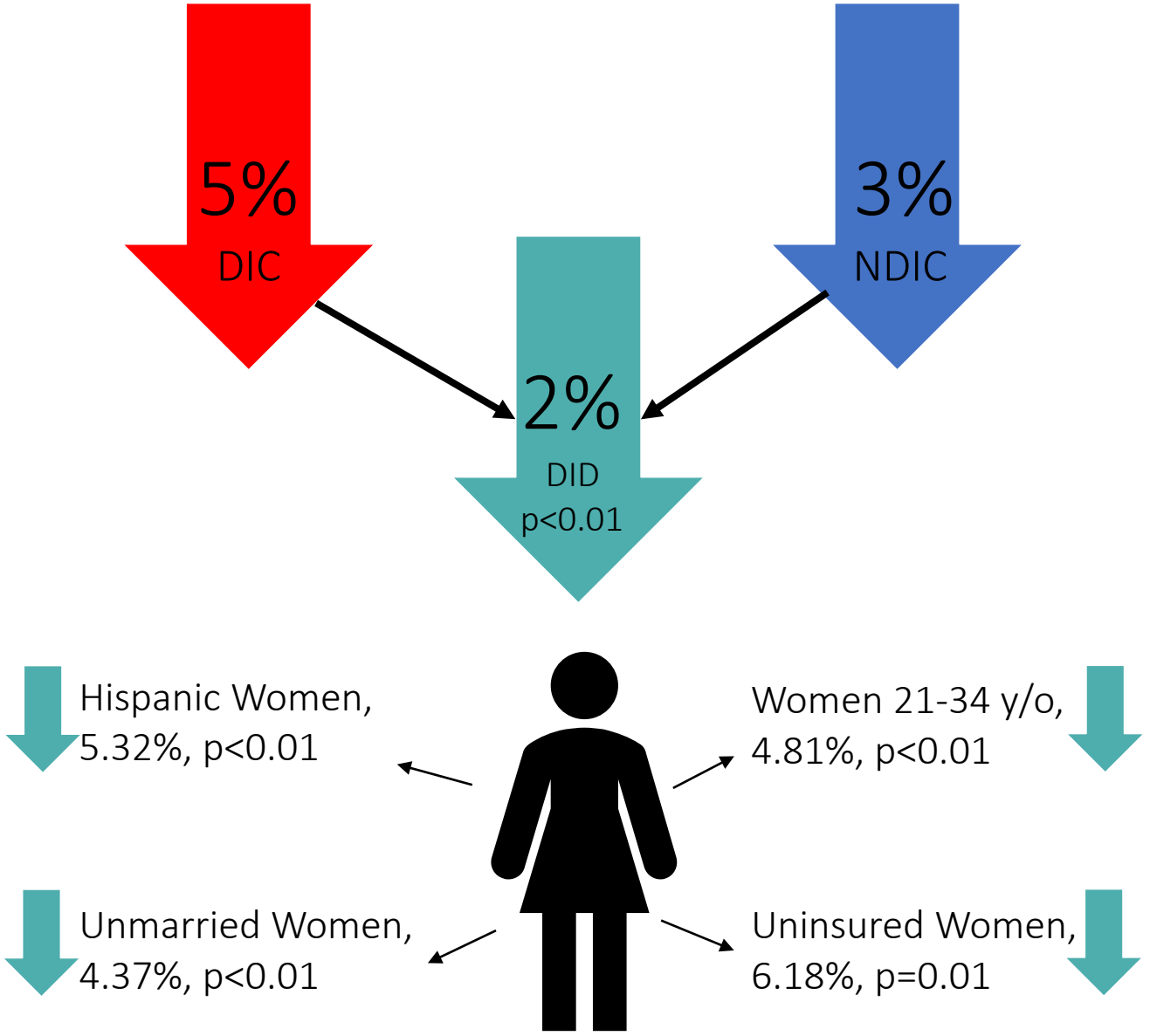
DETECT

REDUCE

Results

PREVENT

BRFSS- Screening with a Pap Smear



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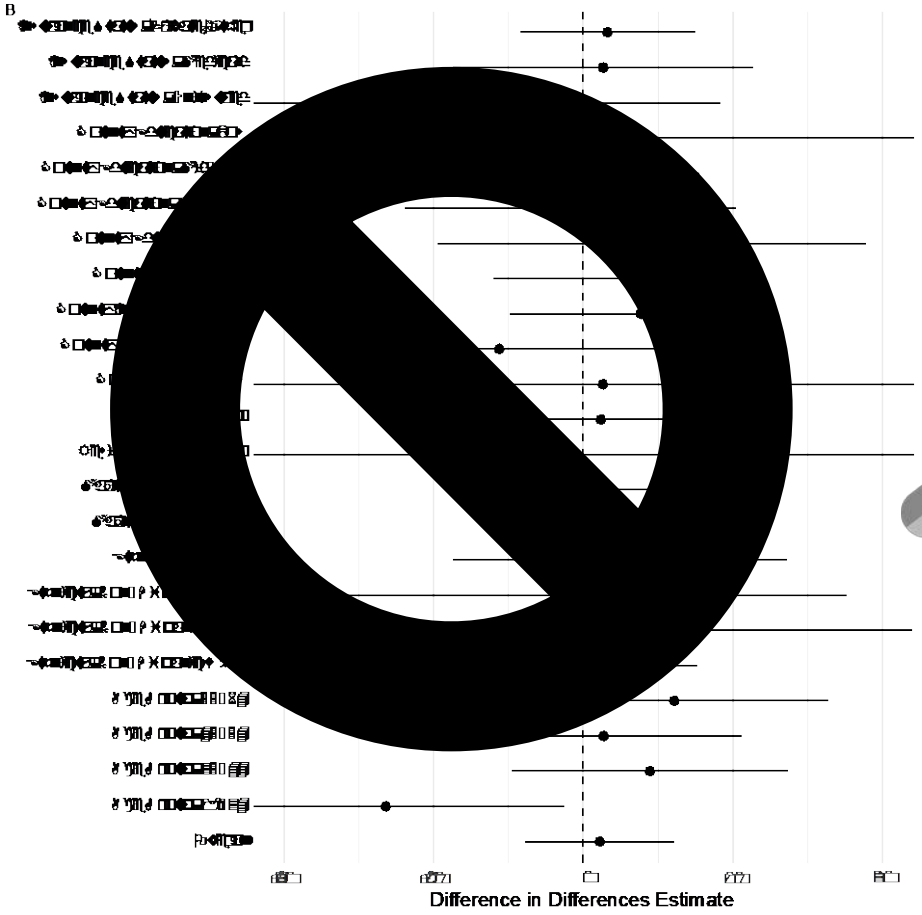


