

# Evaluation of the Breast Cancer Index and fear of cancer recurrence in the BCI Registry study

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## INTRODUCTION

- The BCI Registry study is an ongoing trial with over 3400 enrolled patients with HR+ early-stage breast cancer
- Fear of cancer recurrence (FCR) defined as the “fear, worry, or concern relating to the possibility that cancer will come back or progress” can negatively affect the quality of life in women diagnosed with early-stage breast cancer. In some long-term survivors, FCR persists or increases over time
- The Breast Cancer Index (BCI) is a validated genomic assay that provides the risk of late (post 5y) and overall (0-10y) DR and predicts extended endocrine therapy (EET) benefit in patients with HR+ disease
- The objective of this analysis is to assess the impact of BCI on FCR for patients enrolled in the BCI Registry Study

## METHODS

- The BCI Registry study is a prospective, multi-institutional study that enrolled over 3400 patients with HR+ early-stage breast cancer to evaluate the long-term clinical outcome, decision impact, and medication adherence
- Patients completed pre- and post-BCI test questionnaires to assess the following:**
  - Patient preferences for EET
  - Patient concerns about the cost, side effects, drug safety, and benefit of EET
  - Patient comfort levels regarding their treatment recommendations
  - Patient fears about their cancer returning (FCR)
- Patients’ FCR was stratified into four risk groups:**
  - Low fear level Pre-BCI
  - High fear level Pre-BCI
  - Low fear level Post-BCI
  - High fear level Post-BCI
- FCR patient responses were compared using the Wilcoxon signed-rank test (p-value)

