
# News Briefing: Tuesday, October 25

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NRG/RTOG 1005: A phase III trial of hypofractionated whole breast irradiation with concurrent boost versus conventional whole breast irradiation plus sequential boost following lumpectomy for high risk early-stage breast cancer

*Frank A. Vicini, MD, FASTRO, GenesisCare*

Addition of metastasis-directed therapy to intermittent hormone therapy for oligometastatic prostate cancer (EXTEND): A multicenter, randomized phase II trial

*Chad Tang, MD, The University of Texas MD Anderson Cancer Center*

Machine learning-based prediction of hospitalization using daily step counts for patients undergoing chemoradiation

*Isabel Friesner, University of California, San Francisco*

Evaluation of disparity in physician assessment of sexual dysfunction in women versus men receiving brachytherapy for genitourinary cancers

*Jamie Takayesu, MD, University of Michigan*

Prophylactic radiation therapy versus standard-of-care for patients with high-risk, asymptomatic bone metastases: A multicenter, randomized phase II trial

*Erin F. Gillespie, MD, Memorial Sloan Kettering Cancer Center*

## Featured Experts

- Moderator: Iris C. Gibbs, MD, FASTRO, *Stanford Medicine*; *ASTRO Health Equity, Diversity and Inclusion (HEDI) Council Chair*
- Kathleen C. Horst, MD, *Stanford Medicine*
- Howard M. Sandler, MD, FASTRO, *Cedars-Sinai, ASTRO President-Elect*


# NRG/RTOG 1005:

# A phase III trial of hypofractionated whole breast irradiation with concurrent boost versus conventional whole breast irradiation plus sequential boost following lumpectomy for high risk early-stage breast cancer

## Abstract 1

Presented by:

Frank A. Vicini, MD, FASTRO
GenesisCare

# Disclosure & Study Team

- Disclosure: None.
- This project was supported by grants U10CA180868 (NRG Oncology Operations), U10CA180822 (NRG Oncology SDMC), UG1CA189867 (NCORP), and U24CA180803 (IROC) from the National Cancer Institute.

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# Background

- Randomized trials support a supplemental radiation dose (boost) to the lumpectomy cavity region after whole breast irradiation (WBI)
  - Advantage: 35% relative reduction in ipsilateral breast recurrence (IBR)
  - Disadvantage: Extends treatment duration
- Hypofractionated WBI (H-WBI) in 15-16 fractions (F) is used to deliver adjuvant WBI with acceptable toxicity and comparable IBR as WBI 50 Gy in 2 Gy F.
- H-WBI trials (START trials, RMH) used sequential boost when delivered and was not evaluated as part of the study question.
- The Boost delivery has remained sequential in 5-8 F/ 2 Gy per F adding 1-1.5 weeks additional treatment duration.
- Boost is indicated in patients at high risk of IBR which were not prevalent in prior H-WBI clinical trials.

# Study Objectives

## Primary

- To determine if IBR for a boost delivered concomitantly with H-WBI over 15 fractions is no worse than (i.e. **non-inferior**) IBR for a boost delivered sequentially after WBI, in breast cancer patients considered at *high risk* for IBR.

## Secondary

- To determine that **cosmetic results** after H-WBI with concomitant boost will not be inferior to that after WBI with sequential boost.
- To determine whether CT-based conformal methods IMRT and 3DCRT for WBI are **feasible** in a multi-institutional setting following lumpectomy in early-stage breast cancer patients.

# Schema

Protocol-specified high-risk patients, post-lumpectomy, stages 0, I & II breast cancer

| STRATIFY | RANDOMIZE |
|---|---|
| Age<br>< 50 vs. ≥ 50<br><br>Chemotherapy<br>Yes vs. No<br><br>Histologic Grade<br>1, 2 vs. 3<br><br>ER Status<br>+ vs. – | **ARM 1:** Standard fractionation<br>Whole Breast 50 Gy / 25 F or 42.7 Gy in 16 F<br>Sequential Boost 12 Gy / 6 F or 14 Gy / 7 F<br><br>**ARM 2:** Hypofractionation (15 F total)<br>Whole Breast 40 Gy/15 F/2.67 Gy daily<br>Concurrent boost 48.0 Gy/3.2 Gy daily |

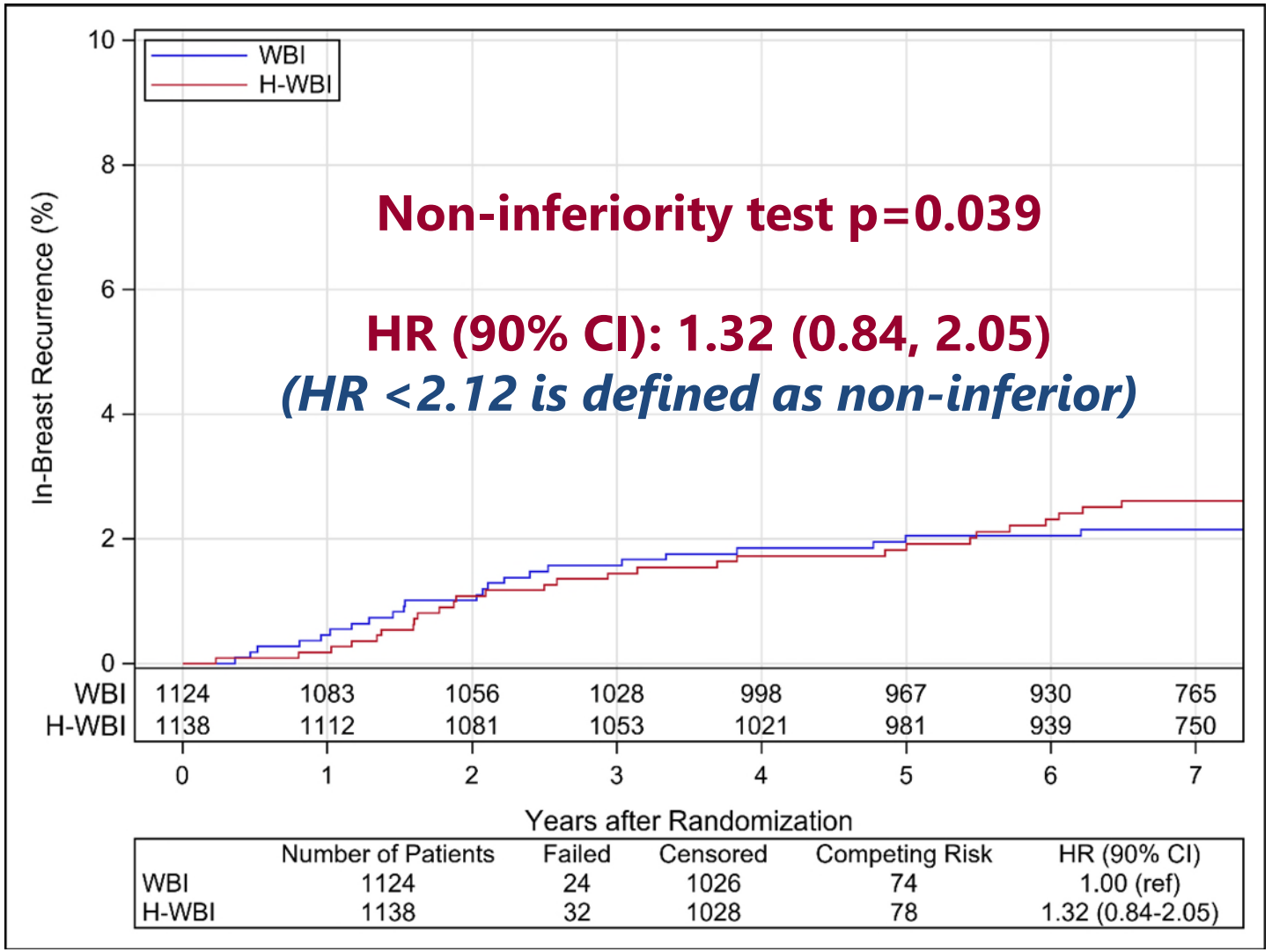
# Patient and Tumor Characteristics

| | WBI Sequential Boost (n=1124) | H-WBI Concurrent Boost (n=1138) |
|---|---|---|
| Median Age | 505 | 55 |
| < 50 years | 403 (36%) | 400 (35%) |
| Pathologic Stage II | 399 (35%) | 376 (33%) |
| Grade 3 histology | 589 (52%) | 593 (52%) |
| ER (-) | 335 (30%) | 350 (31%) |
| Close/(+) margins | 182 (16%) | 196 (17%) |
| Oncotype >25 | 94 (8%) | 124 (11%) |
| Gr 3 DCIS and <50 years | 32 (3%) | 31 (3%) |
| Chemotherapy prior to RT | 678 (60%) | 697 (61%) |
| Endocrine therapy at time of study entry | 119 (11%) | 109 (10%) |

# Results: Primary Endpoint – IBR

- Median follow-up: 7.4 years
- IBR events: 56

| | **WBI** Sequential Boost (n=1124) | **H-WBI** Concurrent Boost (n=1138) |
|---|---|---|
| 5-year estimate (90% CI) | 2.0% (1.4%, 2.9%) | 1.9% (1.3%, 2.7%) |
| 7-year estimate (90% CI) | 2.2% (1.5%, 3.0%) | 2.6% (1.9%, 3.5%) |



