Quality Care in Radiation Oncology: Refining Treatments

ASTRO News Briefing
Monday, September 25, 2017
ASTRO News Briefing
Quality Care in Radiation Oncology: Refining Treatments
Monday, September 25, 11:00am-12:00pm PT
Moderator: Paul Harari, MD, FASTRO, ASTRO President-elect, University of Wisconsin

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A Phase III Trial of Pelvic Radiation Therapy versus Vaginal Cuff Brachytherapy Followed by Paclitaxel/Carboplatin Chemotherapy in Patients with High-risk, Early-stage Endometrial Cancer: A Gynecology Oncology Group Study

M. Randall\textsuperscript{1}, V. Filiaci\textsuperscript{2}, D. McMeekin\textsuperscript{3}, C. M. Yashar\textsuperscript{4}, R. Mannel\textsuperscript{3}, R. Salani\textsuperscript{5}, P. DiSilvestro\textsuperscript{6}, J. Burke\textsuperscript{7}, T. Rutherford\textsuperscript{8}, N. Spirtos\textsuperscript{9}, J. Cho\textsuperscript{10}, J. Kim\textsuperscript{11,12}, P. Anderson\textsuperscript{13}, W. Brewster\textsuperscript{14}, W. Small\textsuperscript{15}, M. Carney\textsuperscript{16}, C. Aghajanian\textsuperscript{17}, and D. S. Miller\textsuperscript{18}

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Background

• Management of high risk, early stage endometrial cancer is controversial.

• Historically, adjuvant pelvic radiation therapy is standard for patients thought to be at significant risk of local recurrence after surgery.

• Most recognized local recurrences occur at the vaginal cuff, although metastatic failure occurs in 1 of 5 patients with high risk disease.

• Combination chemotherapy has demonstrated improved outcomes in more advanced disease, e.g. stage III and IV.

• Trend toward increased use of vaginal brachytherapy. Data suggests similar excellent ability to limit cuff recurrences compared to external RT.

• Needed a direct comparison of the standard approach (pelvic RT) to the more experimental treatment of cuff brachytherapy and chemotherapy.
Method

- 1:1 randomized comparison, phase III study. Intent to treat analysis.
- Designed to test if VCB/C is superior to PXRT (not equivalency study)
- **Primary objective:** To determine if treatment with Vaginal Cuff Brachytherapy and Chemotherapy (VCB/C) reduces the rate of recurrence or death (improves Recurrence Free Survival, RFS) compared to Pelvic Radiation Therapy (PXRT)
- **Secondary objectives:** Overall Survival (OS), patterns of failure, toxicity/functioning between arms
- Close follow-up for recurrence (including regular imaging) and toxicity
- Toxicity grading used NCI Common Terminology Criteria for Adverse Events, version 3
Relapse Free Survival by Randomized Treatment

VBT + Chemotherapy

Hazard Ratio: 0.919
90% Hazard Ratio Confidence Limits: 0.688 to 1.226
Overall Survival by Randomized Treatment

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Hazard</th>
<th>90% Hazard Ratio</th>
<th>Confidence Limits</th>
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<tbody>
<tr>
<td>VBT + Chemotherapy</td>
<td>1.041</td>
<td>0.713</td>
<td>1.518</td>
</tr>
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</table>

Events | Total
-------|-------
39     | 300   
37     | 301   

Months on Study

Proportion Alive
Results

• 36 month RFS = 82% for both PXRT and VCB/C
• 36 months OS = 91% for PXRT and 88% for VCB/C (p = 0.57)
• No difference in vaginal or distant failure rates
• Pelvic and Para-aortic nodal failures more common in VCB/C arm (estimated 9% at 5 years, vs 4% in the PXRT arm, Hazard Ratio 0.47)
• Estimated rate of vaginal and distant recurrences: 2.5% and 18% at 5 years, not different between the arms
• No significant treatment heterogeneity between the 2 arms with respect to RFS and OS
  • Variables studied include Stage, Histology, Performance Status, LND
Cumulative Incidence of Pelvic or PA Recurrence
Competing Event is Death Prior to Recurrence of Interest

Assigned Treatment
- VBT + Chemotherapy
- WPRT

Cumulative Proportion

Months from Study Activation

0 12 24 36 48 60 72
Conclusions

• This large randomized phase III study did not demonstrate superiority of VCB/C over PXRT in a cohort of patients with High Risk, Early Stage Endometrial Carcinoma.