DETECT

SEER- Stage at Diagnosis

Early-Stage Diagnoses among 18-34 y/o pts

3% DIC

3% NDIC

14%

Adjusted DID p=0.03

Adjusted DID p=0.14

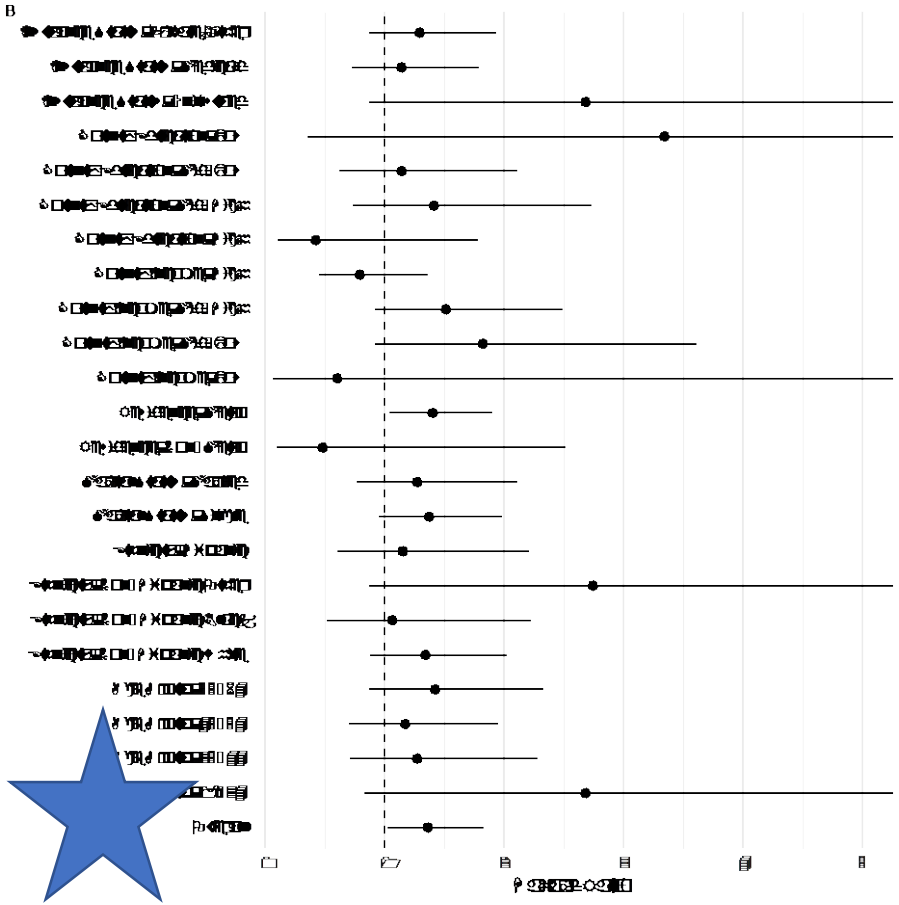
8%

Adjusted DID p=0.16

4%

Late-Stage and Metastatic Diagnoses among 18-34 y/o pts

Results



36%
Risk of Death

Adjusted Hazard Ratio (aHR)=1.36
p=0.04

REDUCE

SEER- Mortality in Women with Cervical Cancer

Results

PREVENT

2%
DID
p<0.01

DETECT

14%
EARLY STAGE
Adjusted DID
p=0.03

Adjusted DID
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REDUCE

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Conclusions

- In this retrospective (observational) study, we noted that closures of women's health clinics throughout the U.S. between 2010 and 2013 were associated with decreased screening for cervical cancer, fewer women being diagnosed with early-stage disease, a trend towards more women being diagnosed with late-stage disease, and significantly increased mortality

- Though causality cannot be confirmed, these findings are concerning and suggest that further consideration should be given to funding and other factors influencing the closure of women's health clinics

ASTRO ANNUAL MEETING 2019

The Impact of the Closure of Women's Health Clinics on Cervical Cancer in the United States

Amar J. Srivastava, MD, MPH

Washington University School of Medicine in St. Louis

Disclosure

I have no conflicts of interest to disclose… except that I consider myself an epidemiologist, of sorts

PREVENT DETECT REDUCE

Full author list:

A. Srivastava[1], J. M. Barnes[2], S. Markovina[1], J. K. Schwarz[1], and P. W. Grigsby[1]

[1]Department of Radiation Oncology, Washington University School of Medicine, St. Louis, MO, [2]Saint Louis University, Saint Louis, MO