# Results: Treatment-Related Adverse Events

| Highest Grade Adverse Event *Definitely, Probably, or Possibly Related* to Protocol Treatment | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **WBI Sequential Boost (n=1100)** | | | | | **H-WBI Concurrent Boost (n=1123)** | | | | |
| | n and % of Patients by Grade | | | | | n and % of Patients by Grade | | | | |
| **Overall Highest Grade** | 1 | 2 | 3 | 4 | 5 | 1 | 2 | 3 | 4 | 5 |
| **All** | 427<br>**39%** | 379<br>**34%** | 34<br>**3%** | 2<br>**<1%** | 0<br>**0%** | 554<br>**49%** | 290<br>**26%** | 35<br>**3%** | 4<br>**<1%** | 0<br>**0%** |
| **50 Gy / 25 F** | 210<br>**37%** | 224<br>**39%** | 22<br>**4%** | 1<br>**<1%** | 0<br>**0%** | - | - | - | - | - |
| **42.7 / 16 F** | 217<br>**41%** | 155<br>**30%** | 12<br>**2%** | 1<br>**<1%** | 0<br>**0%** | - | - | - | - | - |
| **Grade ≥ 3 (p=0.79)** | **36 (3.3%)** | | | | | **39 (3.5%)** | | | | |

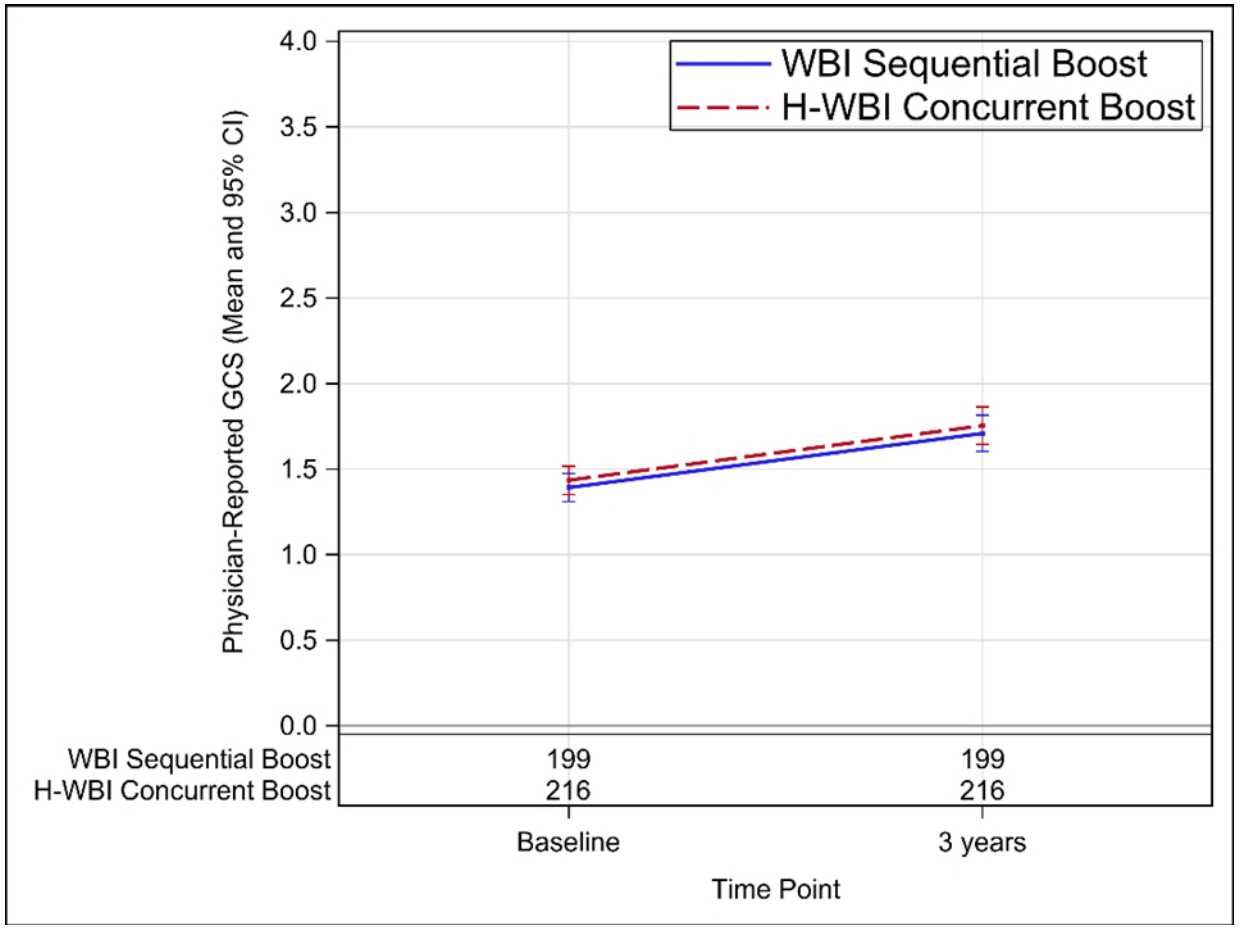
*AEs were graded with NCI CTCAE version 4.* ***39 patients excluded: 35 patients did not receive RT and 4 with no AE data submitted.***

# Results: Physician-Rated Cosmesis

| 3-year Cosmesis Score | WBI Sequential Boost (n=199) | H-WBI Concurrent Boost (n=216) | p-value |
|---|---|---|---|
| **Excellent/ Good** | **86%** | **82%** | 0.33 |
| Fair/ Poor | 14% | 18% | |

No difference in mean or mean change of GCS from baseline to 3 years between arms.

**Global Cosmetic Score (GCS) Mean**




*GCS: 1 = Excellent, 2 = Good, 3 = Fair, 4 = Poor*

# Conclusions

- For patients with "High Risk" early breast cancer undergoing breast conservation, concomitant boost with H-WBI compared to sequential boost after WBI results in:
  - Non-inferior IBR
  - No significant difference in toxicity
  - Non-inferior patient-rated cosmesis per BCTOS
  - No significant difference in physician-rated cosmetic outcome
  - Reduced overall treatment time
- Use of target volume-based Radiation Planning for 3DCRT and IMRT WBI assessed by dose volume analysis is feasible and resulted in low toxicity in the treatment arms regardless of fractionation or boost delivery


# Expert Perspective

Kathleen C. Horst, MD

*Stanford Medicine*

AI & EI: CARING FOR THE PATIENT IN A WIRELESS WORLD

ASTRO ANNUAL 2022 MEETING

# Addition of metastasis-directed therapy to intermittent hormone therapy for oligometastatic prostate cancer (EXTEND):

## A multicenter, randomized phase II trial

**Abstract LBA 05**


Presented by:

Chad Tang, MD

*The University of Texas MD Anderson Cancer Center*

# Disclosure & Study Team

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center
Making Cancer History®

- Disclosure:
  - Royalties: Pocket Radiation Oncology, MD Anderson Handbook of Radiation oncology
  - Patents: Office of Technology Licensing at Stanford
  - Consulting: Bayer, Diffusion Pharmaceuticals
- This study was supported by funding from CPRIT RP180140 and NCI P30CA016672 (to MDACC)

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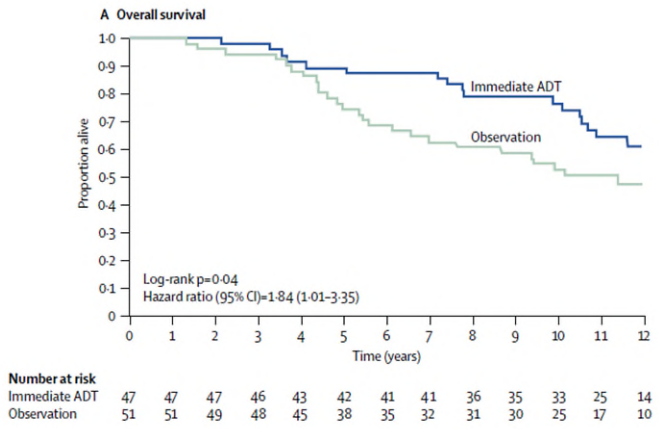
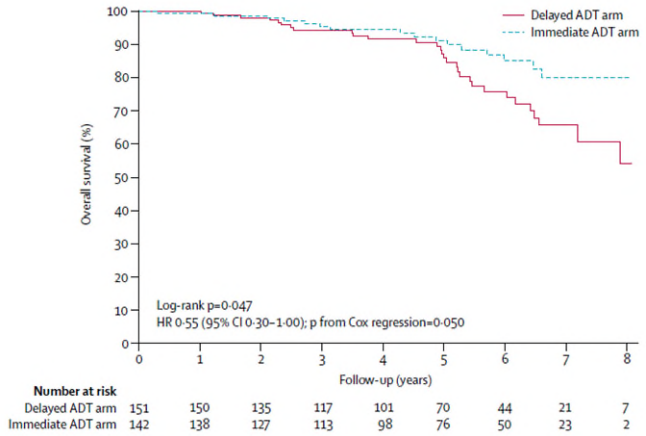
# Upfront HT improves survival and synergizes with RT.

- Hormone therapy (HT) synergizes with radiation therapy (RT) to treat prostate cancer
- Upfront HT has been associated with improvements in overall survival.