• RFS and OS were not improved with VCB/C compared to PXRT. This conclusion applies to all subgroups analyzed, including patients with serous and clear cell histology.

• Analysis of failure patterns showed a significantly lower nodal failure rate in the PXRT arm. Distant failure is the predominant failure pattern in this patient population (18% in both arms).
Conclusions

• Acute toxicity was significantly greater in VCB/C arm, while late toxicity was similar in the 2 arms.

• Pelvic radiation therapy remains an appropriate (and probably preferable) treatment for high risk, early stage endometrial carcinoma.

• Better treatment strategies to address the risk of systemic disease will be necessary to further improve outcomes in this patient group.
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Two Year Results for MC1273, a Phase II Evaluation of Aggressive Dose De-escalation for Adjuvant Chemoradiation in HPV+ Oropharynx Squamous Cell Carcinoma (OPSCC)

D. J. Ma¹, K. Price², E. J. Moore³, S. H. Patel⁴, M. L. Hinni⁵, A. V. Chintakuntlawar², J. J. Garcia⁶,⁷, D. Graner⁸, M. A. Neben-Wittich¹, Y. Garces¹, C. L. Hallemeier¹, D. L. Price³, J. L. Kasperbauer³, J. R. Janus³, N. R. Foster⁹, and R. L. Foote¹

¹Department of Radiation Oncology, Mayo Clinic, Rochester, MN, ²Division of Medical Oncology, Mayo Clinic, Rochester, MN, ³Department of Otolaryngology, Mayo Clinic, Rochester, MN, ⁴Mayo Clinic, Scottsdale, AZ, ⁵Department of Otolaryngology, Mayo Clinic, Phoenix, AZ, ⁶Division of Anatomic Pathology, Mayo Clinic, Rochester, MN, ⁷Department of Laboratory Medicine & Pathology, Mayo Clinic, Rochester, MN, ⁸Department of Neurology, Mayo Clinic, Rochester, MN, ⁹Division of Biomedical Statistics and Informatics, Mayo Clinic, Rochester, MN
Background: HPV-related oropharynx cancer

- Although cure rates for HPV-OPC are high, standard treatment can have serious and potentially life-altering side effects.

- Multiple research groups are currently exploring incremental reductions in radiation dose for HPV-OPC.

- MC1273 explored an aggressive course of treatment reduction by halving the dose of radiation after surgery.
Methods

p16+ oropharynx patients <10 pack-year smoking history margin clearing surgery

Cohort A: n= 37
≥T3, ≥N2, lymphovascular invasion, or perineural invasion

30 Gy (1.5 Gy bid x 10 days) + weekly docetaxel (15 mg/m²) x 2

Cohort B: n=43
Extracapsular extension

36 Gy (1.8 Gy bid x 10 days) + weekly docetaxel (15 mg/m²) x 2

Follow-up
Swallow Studies
Quality of Life Assessment

Standard Treatment: 60 - 66 Gy over six weeks ± cisplatin
Patients

- **Median age**: 60.5 years (range: 25-77 years)

- **Gender**: 73 Male, 7 Female

- **Median follow-up**: 23.6 months (12 – 46)

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<tr>
<th>T Category</th>
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<th>Percent</th>
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<tr>
<td>pN3</td>
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Results: Progression Free Survival

- 2-yr PFS: 91.3%
- RTOG 0234: 2-yr PFS 86.4%
- Distant Recurrence: n = 4
- Locoregional Recurrence: n = 3
Results: Locoregional Control

- 2-yr LRC: 96.3%
- Local Recurrence: n = 2
- Nodal Recurrence: n = 1
Results: Toxicity and Swallowing

• Grade ≥2 toxicity rate at two years post-treatment was 10%
  → RTOG 0234 rate was 55%

• No patients required a feeding tube placed during treatment.

• Swallowing function improved between pre-radiation and 12 month follow-up. (MBSImp Oral: 1.5±1.9 vs 1.5±1.8 p=n.s., Pharyngeal 5.8±3.9 vs 4.7±3.6 p= 0.02.)

• Quality of life (EORTC-HN, FACT-HN and Eq-5D) remained essentially unchanged between pre and post-treatment.
Conclusions

• Aggressive treatment de-escalation resulted in disease control rates comparable to historical controls.