Background

- Cervical cancer is a highly-preventable and screening-detectable, cancer and if diagnosed at an early stage is very curable with low mortality
- Women are generally diagnosed through Pap smears, which can be obtained at low-cost women's health clinics (WHCs)
- Between 2010-13, ~100 WHCs in the U.S. closed due to funding and new laws
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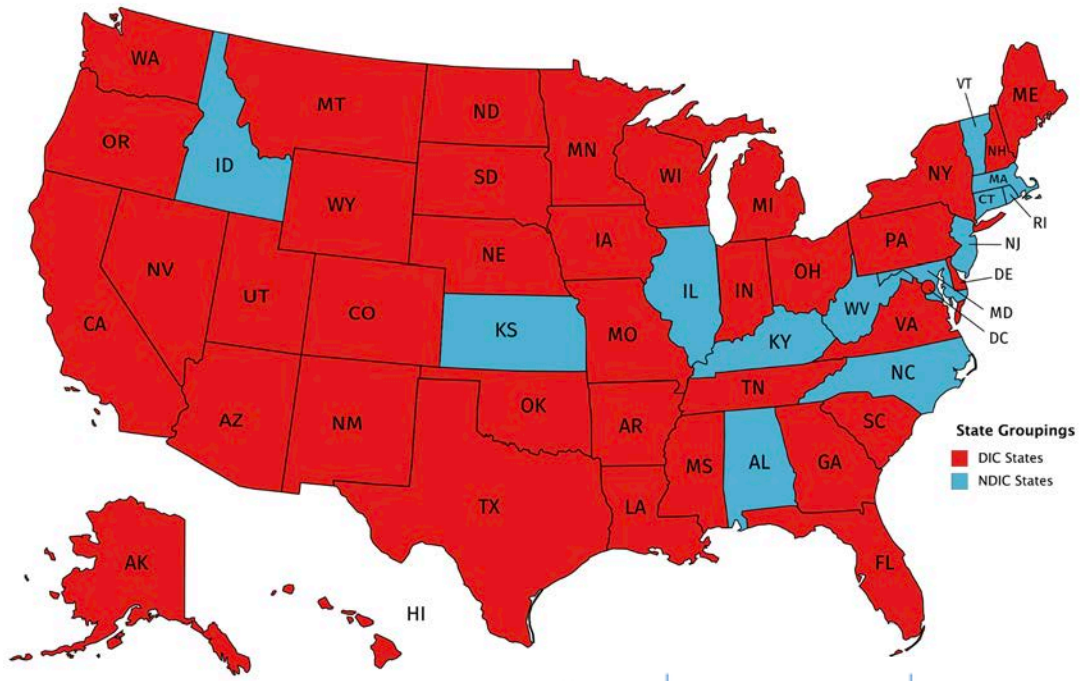

