IORT: is one stop shopping best

Bruce Libby, PhD
University of Virginia Health System

Disclosures

- Honoraria from Varian
- Non-disclosure agreement with Varian Brachytherapy

Learning Objectives

- To review past and current clinical trials for IORT
- To discuss lumpectomy-scan-plan-treat workflow for IORT

History of IORT for breast

- Targit-A trial
- Eliot trial
- Xoft trial

Targit-A Trial

Risk-adapted targeted intraoperative radiotherapy versus whole-breast radiotherapy for breast cancer: 5-year results for local control and overall survival from the TARGIT-A randomised trial

***Lancet* 2014; 383: 603–13**

Targit-A Trial

- 50 kV x-ray source
- Prescribe 20 Gy to the surface of the applicator
- Dose at 1 cm ~5-7 Gy
- No imaging
- No treatment plan
- No pathology

Targit-A Trial results

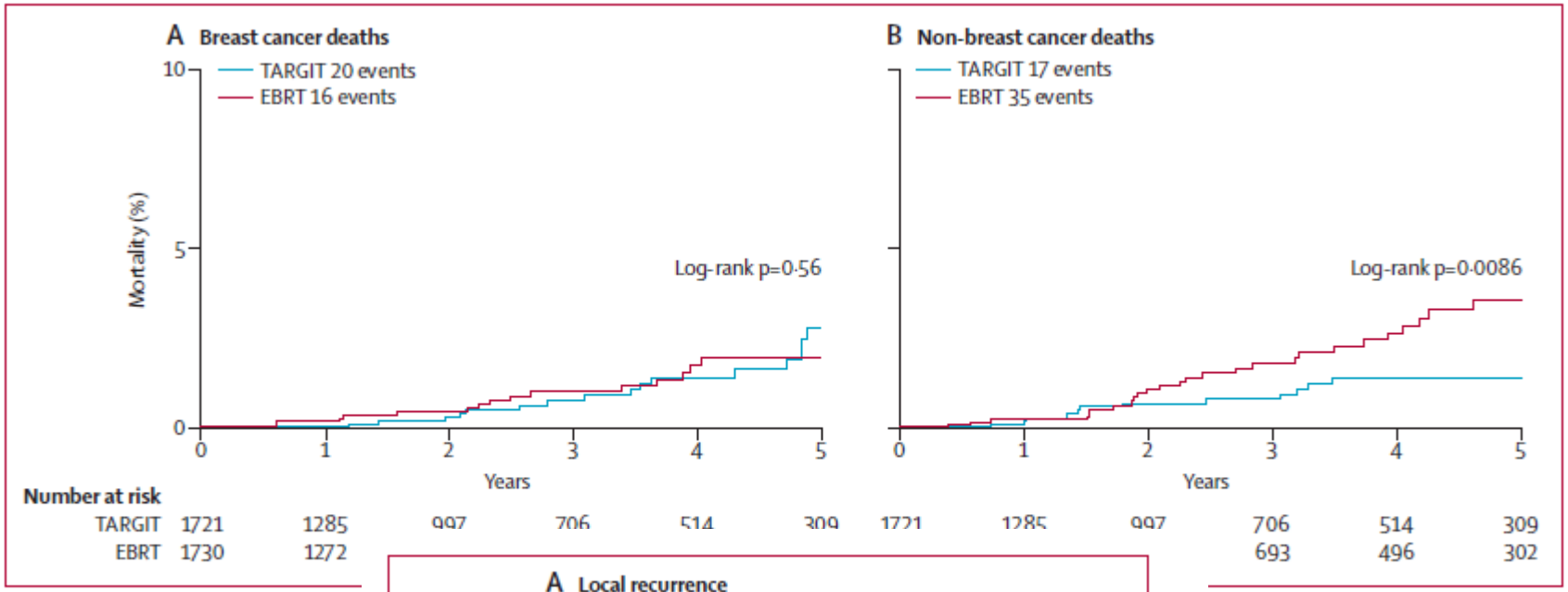
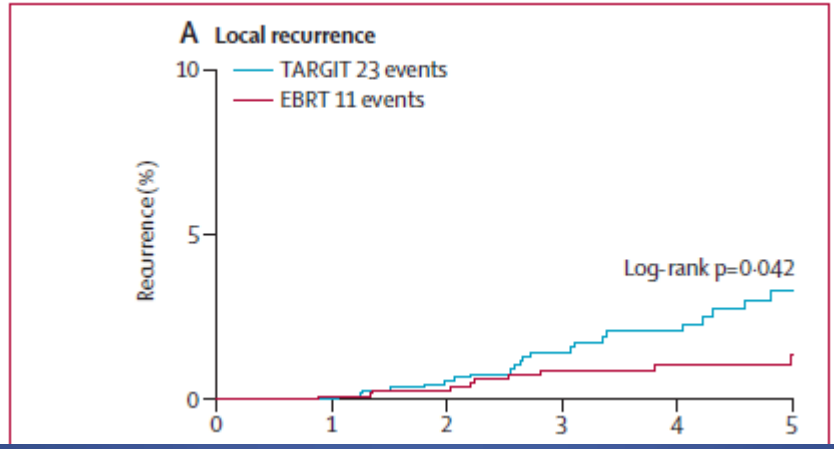