Figure 1. BCI Registry Case Flow

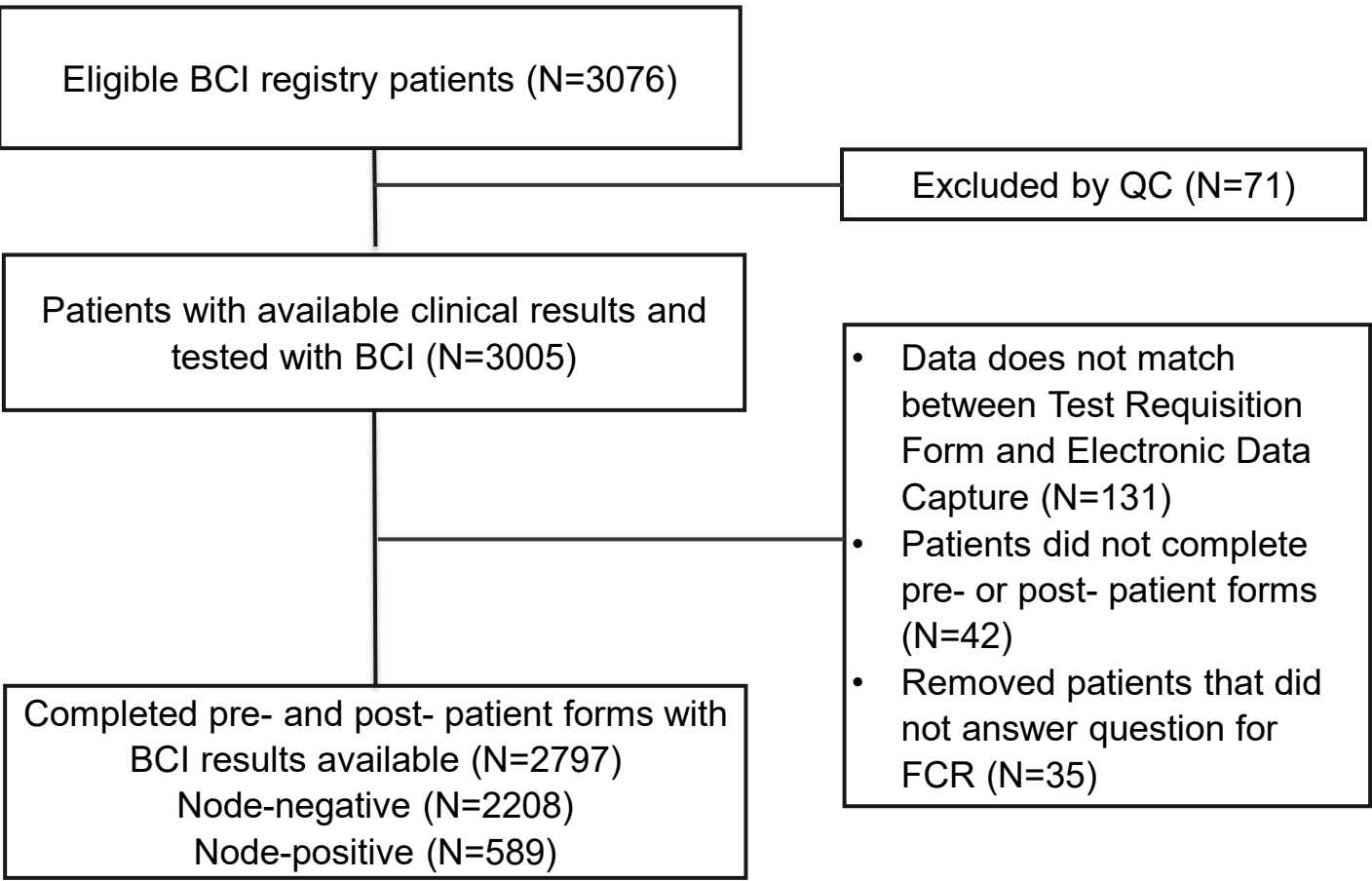


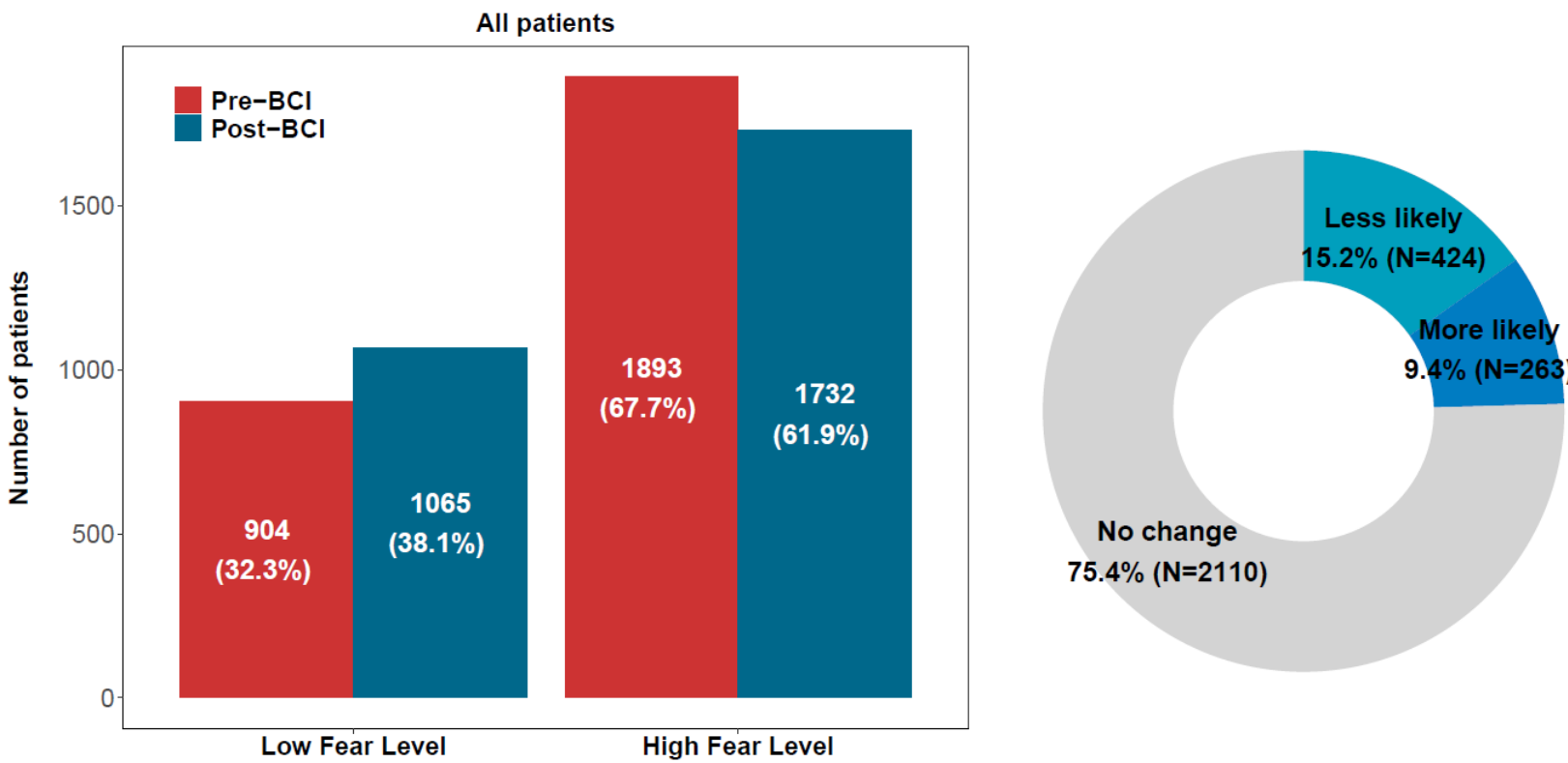
Table 1. Clinicopathologic characteristics of patients in the BCI Registry