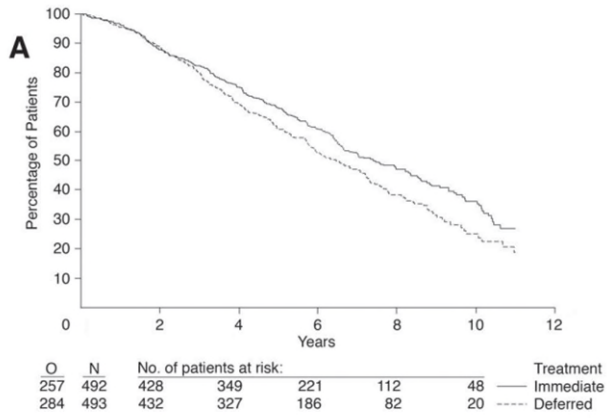
**Messing NEJM 1999 and Lancet Oncol 2006:** Immediate HT vs Observation for pN1




**TOAD:** Immediate vs delayed HT for PSA relapsed after prior definitive treatment




**EORT 30891:** Immediate vs delayed HT for prostate cancer unsuitable for local therapy

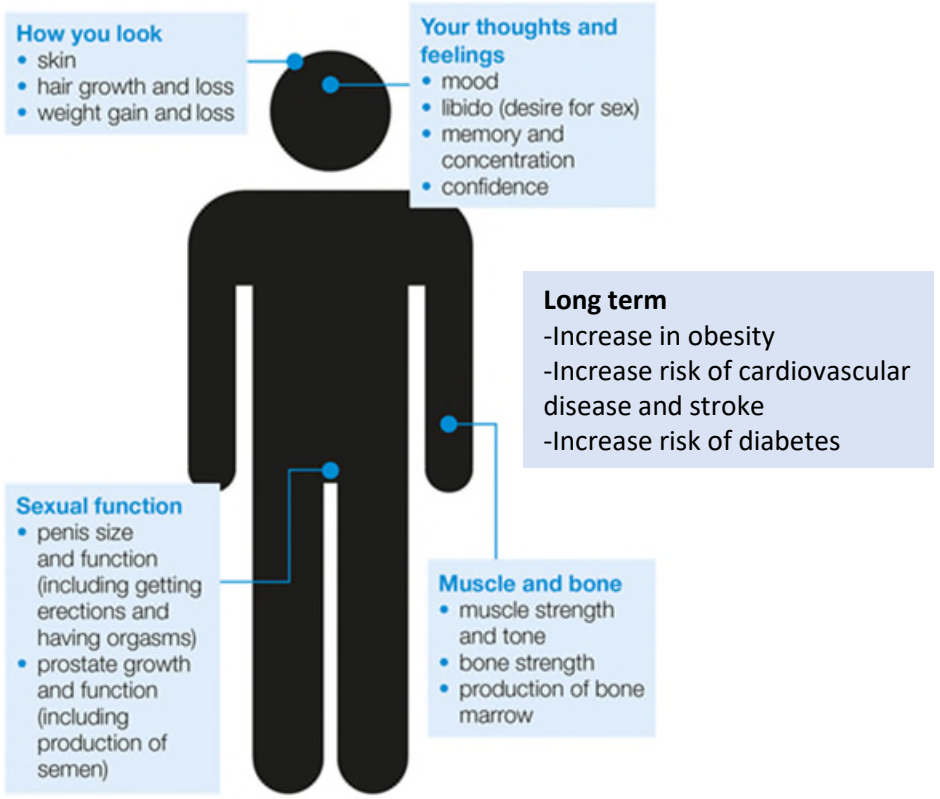



Messing NEJM 1999
Messing Lancet Oncol 2006

Duchesne Lancet Oncol 2016
Studer JCO 2006

# HT has adverse effects, and intermittent regimes may reduce HT exposure.

- HT can have significant short- and long-term side effects. Men generally hate it…




- In metastatic prostate cancer, intermittent HT was not non-inferior to continuous HT

SWOG S9346

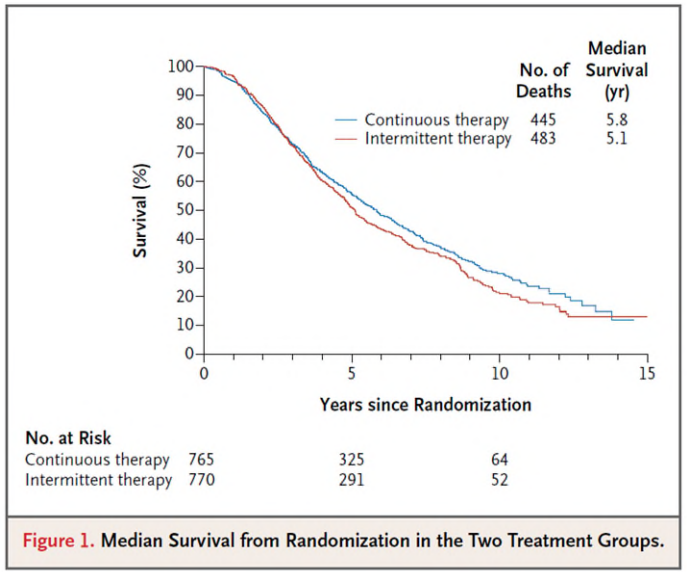



Figure 1. Median Survival from Randomization in the Two Treatment Groups.

**Caveats:**

-Median PSA at diagnosis was 42 (IQR: 15-132)

-PSA after 7 mo HT was >0.2 in 65% of patients

-During HT breaks, HT resumed at PSA ≥ 20

Hussain NEJM 2013

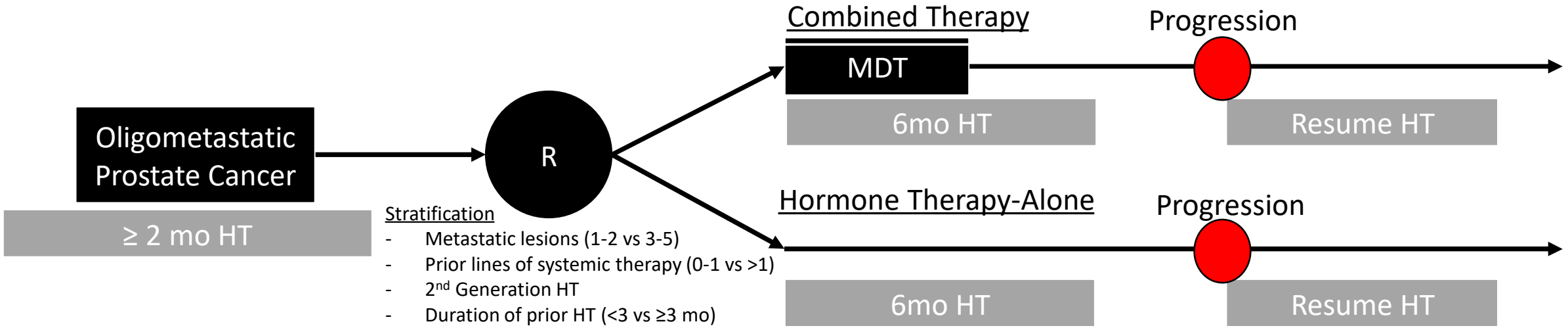
# EXTEND intermittent prostate cancer basket

Major Inclusion Criteria

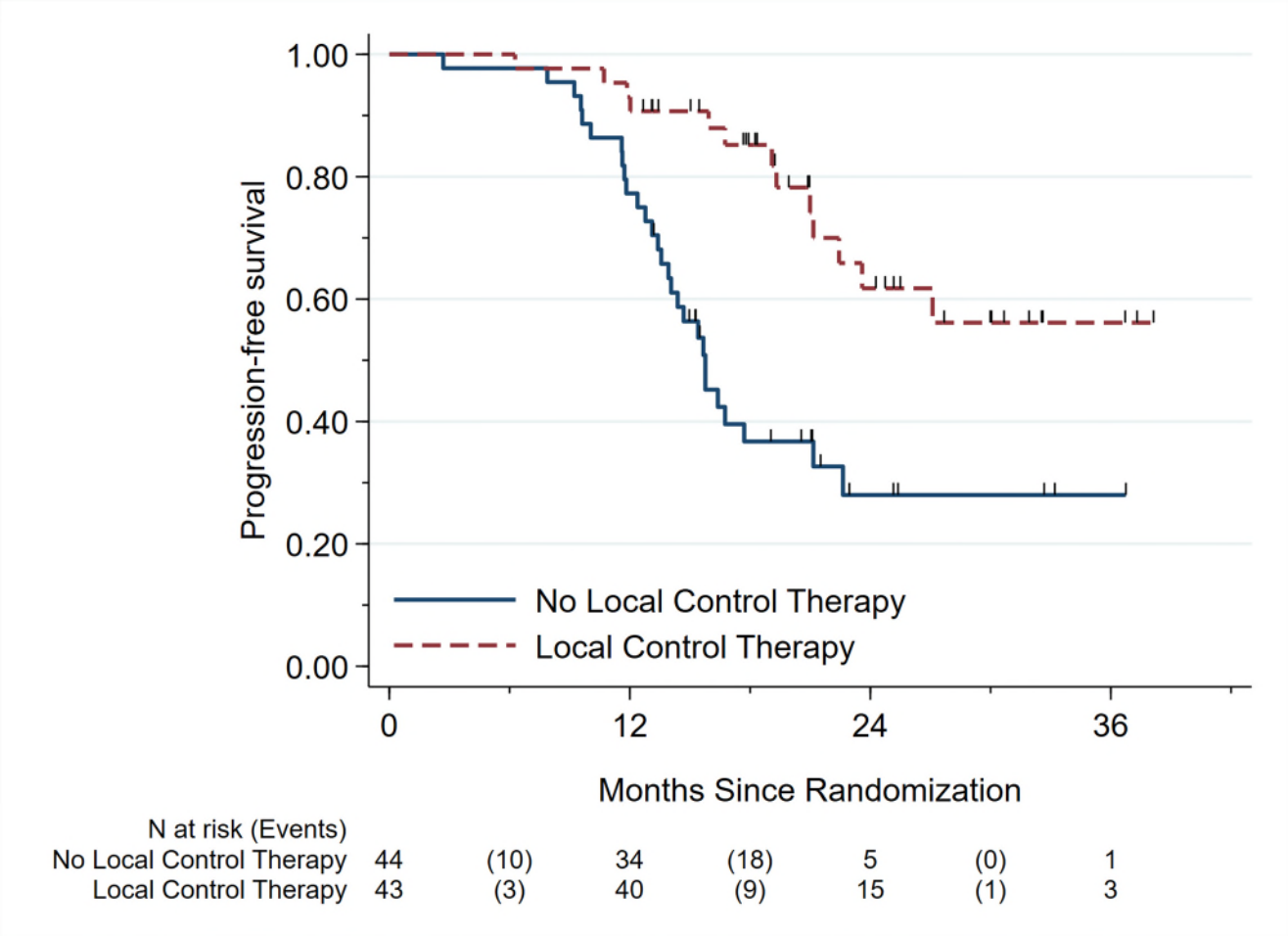
- Histologic diagnosis of prostate cancer
- ≤5 metastases
- ≥2 months of prior HT (either GNRH agonist/antagonist +/- 2nd generation HT)
- Untreated primaries were allowed, but must be treated regardless of randomization