Figure 1: **Kaplan-Meier analysis of br**
(A) Breast cancer. (B) Non-breast-canc



The Targit-A trial prescription depth was….

55% a. The surface of the applicator

15% b. 0.5 cm from the surface of the applicator

23% c. 1 cm from the surface of the applicator

4% d. The distance to the skin

4% e. 2 mm within the skin surface

Answer: A

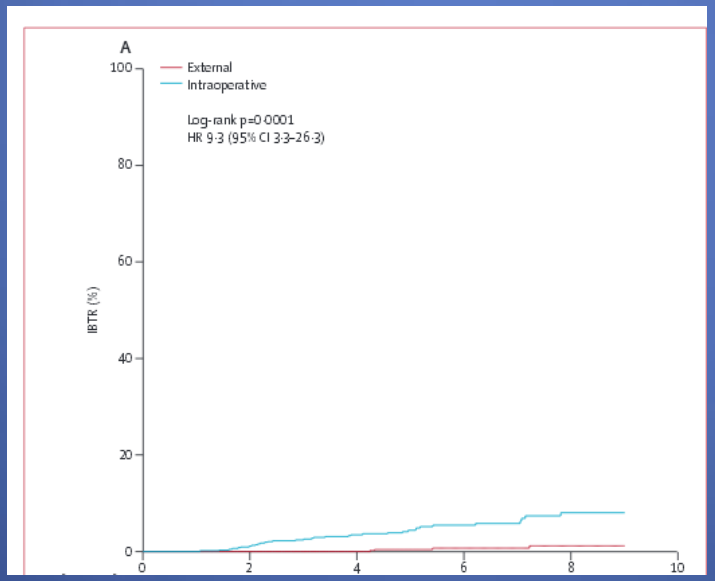
Risk-adapted targeted intraoperative radiotherapy versus whole-breast radiotherapy for breast cancer: 5-year results for local control and overall survival from the TARGIT-A randomised trial

