

#1905: ICE3 trial – Radiation following cryoablation for low-risk breast tumors: assessment of safety and variables that effect referral



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INTRODUCTION

There is a movement towards treatment de-escalation in breast cancer patients (particularly in older women with small, hormone sensitive cancers)

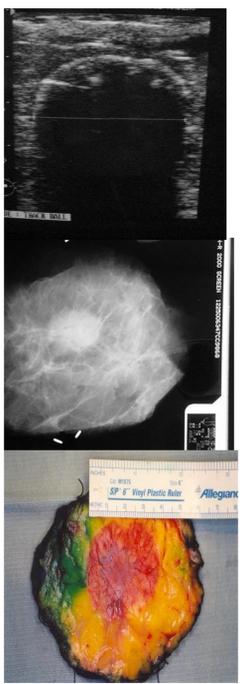
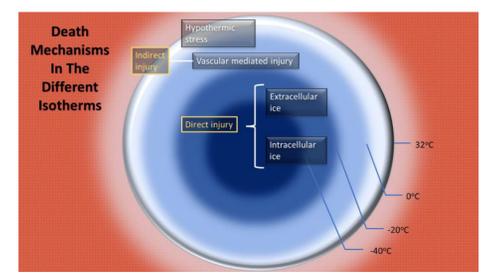
Choosing wisely suggests limiting SLN biopsy in such patients

Percutaneous Cryoablation can replace lumpectomy in select patients

Cryoablation kills cancer cells by 4 mechanisms

Radiation might not be necessary in this population ¹

The safety of radiation in patients who have undergone cryoablation was unknown.



OBJECTIVES

The ICE3 Trial is a study aimed to evaluate safety and efficacy of cryoablation in low-risk early-stage breast cancer in women ≥ 60 years.

We aimed to examine treatment decisions regarding radiation referral of physicians in the ICE3 trial and evaluate safety of the combined modalities in this population.

METHODS

The ICE3 study is a multi-center, single arm, non-randomized controlled clinical trial of cryoablation without excision of small, hormone sensitive breast cancers in women over 60

194 patients were enrolled since 2014 and met inclusion criteria of which 27 (13.9%) had adjuvant radiotherapy.

We evaluated Data regarding factors that may affect recommendation for adjuvant radiotherapy

- Age
- Ethnicity
- Tumor characteristics
- Treatment center details

We evaluated patient factors that might affect adverse events (AEs)

- BMI
- Nicotine D
- Diabetes mellitus
- Adjuvant therapy received.



RESULTS

| Patients | N=194 |
|---|--|
| Mean Age (range) | 75 (61-93) |
| Histology | |
| Infiltrating Ductal | 194 (100%) |
| Nottingham Histologic Grade | |
| Low - I (3-5) | 98 (51%) |
| Intermediate - II (6-7) | 96 (49%) |
| High - III (8-9) | 0 (0%) |
| Receptor Status | |
| ER positive (+) | 194 (100%) |
| PR positive (+) | 184 (92.9%) |
| Her 2 Negative (-) | 194 (100%) |
| Tumor size by ultrasound (Procedure Day) | |
| Mean (range), mm | Sagittal; 8.1 (2.5 -14.9) Transverse; 7.4 (2.8 - 14) |



FACTORS AFFECTING REFERRAL:

Total: Mean age 75.32 years (SD= 7.01)
 Radiated: 70.81 years (n=27, SD=6.48)
 Non-radiated: 76.05 years (n=167, SD=6.83)

Age (P-value=0.0006) and the Center (P-value=0.0009) were the only factors that influenced if the patient received adjuvant radiation.

Other factors including ethnicity, Nottingham score, tumor borders, tumor size, depth and shape did not impact the decision to offer radiation.

ADVERSE EVENTS: NO statistical difference b/w two groups

21 /194 (10.8%) reported mild AEs.

Radiated group: 3/ 27 (11.1%) patients. AEs were classified as mild (injection site pain, bruising, localized edema and breast infection)

Non-radiated group: 36 /167 (10.8%) patients. AEs were classified as non-serious; 31 were mild and 5 were moderate (included pain, bruising, hemorrhage, rash, induration and thermal injury)

We also considered other factors such as age, adjuvant therapy, BMI, nicotine use and whether the patient had diabetes mellitus. No statistically significant factor was observed to effect AE.

CONCLUSIONS

CRYOABLATION FOLLOWED BY RADIATION



Cryoablation in the ICE3 trial was used as a replacement for surgical resection in patients with low-risk breast tumors with 2.06% recurrence rate at 3 years interim results.

Many of these patients were elderly and could avoid radiation.

13.9% of patients received radiation after cryoablation: patient's age and referral practice of the treatment center were contributing factors

AEs were infrequent and minor with no difference between the radiated and nonradiated groups.

Radiation in the setting of cryoablation is safe with minimal short-term side effects.

REFERENCES

1 Lumpectomy plus Tamoxifen with or without irradiation in women over 70 years or older with early breast cancer: long term follow-up of CALGB 9343 Hughes KS, Schnaper LA, Bellon R, Cirincione CT, Berry DA, McCormick B, Muss HB, Smith BL, Hudis CA, Winer EP Wood WC Clin Oncol. 2013 July 1; 31(19): 2382-7.

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