Primary Endpoint: Progression

- Biochemical progression (≥2 ng/mL or ≥25% increase above nadir)
- Clinical progression (symptoms or need to restart HT)
- RECIST 1.1 radiographic progression
- Death



# Primary Endpoint: Progression-Free Survival

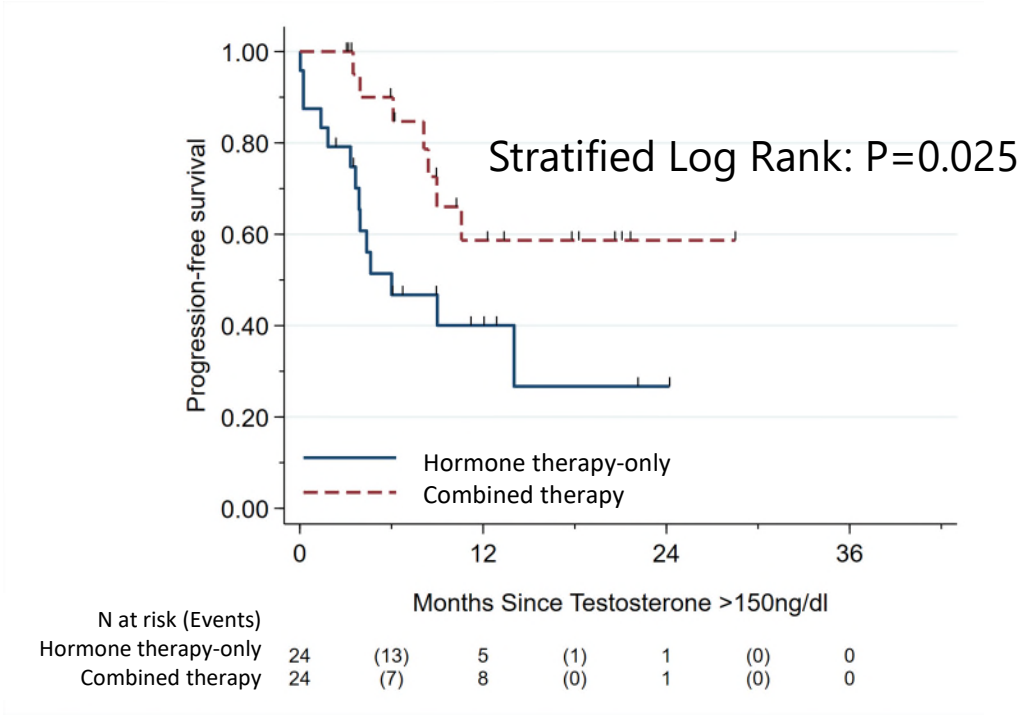



Median follow: 22.1 mo
Stratified Log Rank: P<0.001
HR = 0.25 (95% CI: 0.12-0.55)

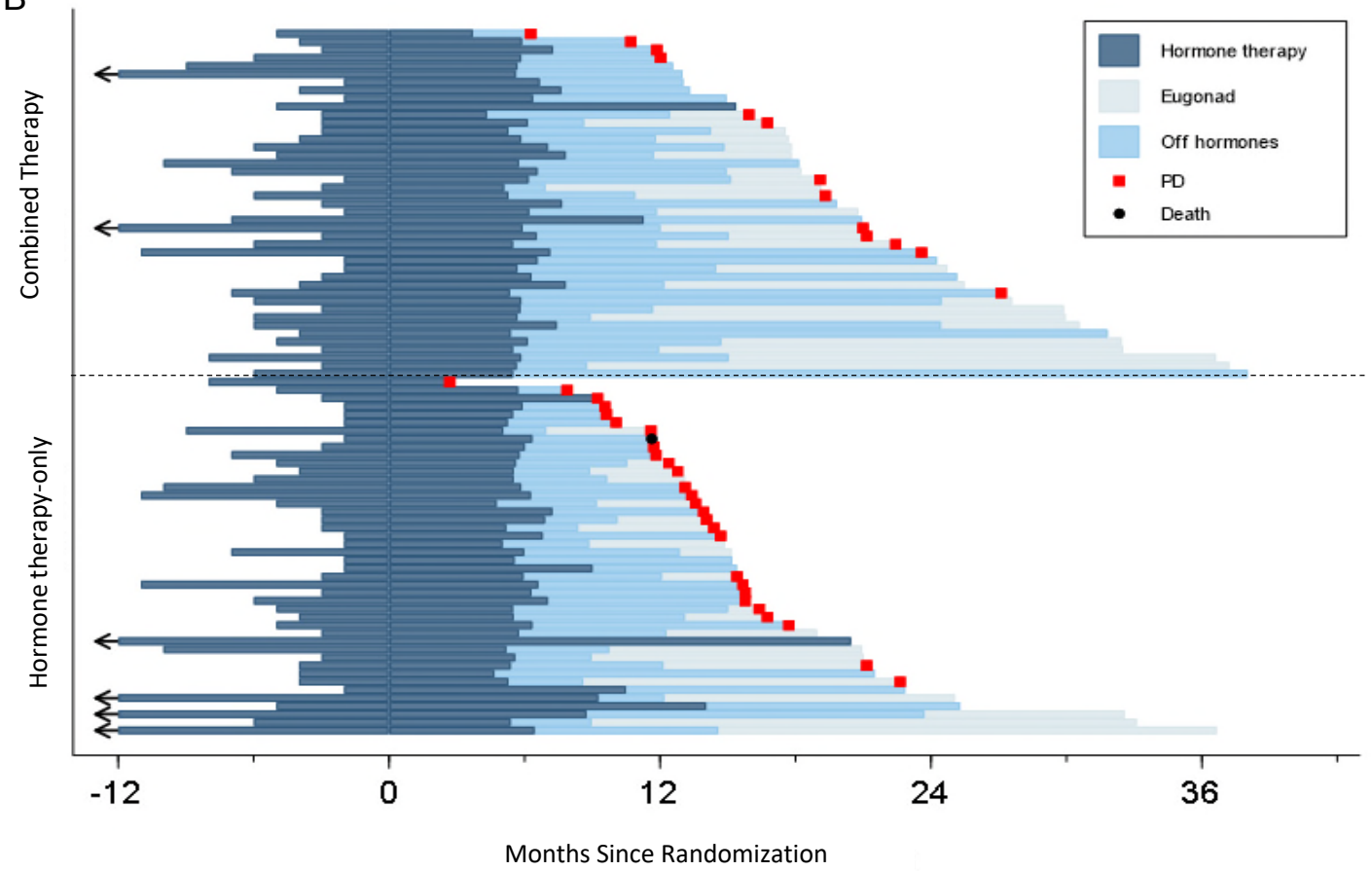
<u>Median PFS</u>
Hormone therapy-only: 15.8 mo
Combined therapy: not reached

# Secondary Endpoint: Eugonad Progression-Free Survival

Time-to-event analysis starting from eugonad testosterone (>150 ng/dL) to progression




B



# Conclusions

- MDT combined with HT as part of an intermittent regime improves PFS and thus time off HT.
- MDT combined with HT as part of an intermittent regime improves time with eugonad testosterone.
- Intermittent HT in combination with MDT may facilitate prolonged eugonad testosterone intervals while maintaining excellent disease control in men with oligometastatic prostate cancer.


# Expert Perspective

Howard M. Sandler, MD, FASTRO

*Cedars-Sinai*

*ASTRO President-Elect*


# Machine learning-based prediction of hospitalization using daily step counts for patients undergoing chemoradiation

## Abstract 132

Presented by:

Isabel Friesner, BA
*University of California, San Francisco*

# Disclosure & Study Team

UCSF Bakar Computational Health Sciences Institute

UCSF Helen Diller Family Comprehensive Cancer Center

Montefiore Einstein Cancer Center

- I have no conflicts of interest to disclose.
- This study was supported by funding from the Radiation Oncology Institute.

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ROI Radiation Oncology Institute

# Background

- Acute care events are a major concern during cancer care because they cause increased costs, delayed treatments, and reduced treatment efficacy
- Wearable devices allows for the **continuous, objective** capture of patient-generated health data, which has the potential to provide valuable insight into a patient's current health status
- The objective of this study was to develop and internally validate **machine learning approaches** based on daily step counts during chemoradiation (CRT) to predict hospitalization events
    - NRGF-001 (NCT04878952)

# Method

- Three **prospective, single-institution trials** of activity monitoring (NCT02649569, NCT03115398, NCT03102229) for patients undergoing chemoradiation
- Train/test split


- **Model output:** predict hospitalization one week out

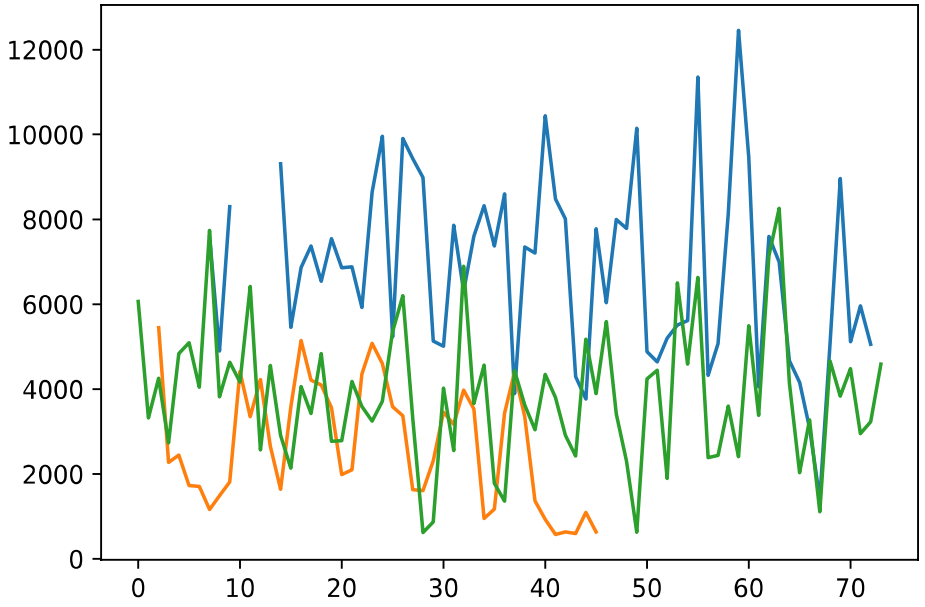
Ohri, N. et al. *Int. J. Radiat. Oncol.* 2017., Ohri, N. et al. *Int. J. Radiat. Oncol.* 2019., Paul, S. et al. *Int. J. Radiat. Oncol.* 2020.