***Lancet* 2014; 383: 603–13**

Eliot Trial

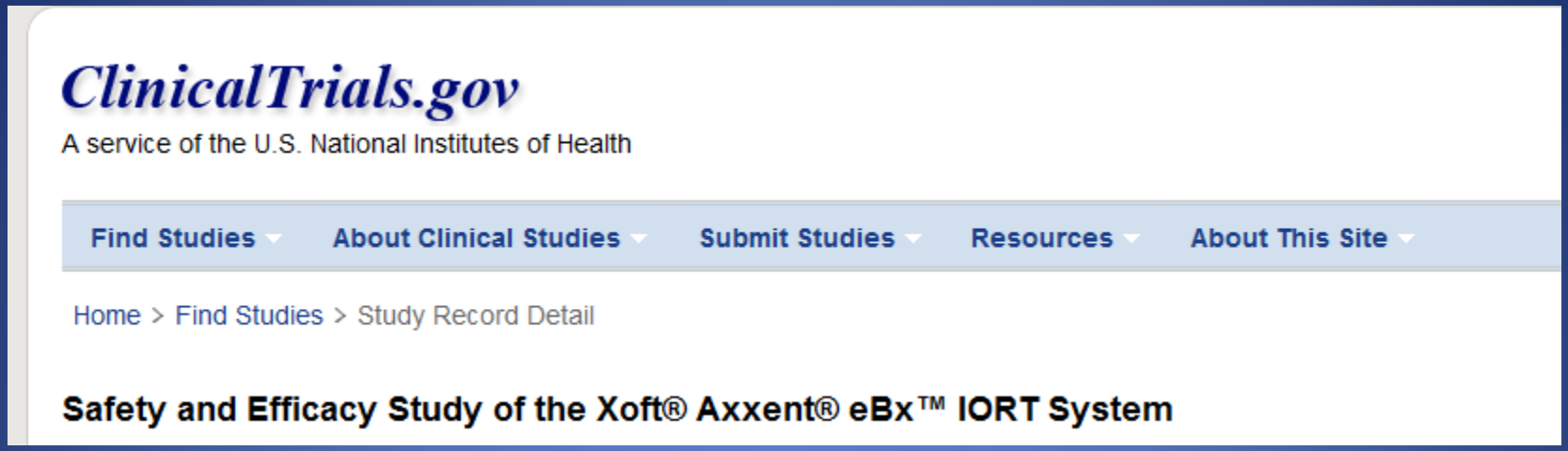
Intraoperative radiotherapy versus external radiotherapy for early breast cancer (ELIOT): a randomised controlled equivalence trial (*Lancet Oncol. 2013)*

21 Gy to the tumor bed using 6-9 MeV electrons



recurrences

Xoft Trial



ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site

Home > Find Studies > Study Record Detail

Safety and Efficacy Study of the Xoft® Axxent® eBx™ IORT System

iCAD Announces More Than 500 Patients Treated In Study of Intraoperative RadiationTherapy (IORT) For Early-stage Breast Cancer


