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

ASTRO
ANNUAL 2022 MEETING

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News Briefing: Tuesday, October 25
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

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

<table>
<thead>
<tr>
<th>STRATIFY</th>
<th>RANDOMIZE</th>
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<tbody>
<tr>
<td>Age</td>
<td>ARM 1: Standard fractionation</td>
</tr>
<tr>
<td>&lt; 50 vs. ≥ 50</td>
<td>Whole Breast 50 Gy / 25 F or 42.7 Gy in 16 F</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>Sequential Boost 12 Gy / 6 F or 14 Gy / 7 F</td>
</tr>
<tr>
<td>Yes vs. No</td>
<td>ARM 2: Hypofractionation (15 F total)</td>
</tr>
<tr>
<td>Histologic Grade</td>
<td>Whole Breast 40 Gy/15 F/2.67 Gy daily</td>
</tr>
<tr>
<td>1, 2 vs. 3</td>
<td>Concurrent boost 48.0 Gy/3.2 Gy daily</td>
</tr>
<tr>
<td>ER Status</td>
<td>+ vs. –</td>
</tr>
</tbody>
</table>
### Patient and Tumor Characteristics

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

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

<table>
<thead>
<tr>
<th></th>
<th>WBI</th>
<th>H-WBI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sequential Boost (n=1124)</td>
<td>Concurrent Boost (n=1138)</td>
</tr>
<tr>
<td>5-year estimate (90% CI)</td>
<td>2.0% (1.4%, 2.9%)</td>
<td>1.9% (1.3%, 2.7%)</td>
</tr>
<tr>
<td>7-year estimate (90% CI)</td>
<td>2.2% (1.5%, 3.0%)</td>
<td>2.6% (1.9%, 3.5%)</td>
</tr>
</tbody>
</table>

Non-inferiority test p = 0.039

HR (90% CI): 1.32 (0.84, 2.05)

(HR < 2.12 is defined as non-inferior)
## Results: Treatment-Related Adverse Events

### Highest Grade Adverse Event

Definitely, Probably, or Possibly Related to Protocol Treatment

<table>
<thead>
<tr>
<th></th>
<th>WBI Sequential Boost (n=1100)</th>
<th>H-WBI Concurrent Boost (n=1123)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n and % of Patients by Grade</td>
<td>n and % of Patients by Grade</td>
</tr>
<tr>
<td>Overall Highest Grade</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>All</td>
<td>427</td>
<td>379</td>
</tr>
<tr>
<td>50 Gy / 25 F</td>
<td>210</td>
<td>224</td>
</tr>
<tr>
<td>42.7 / 16 F</td>
<td>217</td>
<td>155</td>
</tr>
</tbody>
</table>

| 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

<table>
<thead>
<tr>
<th>3-year Cosmesis Score</th>
<th>WBI Sequential Boost (n=199)</th>
<th>H-WBI Concurrent Boost (n=216)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent/Good</td>
<td>86%</td>
<td>82%</td>
<td>0.33</td>
</tr>
<tr>
<td>Fair/Poor</td>
<td>14%</td>
<td>18%</td>
<td></td>
</tr>
</tbody>
</table>

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

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
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

• 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
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...
  - Long term: 
    - Increase in obesity
    - Increase risk of cardiovascular disease and stroke
    - Increase risk of diabetes
  
- In metastatic prostate cancer, intermittent HT was not non-inferior to continuous HT

**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

**Stratification**
- Metastatic lesions (1-2 vs 3-5)
- Prior lines of systemic therapy (0-1 vs >1)
- 2nd Generation HT
- Duration of prior HT (<3 vs ≥3 mo)

**Combined Therapy**
- 6mo HT
- Resume HT

**Hormone Therapy-Alone**
- 6mo HT
- Resume HT
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)

Median PFS
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

Stratified Log Rank: P=0.025
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:
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University of California, San Francisco
Disclosure & Study Team

• I have no conflicts of interest to disclose.

• This study was supported by funding from the Radiation Oncology Institute.

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Background

• Acute care events are a major concern during cancer care because they cause increased costs, delayed treatments, and reduced treatment efficacy.

• Wearable devices allow 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

214 Patients  
11 primary cancer sites

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

Clinical features

- Age
- ECOG performance status
- Sex
- Primary cancer site
Step count preprocessing

- **Raw Data**
- **Smoothed (3-day average)**
Step count preprocessing

Start: 1 week before start of CRT

Prediction Window

Two-week time period

Prediction Day

Start of CRT

End: First hospitalization or end of CRT
Step count preprocessing

Start: 1 week before start of CRT

Prediction Window

Prediction Day

End: First hospitalization or end of CRT

Two-week time period

Start of CRT
Step count preprocessing

Two-week time period

One week prediction window

Day
-7 Day
-6 Day
-5 Day
-4 Day
-3 Day
-2 Day
-1

Aggregate statistics from week one

Aggregate statistics from week two

Absolute and relative change in aggregate statistics from week one to week two
Machine Learning approaches

Elastic net

Random Forest

Neural net

Receiver operating characteristic curves
Features contributing to best performing elastic net model

<table>
<thead>
<tr>
<th>Rank</th>
<th>Feature</th>
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<tbody>
<tr>
<td>1</td>
<td>Adjusted step count, Day -1</td>
</tr>
<tr>
<td>2</td>
<td>Adjusted step count, Day -2</td>
</tr>
<tr>
<td>3</td>
<td>Relative change in weekly maximum step</td>
</tr>
<tr>
<td>4</td>
<td>Cervical cancer diagnosis</td>
</tr>
<tr>
<td>5</td>
<td>Relative change in weekly step count range</td>
</tr>
<tr>
<td>6</td>
<td>Male</td>
</tr>
<tr>
<td>7</td>
<td>Absolute change in weekly minimum step</td>
</tr>
<tr>
<td>8</td>
<td>Median step count from week two</td>
</tr>
<tr>
<td>9</td>
<td>Non gastric cancer diagnosis</td>
</tr>
<tr>
<td>10</td>
<td>Standard deviation of step counts from week one</td>
</tr>
</tbody>
</table>
Features contributing to best performing elastic net model

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<tr>
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</tr>
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</table>
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)
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

- 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?
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

- 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

Patients with high-risk asymptomatic bone metastases

RANDOMIZATION

ARM 1
No Radiation

ARM 2
Radiation

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

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ANNUAL 2022 MEETING