• De-escalated therapy led to significantly improved post-treatment side effects, improved long-term swallowing function and improved quality of life.

• A multi-institutional, phase III study (NCT02908477: “DART-HPV”) is currently open for accrual.
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Novel Associations Between the Immune Landscape of Prostate Cancer and Postoperative Radiation Response

S. G. Zhao\textsuperscript{1}, J. Lehrer\textsuperscript{2}, S. L. Chang\textsuperscript{3}, N. G. Erho\textsuperscript{2}, M. Sjostrom\textsuperscript{4}, R. B. Den\textsuperscript{5}, S. J. Freedland\textsuperscript{6}, E. A. Klein\textsuperscript{7}, R. J. Karnes\textsuperscript{8}, E. M. Schaeffer\textsuperscript{9}, M. Xu\textsuperscript{10}, R. Das\textsuperscript{11}, A. J. Chang\textsuperscript{12}, P. L. Nguyen\textsuperscript{13}, E. Davicioni\textsuperscript{2}, A. E. Ross\textsuperscript{14}, L. Fong\textsuperscript{3}, D. E. Spratt\textsuperscript{1}, and F. Y. Feng\textsuperscript{15}

\textsuperscript{1}University of Michigan, Ann Arbor, MI, \textsuperscript{2}GenomeDx Biosciences, Vancouver, BC, Canada, \textsuperscript{3}University of California - San Francisco, San Francisco, CA, \textsuperscript{4}Lund University, Lund, Sweden, \textsuperscript{5}Sidney Kimmel Medical College at Thomas Jefferson University, Sidney Kimmel Cancer Center, Philadelphia, PA, \textsuperscript{6}Cedars-Sinai, Los Angeles, CA, \textsuperscript{7}Cleveland Clinic, Cleveland, OH, \textsuperscript{8}Department of Urology, Mayo Clinic, Rochester, MN, \textsuperscript{9}Northwestern University, Evanston, IL, \textsuperscript{10}UCSF Department of Radiation Oncology, San Francisco, CA, \textsuperscript{11}University of California - San Francisco, Ann Arbor, MI, \textsuperscript{12}University of California, San Francisco, San Francisco, CA, \textsuperscript{13}Dana-Farber Cancer Institute and Brigham and Women's Hospital, Boston, MA, \textsuperscript{14}Johns Hopkins Medicine, Baltimore, MD, \textsuperscript{15}University of California at San Francisco, San Francisco, CA
Background

- Role of immunotherapy in prostate cancer is not well defined
- Sipuleucel-T: first FDA approved cellular therapy shown to improve OS (Kantoff et al. NEJM 2010)
- Negative randomized trials for ipilimumab (CTLA-4) for primary endpoint OS (Beer et al. JCO 2017; Kwon et al. Lancet Onc 2014)
  - Improved PSA response suggesting therapeutic effect in subset
- Understanding immune infiltrate may be critical to predict response to various therapeutic strategies
- Difficult to histologically assess intra-tumoral immune infiltrate directly
Purpose

Leverage high throughput transcriptomic profiling and computational methods to characterize the immune landscape of localized prostate cancer.
Methods

• Retrospective (N=1567) and prospective (N=7826) radical prostatectomy samples on a clinical grade microarray platform
  • Clinical outcomes available on retrospective data only
• Immune Content Score derived from immune cell specific genes in the literature
• Relative fractions of immune cells estimated using Cibersort
Immune Pathways Cluster in Prostate Cancer

Tumor samples
N=9393
Immune Content Score May Predict Response to Post-op RT

Multivariate (adjusting for clinicopathologic variables and ADT use) interaction: **P-value = 0.017**
Conclusions

• Computationally estimated the immune infiltrate in 9393 localized prostate cancer samples and identified a potentially high-immune subset
• Immune content appears to be prognostic as well as predict response to post-op radiotherapy
• First report of PD-L2 as a potential novel target for checkpoint inhibition in prostate cancer
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Hypofractionated Radiation Therapy After Mastectomy for the Treatment of High-Risk Breast Cancer: Five-Year Follow-Up Results of a Randomized Trial

Guang-yi Sun, Shulian Wang, Yong-wen Song, Jing Jin, Wei-hu Wang, Yue-ping Liu, Hua Ren, Hui Fang, Zi-hao Yu, Xin-fan Liu, and Ye-xiong Li