BETTER
GOOD

IORT at UVa

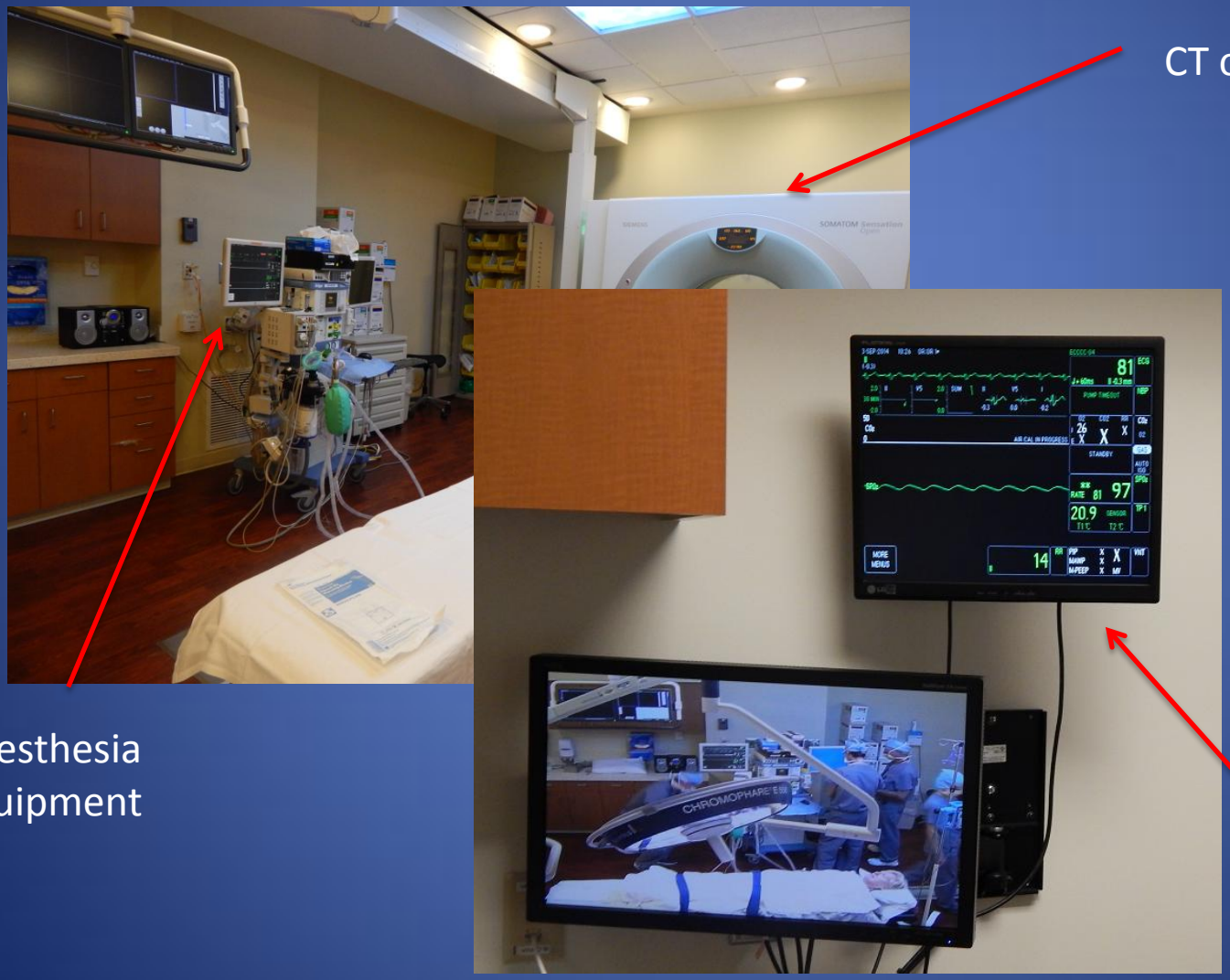
“Dosimetric comparison of 192Ir high-dose-rate brachytherapy vs. 50 kV x-rays as techniques for breast intraoperative radiation therapy: Conceptual development of image-guided intraoperative brachytherapy using a multilumen balloon applicator and in-room CT imaging”