Montefiore Einstein Cancer Center

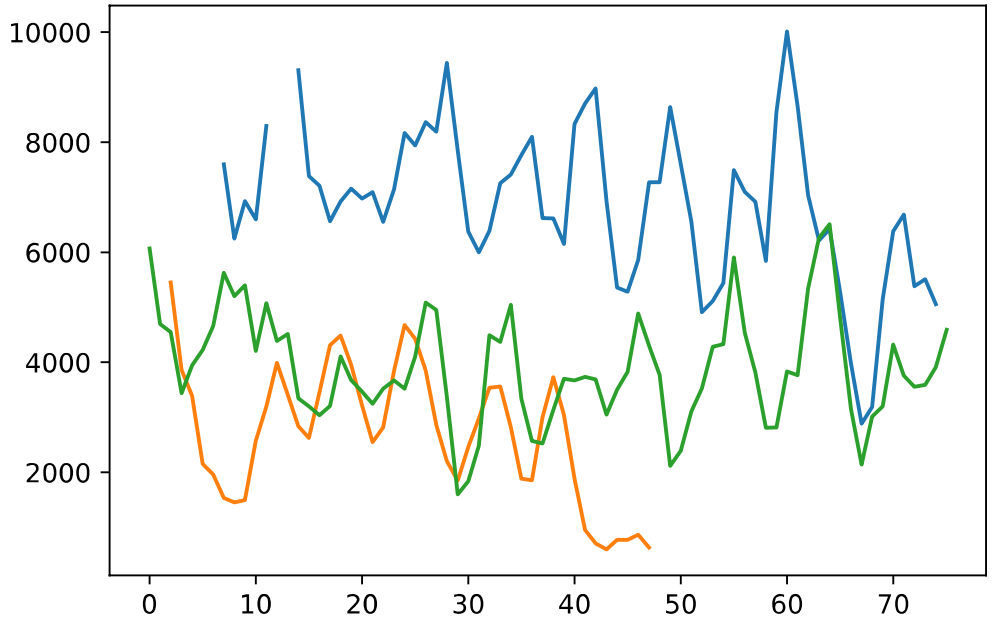
# Clinical features

- Age
- ECOG performance status
- Sex
- Primary cancer site

# Step count preprocessing

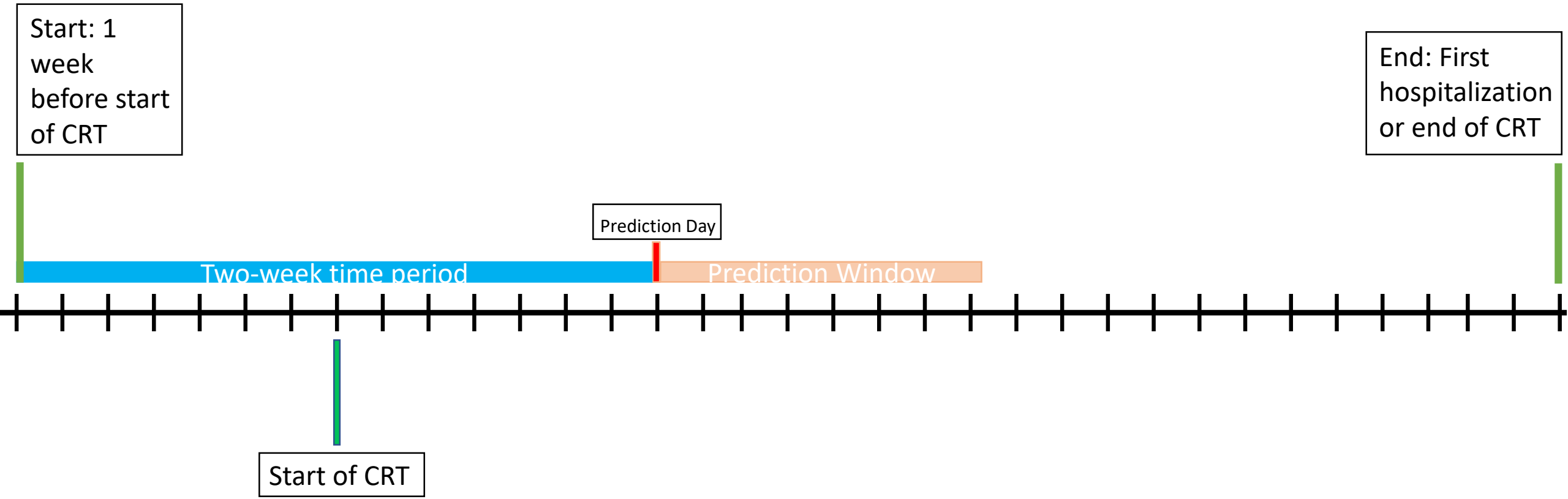



Raw Data

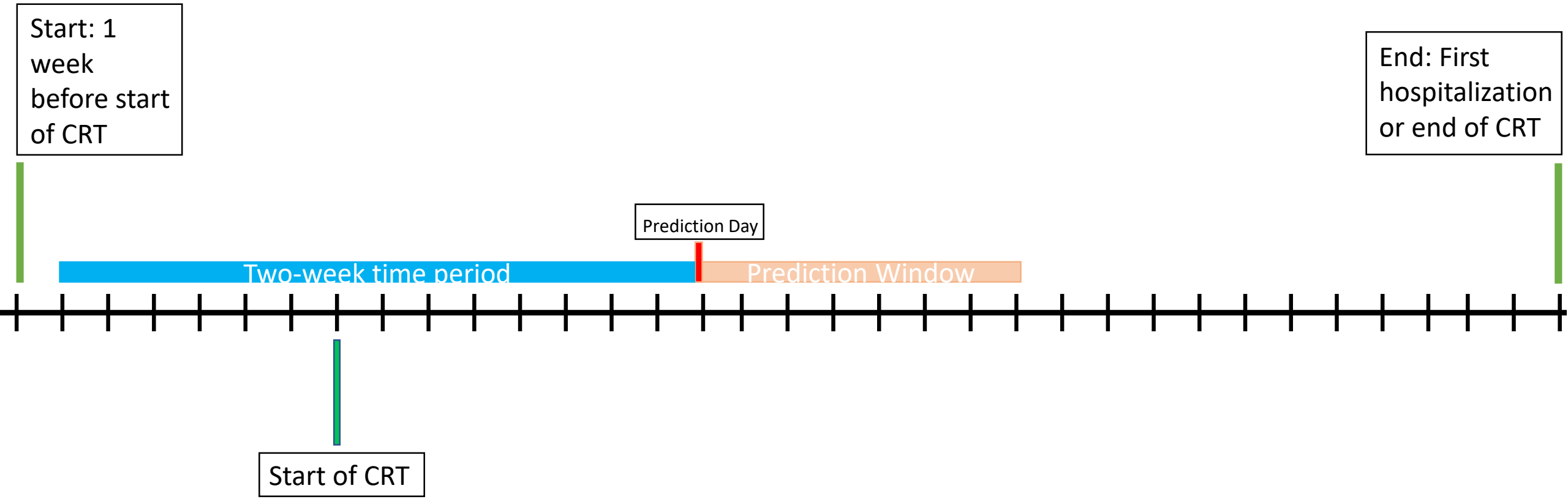



Smoothed (3-day average)

