

## BACKGROUND

- Ductal Carcinoma in situ: non-invasive breast cancer confined to the breast ducts and lobules. [Figure 1]
- DCIS comprises 25% of all breast cancers diagnosed in the U.S. (> 60,000 women diagnosed each year).
- DCIS has a recurrence risk of up to 30%.
- Since 2011, individualized 10-year risk of local recurrence (LR) with DCIS can be estimated with a 12-gene assay yielding a DCIS Score (0-100).
- The **DCIS Score** has been validated in the E5194 DCIS trial (lumpectomy alone as treatment) and categorizes LR risk into 3 categories: low, intermediate, and high.

## PURPOSE

- To evaluate the utilization of the DCIS score in a large single-institution population and understand reasons for avoidance in eligible patients

## METHODS

- IRB-approved, single-institution retrospective chart review of 188 consecutive pure DCIS patients treated with lumpectomy from 1/2011-5/2015 .
- Data collected: demographics, clinical-pathologic variables, DCIS score, treatment and outcomes.
- Eligibility criteria for E5194:
  - lumpectomy to negative-margin ( $\geq 3$  mm)
  - tumor size  $\leq 2.5$  cm for low/intermediate or  $\leq 1.0$  cm for high grade tumors
- Eligibility at our institution was modified to include  $\geq 2$ mm negative margin and ER+ tumors.
- Data analyzed using Fisher's exact Chi-square test.
- Primary Endpoint:
  - Assess utilization of the DCIS Score assay in patients meeting eligibility criteria

## RESULTS

- 188 consecutive patients with pure DCIS:
  - 41 (22%) had a DCIS Score (DS+)**
  - 147 (78%) did not (DS-)
  - 6/188 (1DS+, 5 DS-) did not have sufficient data to determine eligibility for E5194 study entry
- 82.5% of DS+ patients and 47.9% of DS- patients met our eligibility criteria.**
- Several characteristics were significantly different between DS+ and DS- patients (Table 1).
- Median follow-up:
  - 6.97 months (range 0-38.4) in DS+
  - 23.8 months (range 0.2-52.5) in DS- ( $p < 0.001$ )
- Distribution of DCIS grade favored low to intermediate in DS+ and intermediate to high in DS-.
- The **majority of DS+ patients** were categorized as **low-risk** for recurrence.
- 81.3% of the DS+ patients that declined radiation had low risk DCIS scores.
- In this cohort, hormonal therapy was recommended for 88.9% of DS+ and 70.4% of DS- ( $p=0.033$ ); partial breast irradiation was recommended for 10% of DS+ and 2.1% of DS- ( $p=0.043$ ).