PI: Ye-xiong Li, Shulian Wang

National Cancer Center/Cancer Hospital and Institute, Chinese Academy of Medical Sciences (CAMS) and Peking Union Medical College (PUMC), Beijing, China
Background

• For high-risk breast cancer after mastectomy, conventionally fractionated radiation therapy (CFRT), 2.0Gy/fx, 25fx over five weeks, to chest wall and nodal regions can improve outcomes

• There is an underuse of RT after mastectomy (PMRT) in China, because of a lack of RT facilities, medical cost burden, et. al. – 52% in stage III

• Hypofractionated RT (HFRT) (>2.0Gy/fx, fewer total fractions) is safe and effective after breast-conserving surgery

• There is no level I efficacy evidence for HFRT after mastectomy
Method

A randomized phase III non-inferior trial comparing HFRT and CFRT (Noninferiority margin: 5% difference in 5-yr LRR rate)

Target sample = 820 (June 2008 - June 2016)

Stage III breast cancer patients after mastectomy

R

1:1

CFRT
2Gy*25f, 5wks
(n=414)

HFRT
2.9Gy*15f, 3wks
(n=404)
Results

• The two arms were well balanced according to majority of prognostic factors.

• No grade 4-5 toxicities occurred in either arm.

• Hypofractionated RT arm had less grade 3 acute skin toxicity (p=0.008).

• No differences in radiation pneumonitis, late skin toxicity, lymphedema, and brachial plexopathy (at any grade) between the two arms.
Results – Locoregional Recurrence

Median follow up time: 53 months (5-111)

<table>
<thead>
<tr>
<th>5-year Actuarial Rates (95% CI)</th>
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<tbody>
<tr>
<td>CFRT</td>
</tr>
<tr>
<td>HFRT</td>
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<tr>
<td>Difference</td>
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<tr>
<td>HR</td>
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Results – Overall Survival

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<tr>
<th>Treatment Assignment</th>
<th>CFRT</th>
<th>5-year OS Rate (95% CI)</th>
<th>HFRT</th>
<th>5-year OS Rate (95% CI)</th>
<th>HR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>85.6%</td>
<td>(80.9, 89.2)</td>
<td>83.2%</td>
<td>(78.3, 87.1)</td>
<td>1.13</td>
<td>(0.78, 1.62)</td>
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Overall Survival

Number at risk

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<th>Time(years)</th>
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<th>2</th>
<th>3</th>
<th>4</th>
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<tbody>
<tr>
<td>Number at risk</td>
<td></td>
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<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>CFRT</td>
<td>409</td>
<td>403</td>
<td>355</td>
<td>296</td>
<td>225</td>
<td>167</td>
</tr>
<tr>
<td>HFRT</td>
<td>401</td>
<td>396</td>
<td>346</td>
<td>289</td>
<td>234</td>
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Cumulative number of events

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<td>Cumulative number of events</td>
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<tr>
<td>CFRT</td>
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Results – Disease-free Survival

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<tr>
<th>5-year DFS Rates (95% CI)</th>
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<tbody>
<tr>
<td>CFRT</td>
<td>70.7% (65.2, 75.4)</td>
</tr>
<tr>
<td>HFRT</td>
<td>74.6% (69.6, 79.3)</td>
</tr>
<tr>
<td>HR</td>
<td>0.88 (0.67, 1.16)</td>
</tr>
</tbody>
</table>
Results – Distant Failure

5-year DF Rates (95% CI)

- CFRT: 26.2% (21.5, 31.2)
- HFRT: 23.2% (18.9, 27.8)
- HR: 0.90 (0.67, 1.20)
Conclusions

• Hypofractionated RT after mastectomy (2.9Gy/fx, 15fx, in 3wks) is not inferior to and is as safe as conventional fractionated RT.

• It shortens treatment time, saves medical resources, reduces medical cost, makes RT more convenient.

• This is the first large, well-conducted randomized trial to demonstrate conclusively that hypofractionated radiation therapy to nodal regions of breast cancer is safe and effective in the postmastectomy setting.
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Q & A

Online attendees: Please use the Question function to submit questions.
Interview Requests and Other Questions:

ASTRO’s On-site Press Office in San Diego
   Room 24B, San Diego Convention Center
   September 24-26, 8am-5pm PT; September 27, 8am-12pm PT

Phone: 703-286-1600

Email: press@astro.org

Slides, audio and hi-res photos will be available following the briefing at www.astro.org/AMpress