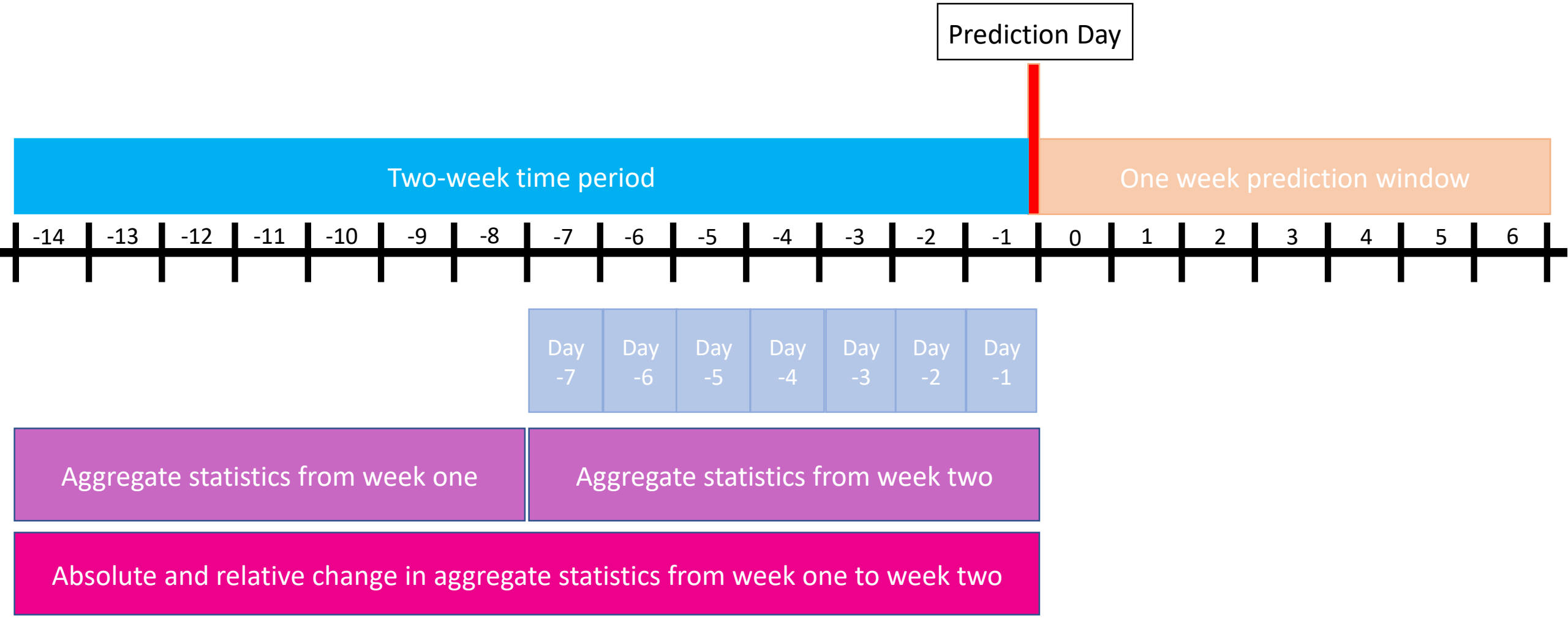
# Step count preprocessing



# Step count preprocessing

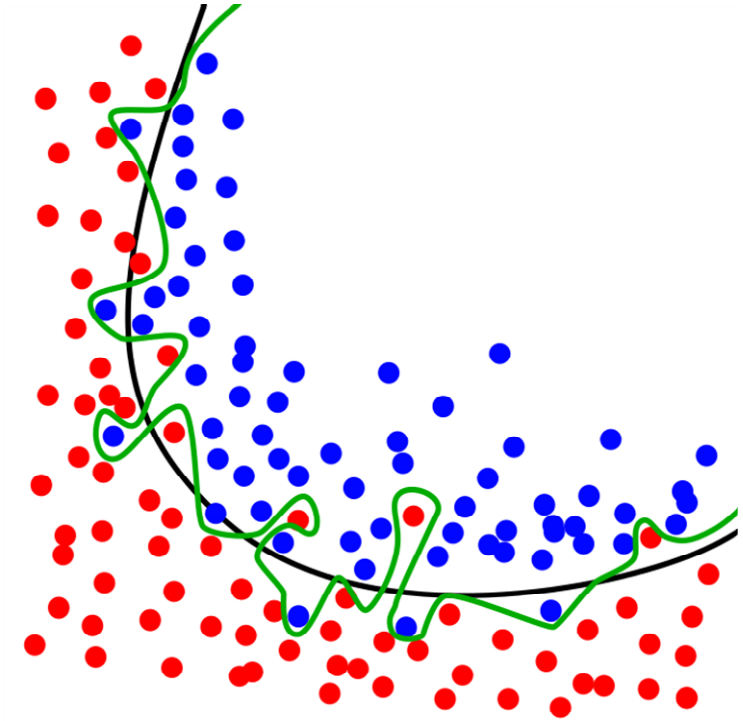


# Step count preprocessing

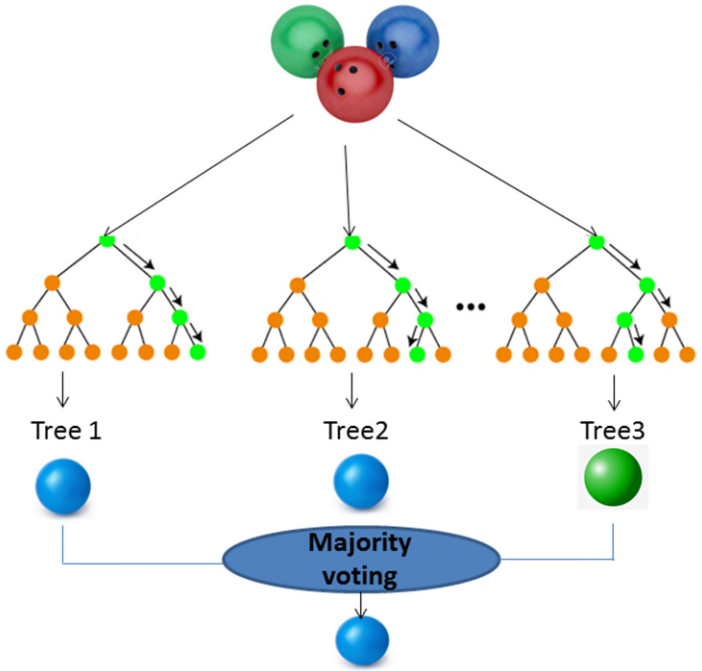


# Machine Learning approaches

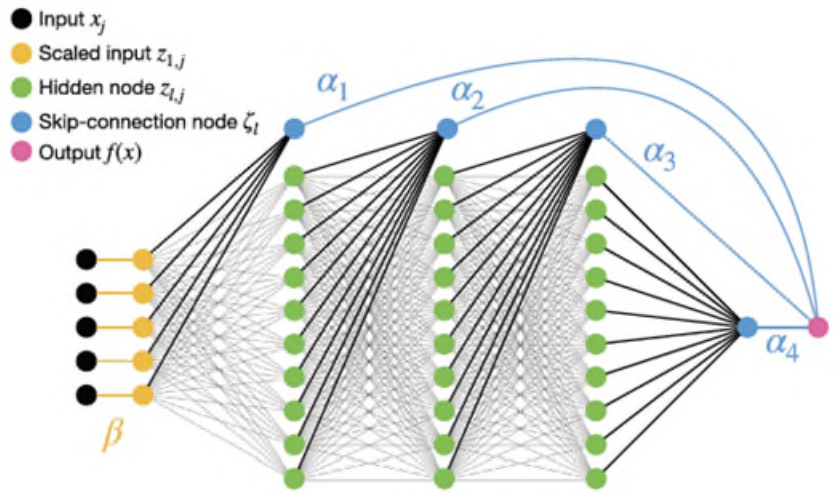
## Elastic net



## Random Forest



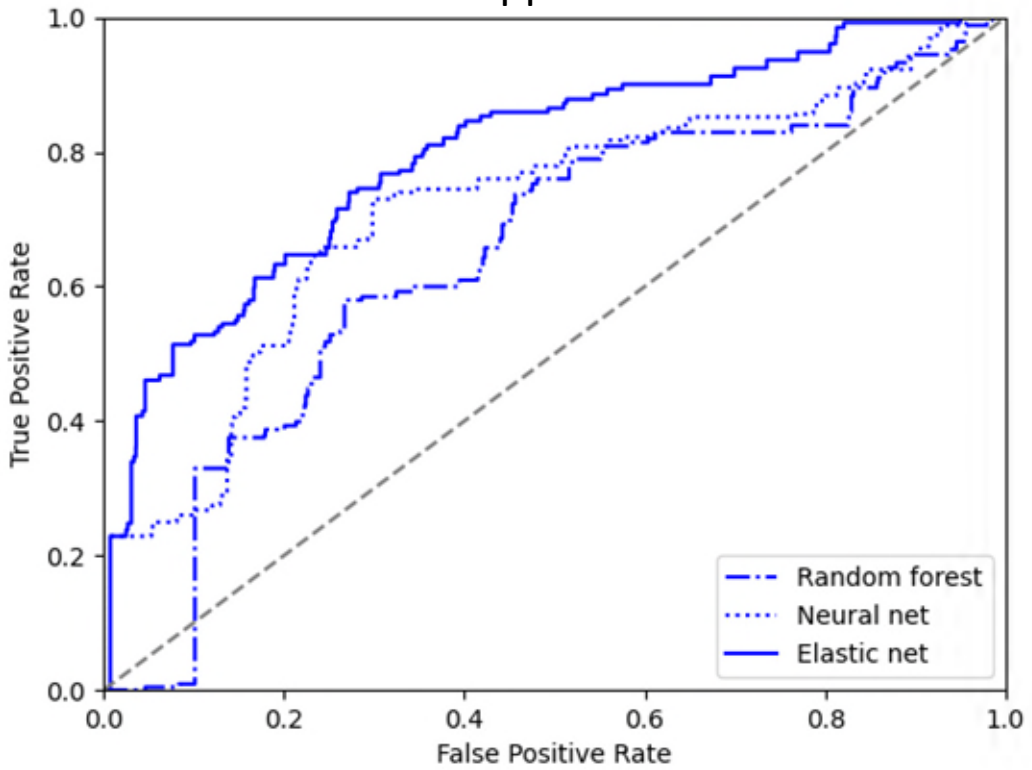

## Neural net



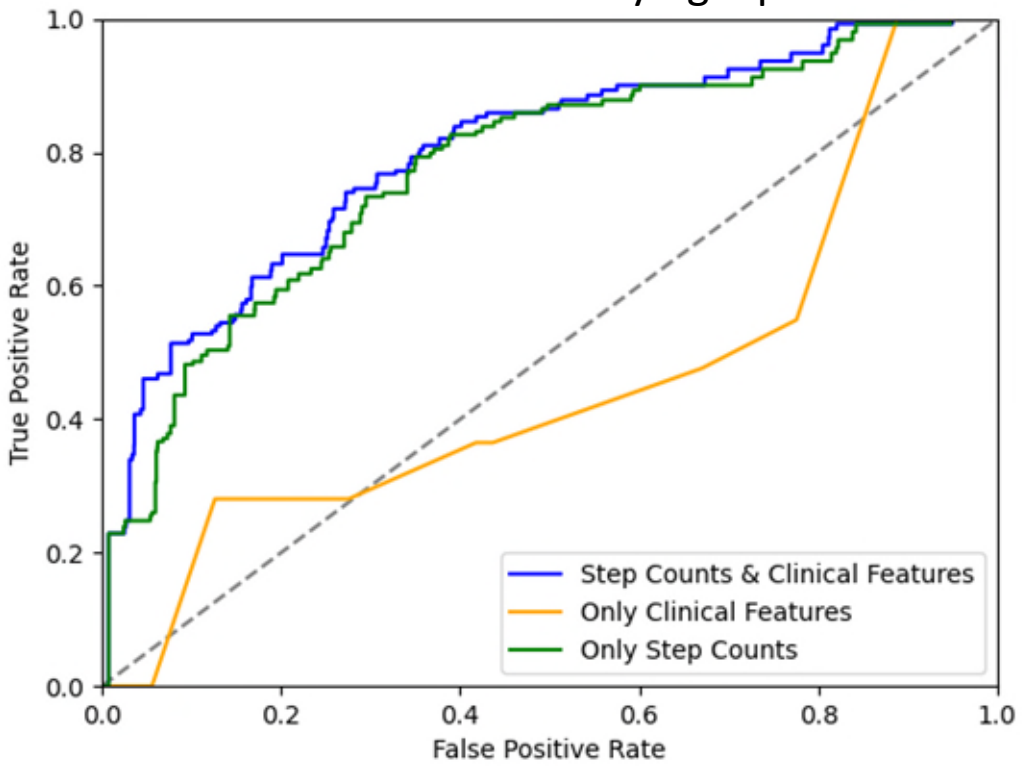

Feng, J. et al. *Stat. Anal. Data Min. ASA Data Sci. J.* 2022

# Receiver operating characteristic curves

ML approaches




Elastic net with varying inputs



# Features contributing to best performing elastic net model

| Rank | Feature |
|---|---|
| 1 | Adjusted step count, Day -1 |
| 2 | Adjusted step count, Day -2 |
| 3 | Relative change in weekly maximum step |
| 4 | Cervical cancer diagnosis |
| 5 | Relative change in weekly step count range |
| 6 | Male |
| 7 | Absolute change in weekly minimum step |
| 8 | Median step count from week two |
| 9 | Non gastric cancer diagnosis |
| 10 | Standard deviation of step counts from week one |

# Features contributing to best performing elastic net model

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| 7 | Absolute change in weekly minimum step |
| 8 | Median step count from week two |
| 9 | Non gastric cancer diagnosis |
| 10 | Standard deviation of step counts from week one |

# Conclusions

- Machine learning can be applied to daily activity monitoring data to predict hospitalization
- We applied this approach to build models based on three prospective trials of step count monitoring
- Enables continuous assessment of health status
- Limitations: small data set
- Results of this study will be implemented in NRGF-001 (NCT04878952)

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**NRGF-001**: ACTIVITY MONITORING TO IMPROVE PATIENT CARE DURING CHEMORADIOTHERAPY FOR LOCALLY ADVANCED NON-SMALL CELL LUNG CANCER (LA-NSCLC)

AI & EI: CARING FOR THE PATIENT IN A WIRELESS WORLD

ASTRO ANNUAL 2022 MEETING

# Evaluation of disparity in physician assessment of sexual dysfunction in women versus men receiving brachytherapy for genitourinary cancers

## Abstract 2306


Presented by:

Jamie Takayesu, MD

*University of Michigan*

# Disclosure & Study Team

- Disclosure: I have no conflicts of interest to disclose.

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# Background

- Brachytherapy is a commonly used treatment for prostate cancer and gynecologic cancers