Brachytherapy 13 (2014) 502-507

How is UVa different

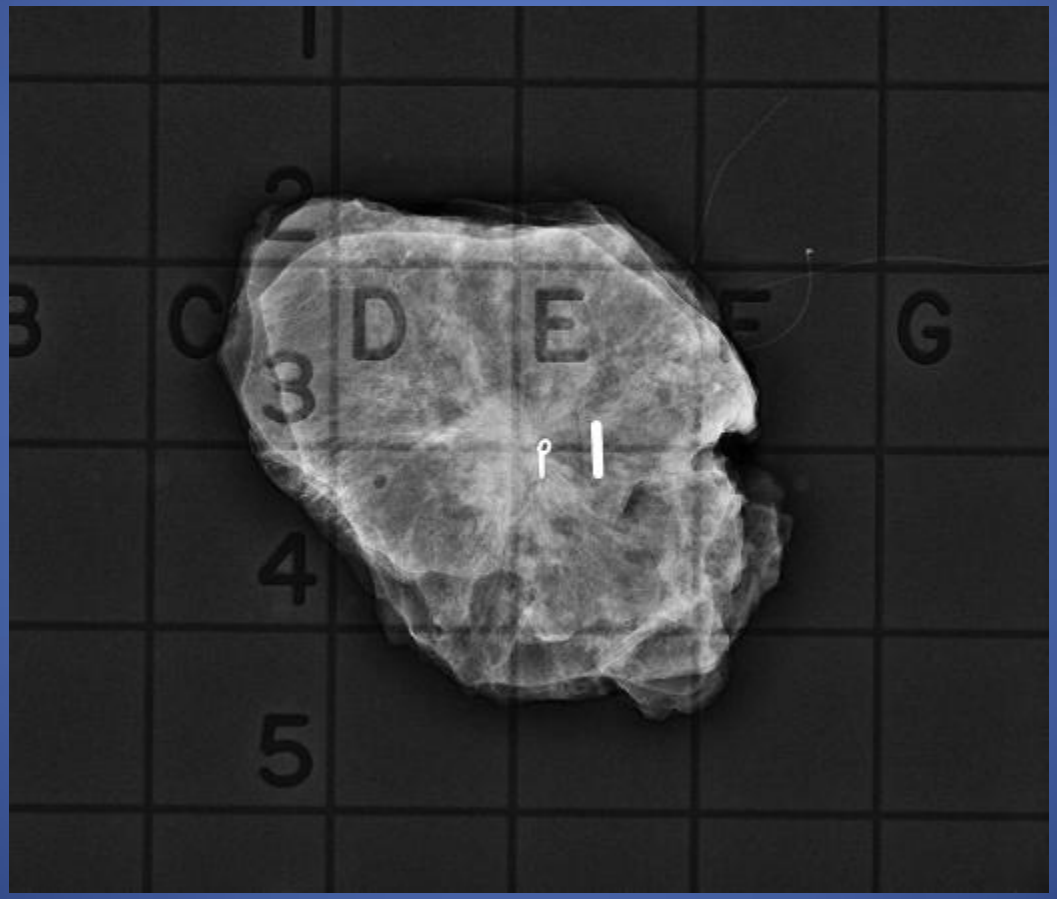
- Lumpectomy/re-excision performed in brachy suite
- Imaging of sample prior to applicator placement
- Patient is imaged with CT scan (can check placement)
- Multicatheter approach (Contura balloon)
- Volume optimization of dose
- Ir-192 vs 50 kV source

Brachytherapy suite at UVa



Hologic Trident Specimen Radiography System

Typical Image from Trident system



Why Ir-192 instead of 50 kV source

- 50 kV dose at surface is 20 Gy
- Dose at 1 cm 5-7 Gy

Is that dose at 1 cm high enough?

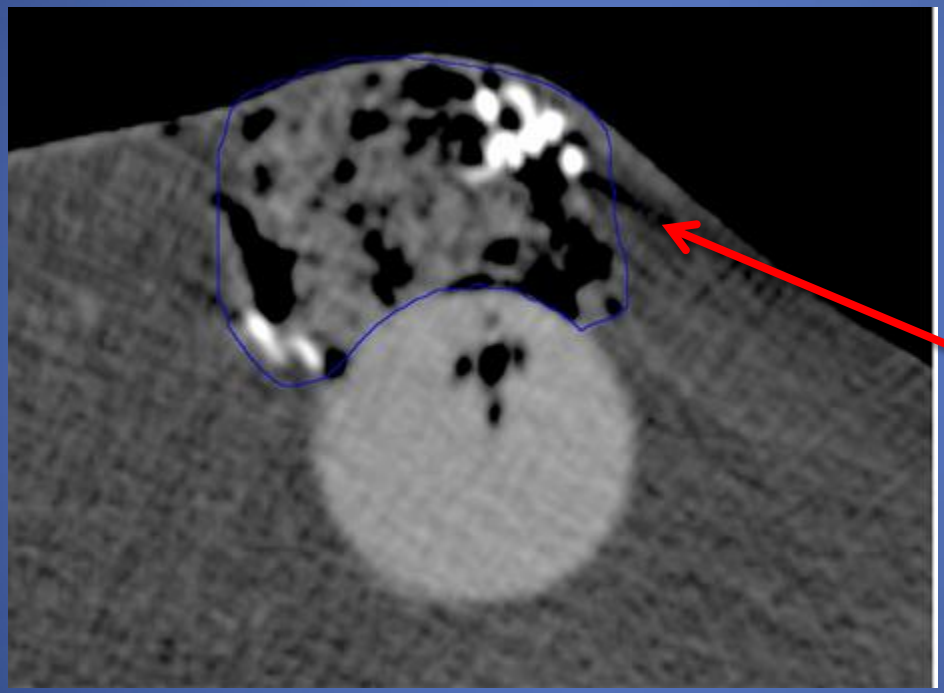
- Ir-192 dose at 1 cm (PTV_eval) is 12.5 Gy
- Dose at surface of balloon is still ~20 Gy