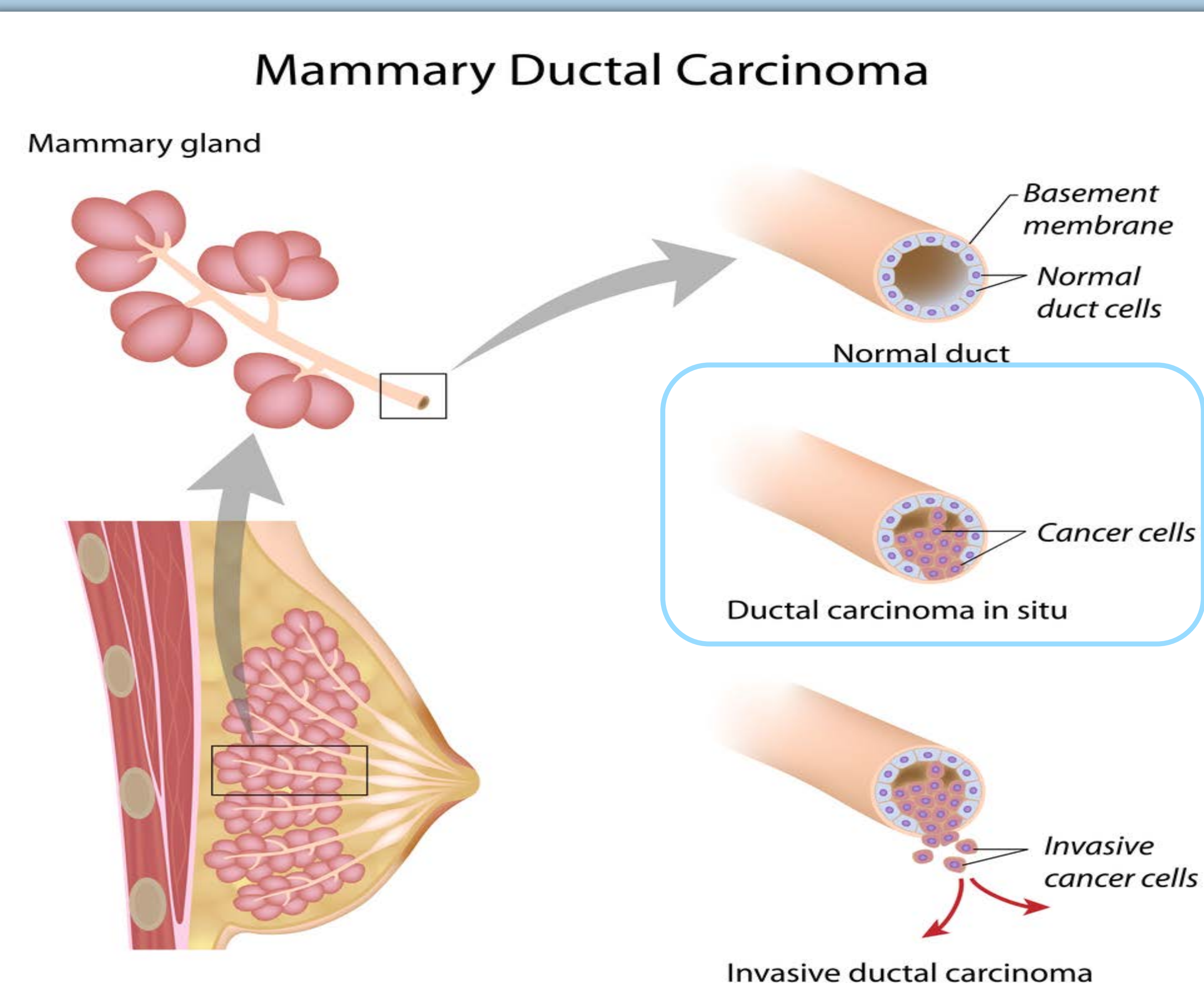
## RESULTS

Table 1: Selected Patient Characteristics

	DCIS Score (n=41)	No DCIS Score (n=147)	P-Value
<b>Met Our Eligibility Criteria, N (%)</b>	33 (82.5%)	68 (47.9%)	
Median Age	60	62	0.252
1 <sup>st</sup> Degree Family History of Breast Cancer	34.1%	29.9%	0.695
Mammographic Size of Tumor Area (Median, Range) cm	0.95 (0.5-4.1)	1.2 (0.2,9.4)	0.182
Presented as Palpable DCIS	4.9%	3.4%	1.000
<b>% Calcifications+</b>	36.6	57.8	<b>0.020</b>
<b>Tumor Size (Median, Range) cm</b>	0.4 (0.1-2.3)	0.8 (0.1-10)	<b>0.010</b>
Presence of Necrosis	48.8%	56.5%	0.476
<b>% ER+</b>	100	83.2	<b>0.006</b>
<b>% PR+</b>	95.1	77.3	<b>0.011</b>
<b>DCIS Grade</b>			<b>0.006</b>
Low	26.8%	10.2%	
Intermediate	46.3%	41.5%	
High	26.8%	48.3%	
<b>DCIS Score Risk Category</b>			
Low	<b>78.4%</b>		
Intermediate	16.2%		
High	5.4%		
<b>Recommended Radiation Declined Radiation Treatment</b>	<b>33 13(40%)</b>	<b>137 19(15%)</b>	<b>&lt;0.005</b>

## CONCLUSIONS

- Tumor size, grade, ER status, and calcifications were drivers of patient selection for 12-gene assay use.
- E5194 eligibility criteria selected for low risk population.
- Although a large proportion of our patients met eligibility criteria, **DCIS Score was infrequently considered** for recurrence risk estimation.
- When performed, assay scores supported omission of radiation for over 75% of cases.



**Fig. 1 Ductal Carcinoma In Situ of the Breast.** The malignant cells are contained by the basement membrane and do not spread into surrounding tissue, unlike invasive disease.