- Up to 90% of women and 50% of men will experience sexual dysfunction after brachytherapy
- 62.79% of women think they should be regularly asked about sexual function (Chapman J Cancer Res Clin Oncol 2019)

# Method

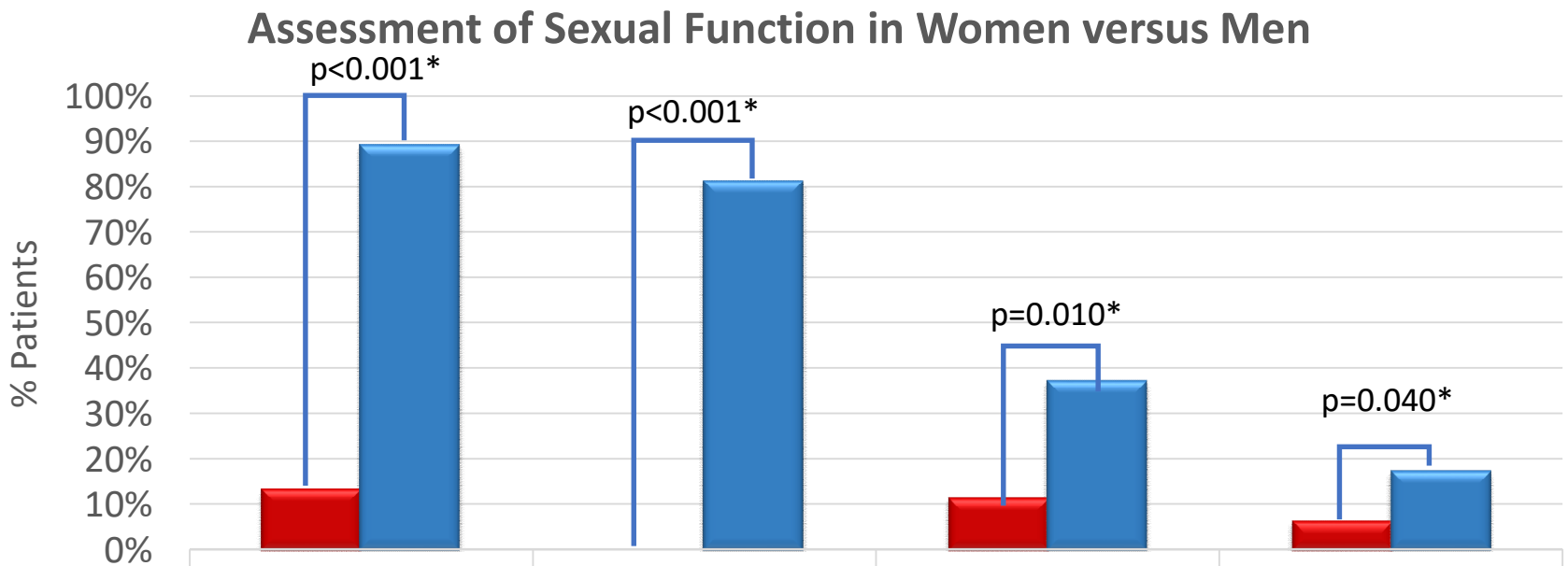
**Part 1**

- Retrospective review of patients treated with brachytherapy at a single institution
- 126 women with cervical cancer
- 75 men with prostate cancer
- *How many people are being asked about sexual function at consult?*

**Part 2**

- Query NIH Clinical Trials Database
- 53 trials on brachytherapy for cervical cancer
- 78 trials on brachytherapy for prostate cancer
- *How many trials are studying sexual function?*

# Results




| | Institutional - Assessment of sexual function | Institutional - Sexual function assessed with PRO | Clinical Trial - Assessing QOL | Clinical Trial - Assessing sexual function |
|---|---|---|---|---|
| Women | 13% | 0% | 11% | 6% |
| Men | 89% | 81% | 37% | 17% |

- Women were younger (median 51yo v. 69yo)
- Men were asked about sexual function regardless of ADT use

# Conclusions

- Women are significantly less likely to be asked about their sexual health prior to receiving brachytherapy for cancer treatment
- Next steps at our institution
  - Implementing standardized PROs in our clinic along with physician education
  - Currently discussing with other specialties regarding management of sexual dysfunction in women
- Where do we go next?
  - What implicit biases and social constructs impact MD discussion of female sexual health?
  - How can we alter radiation to decrease sexual toxicity?
  - How can we improve therapies to address female sexual dysfunction?

AI & EI: CARING FOR THE PATIENT IN A WIRELESS WORLD

ASTRO ANNUAL 2022 MEETING

# Prophylactic radiation therapy vs. standard-of-care for patients with high-risk, asymptomatic bone metastases:

## A multicenter, randomized phase II trial

**Abstract LBA 04**

Presented by:

Erin F. Gillespie, MD
Memorial Sloan Kettering Cancer Center

# Disclosure & Study Team


Memorial Sloan Kettering Cancer Center

- Disclosure: I have no conflicts of interest to disclose.

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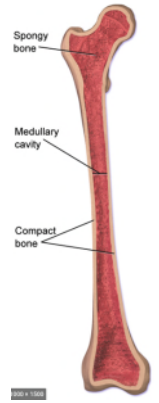
# Background

Radiation for *symptomatic* bone metastases is standard of care.

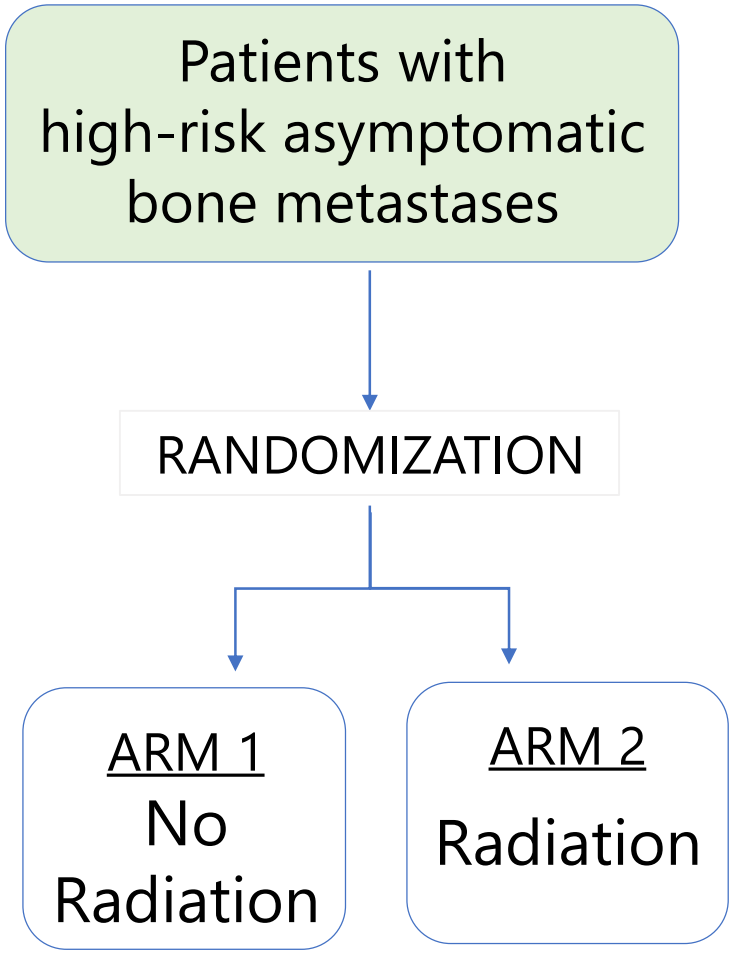



But questions arise frequently about whether to use radiation to treat *asymptomatic* bone metastases in critical locations.