"A Pilot, Single Arm Study of the Safety and Feasibility of Single Fraction IORT with CT-on-Rails Guided HDR Brachytherapy for the Treatment of Early Stage Breast Cancer"

- Lumpectomy or re-excision performed in brachy suite
- Contura balloon placed (scan-plan-treat workflow)
- Balloon removed, final closure of wound
- 12.5 Gy to PTV_eval (1cm from surface of applicator)
- Protocol Goal: initial CT scan to completion of brachy in 90 minutes

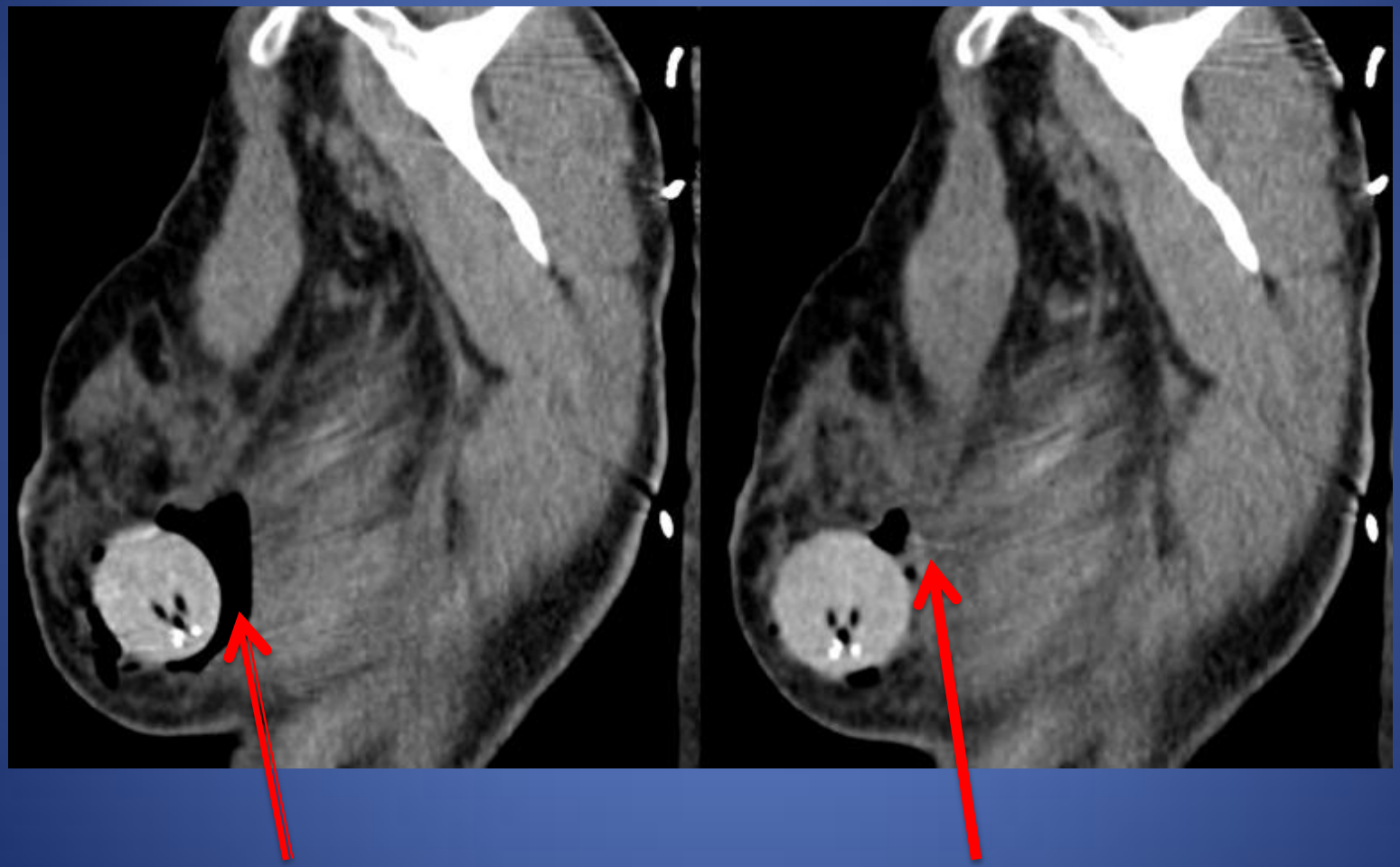
What to do if placement could be suboptimal?