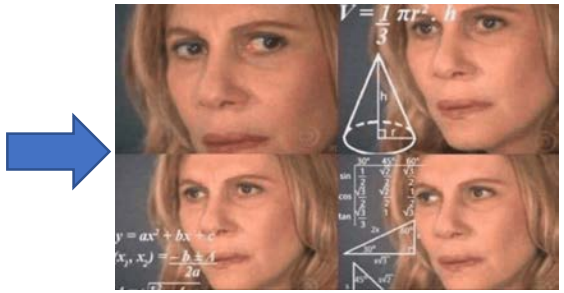

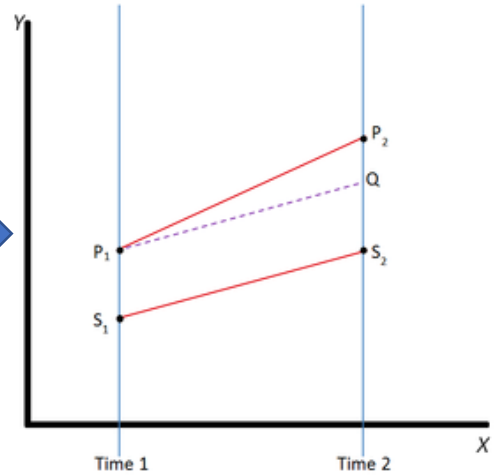

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