Importantly, painful bone metastases can lead to hospitalization, and these tumors are often present on prior imaging.

💡 Can radiation to asymptomatic high-risk bone metastases prevent complications (i.e. cord compression, fracture), hospitalizations, and improve quality of life?

# Methods



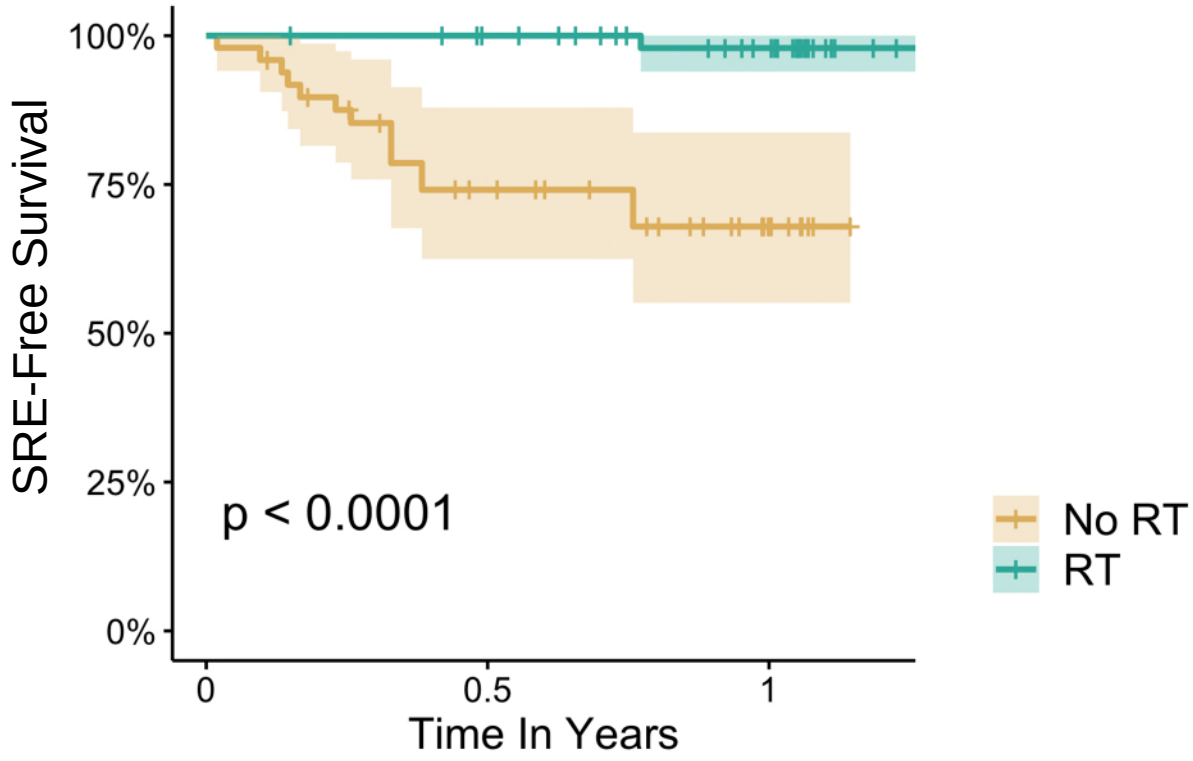

- 78 patients with widespread metastatic disease from solid tumors (breast, prostate, lung, etc) and ≧1 high-risk bone metastasis were enrolled
- Randomized (1:1 ratio) to radiation or no radiation
- Primary endpoint → **skeletal-related event (SRE)**, defined as:
  - Bone fracture due to cancer,
  - Spinal cord compression,
  - Surgery for bone instability, or
  - Radiation for pain
- Other data collected → hospitalizations, overall survival, and pain-related quality of life

# Results

1. Skeletal-related events (SRE) were ↓ with radiation (29% vs 1.6%).

2. Hospitalizations 🏥 for SRE occurred less often (11% vs 0%).

3. Pain-related quality of life was better at 1 year with radiation.



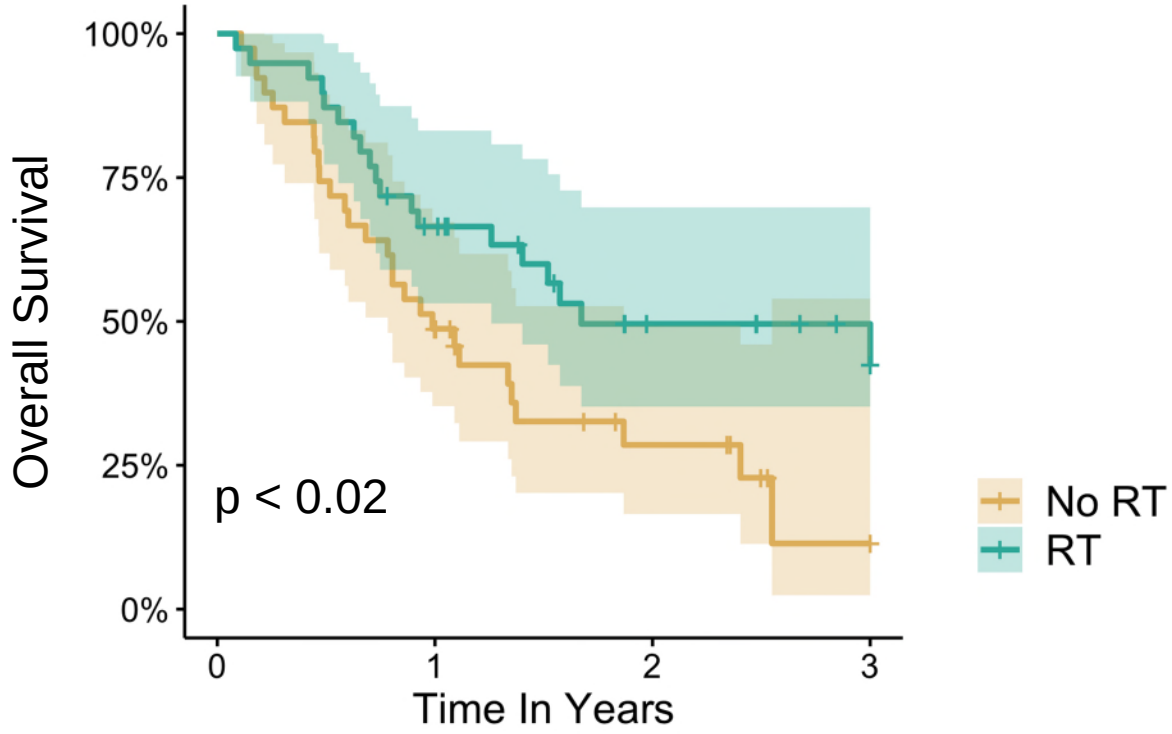
# Results

Patients that received radiation also lived longer.

Median Overall Survival (OS):

1 year (w/o radiation)

vs 1.7 years (w/ radiation)




➢This finding persisted after adjusting for other patient characteristics.

# Conclusions

This 1st randomized trial ⚖ of its kind suggests radiation for high-risk bone metastases in patients *without pain* may be a promising new treatment approach because:

1. Radiation reduced skeletal-related events and hospitalizations 🏥.
2. Patients appeared to live longer with radiation than without it.
3. Patients developed less pain after receiving radiation.

❑Future research is needed to confirm the overall survival benefit, as well as optimize which patients to treat and ensure timely referral.


# Expert Perspective

Iris C. Gibbs, MD, FASTRO

*Stanford Medicine*

*Chair, ASTRO Health Equity, Diversity and Inclusion (HEDI) Council*


# Q&A Session

Please submit your questions in the chat, including your name/outlet, or raise your hand to ask via audio.

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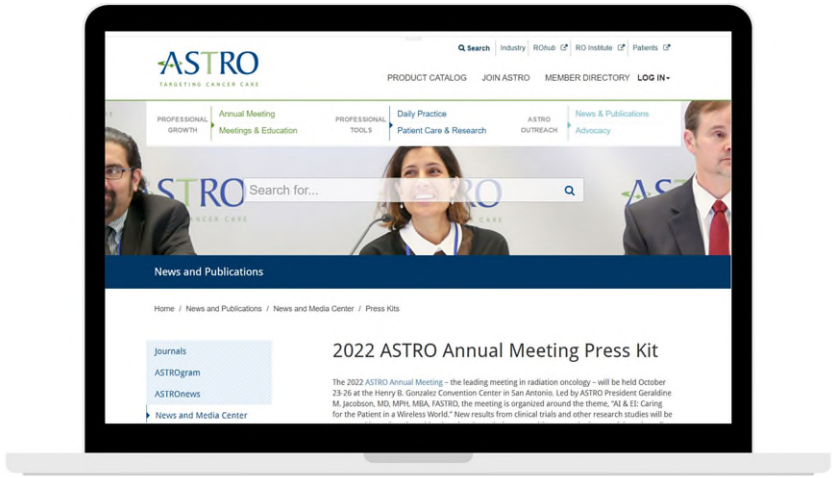


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