What if the balloon to skin distance will be < 5 mm?



Wet gauze between balloon and skin

Correction of Balloon Placement



Air between balloon and tissue

Air removed

Results of trial

- Dosimetric parameters recorded- PTV_eval, ptv_1mm, max skin, mean heart, max rib,

Dosimetric Quality Parameters

Structure	ID	Value
PTVeval	D99	D99.00 [% of dose]: 84.84
PTVeval	D95	D95.00 [% of dose]: 91.93
PTVeval	D90	D90.00 [% of dose]: 96.54
PTVeval	D10	D10.00 [% of dose]: 180.97
PTVeval	V100	V100.00 [% of volume]: 85.55
PTVeval	V150	V150.00 [% of volume]: 30.05
PTVeval	V200	V200.00 [% of volume]: 3.46
PTV1mm	D99	D99.00 [% of dose]: 142.67
PTV1mm	D95	D95.00 [% of dose]: 150.96
PTV1mm	D50	D50.00 [% of dose]: 182.38
PTV1mm	D10	D10.00 [% of dose]: 213.88

The UVa IORT trial prescription depth is…?

18% a. The surface of the applicator

11% b. 0.5 cm from the surface of the applicator

61% c. 1 cm from the surface of the applicator

3% d. The distance to the skin

7% e. 2mm within the skin surface

Answer: c

"Dosimetric comparison of 192Ir high-dose-rate brachytherapy vs. 50 kV x-rays as techniques for breast intraoperative radiation therapy: Conceptual development of image-guided intraoperative brachytherapy using a multilumen balloon applicator and in-room CT imaging"

Brachytherapy 13 (2014) 502-507

Phase I complete, phase II recently initiated

- “A prospective single arm Phase II study to investigate the efficacy of single fraction IORT with CT on rails guided HDR brachytherapy for the treatment of early stage breast cancer”
- ~240 patients to be studied

Conclusions

There have been weaknesses in previous IORT studies, such as the lack of pathology, imaging, or a true treatment plan, along with low dose away from the applicator, that may have led to poor long term results

The UVa study using Ir-192, Contura applicators, an optimized treatment plan, and higher dose to the PTV_eval may lead to better long term results

To date we have shown it is possible to perform this treatment within an acceptable time scale and patient satisfaction has been high

(Part of)The IORT team at UVa

Radiation Oncology: Tim Showalter, MD, Kelli Reardon, MD, Bruce Libby, PhD
Grace Moyer, CMD
Breast Surgery: Shayna Showalter, MD, David Brenin, MD, Anneke Schroen, MD
OR: Bonnie LaPierre, RN
Anesthesiology: Carl Lynch, MD, PhD