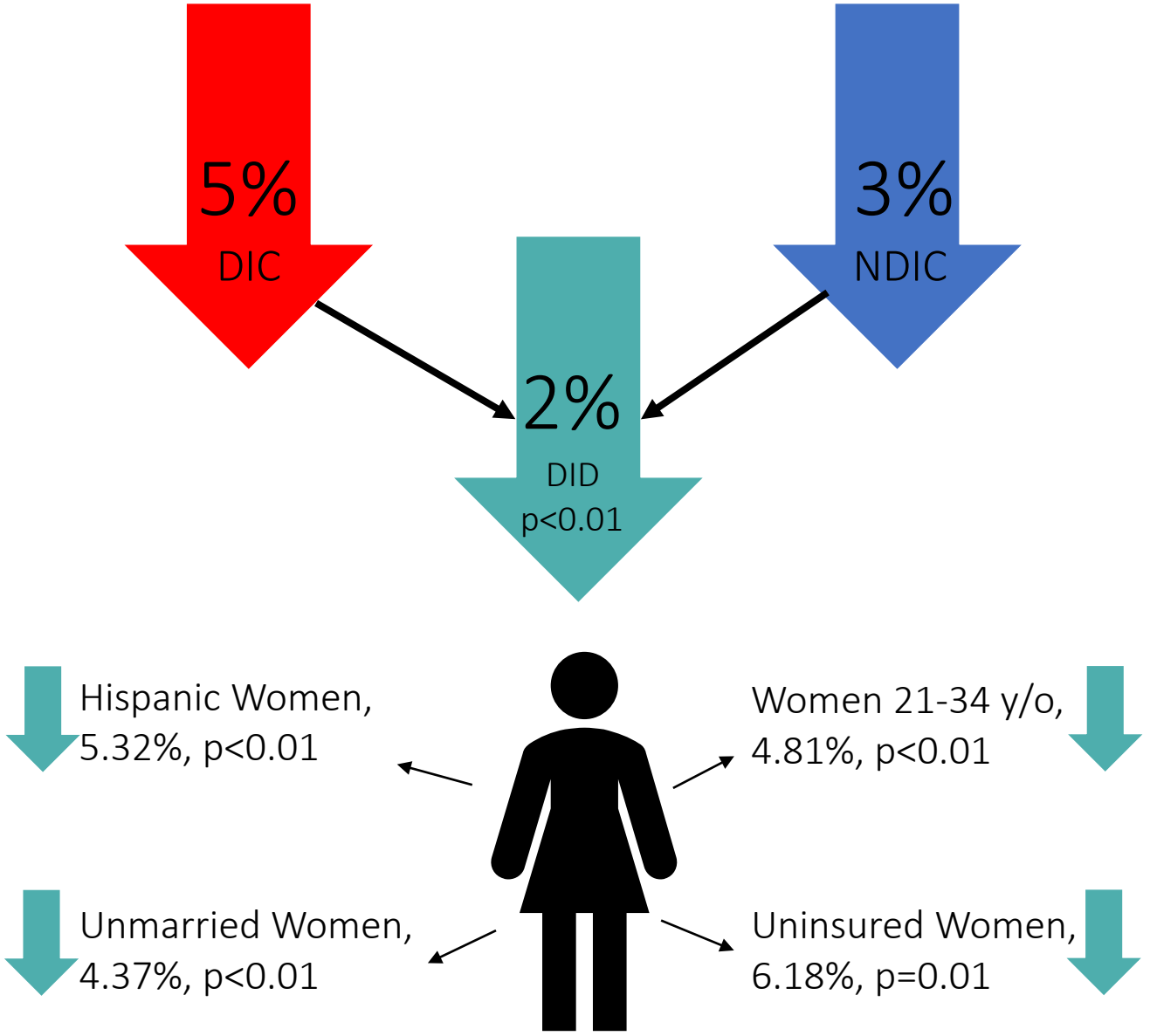

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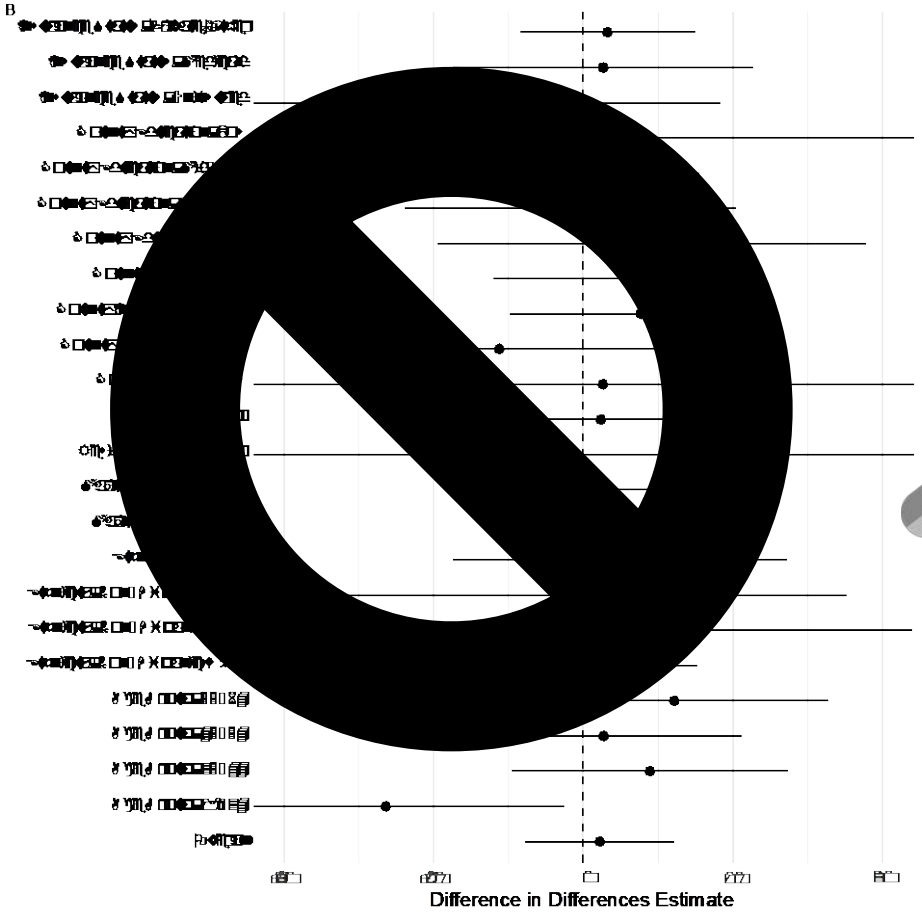

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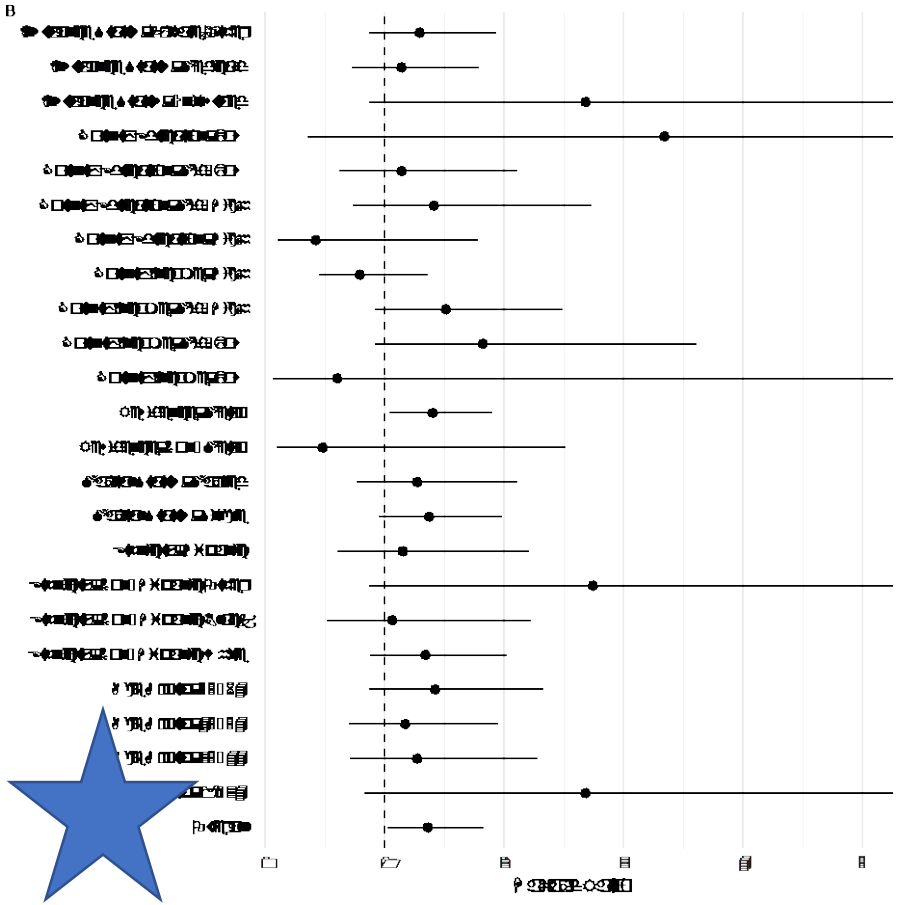

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Expert Perspective

Geraldine M. Jacobson, MD, MPH, FASTRO

ASTRO Board of Directors
Chair of Radiation Oncology, West Virginia University Cancer Institute

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