	Patient Response (N = 2,797)
<b>Age</b>	
<40	23 (0.8%)
40-49	185 (6.6%)
50-59	613 (21.9%)
60-74	1,437 (51.4%)
>=75	539 (19.3%)
<b>Menopausal status</b>	
Perimenopausal	51 (1.8%)
Postmenopausal	2,484 (88.8%)
Premenopausal	262 (9.4%)
Unknown	0 (0.0%)
<b>T stage</b>	
T1	2,058 (73.6%)
T2	683 (24.4%)
T3	56 (2.0%)
Unknown	0 (0.0%)
<b>Grade</b>	
1	796 (28.5%)
2	1,507 (53.9%)
3	492 (17.6%)
Unknown	2 (0.1%)
<b>Histological type</b>	
Ductal	2,346 (83.9%)
Lobular	362 (12.9%)
Other	89 (3.2%)
Unknown	0 (0.0%)
<b>Nodal status</b>	
N0	2,208 (78.9%)
N1	589 (21.1%)
Unknown	0 (0.0%)
<b>ER status</b>	
Negative	9 (0.3%)
Positive	2,788 (99.7%)
<b>PR status</b>	
Negative	322 (11.5%)
Positive	2,475 (88.5%)
<b>HER2 status</b>	
Negative	2,414 (86.3%)
Positive	360 (12.9%)
Uncertain	23 (0.8%)

- 89% were post-menopausal
- Patient tumors were: 79% N0, 74% T1, 54% grade 2, 86% HER2-

## RESULTS

Figure 2. Pre- and Post-BCI FCR in all patients



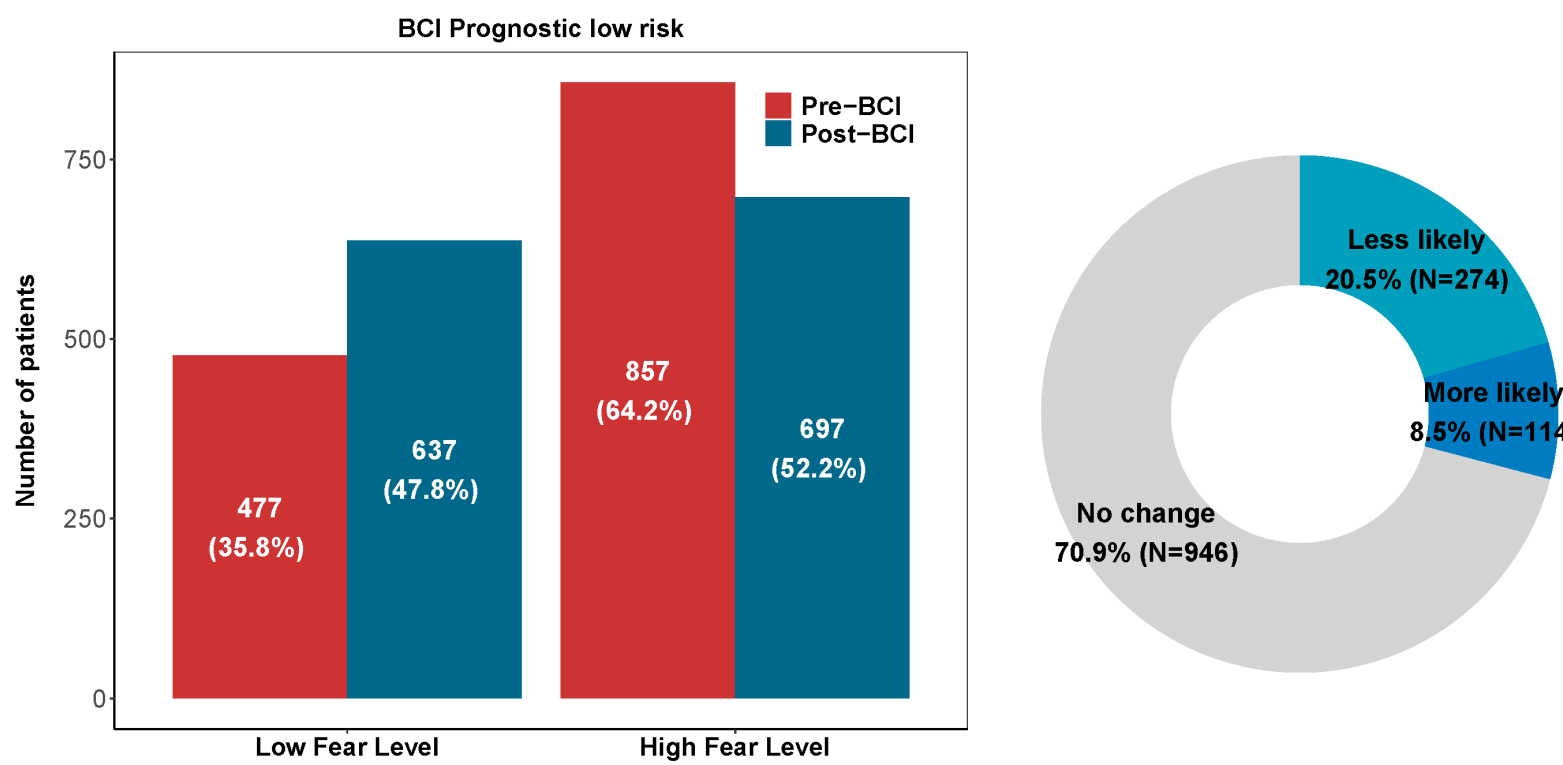
- Low patient fear levels increased from 32.3% (904/2797) before BCI testing to 38.1% (1065/2797) after BCI testing
- High patient fear levels decreased from 67.7% (1893/2797) before BCI testing to 61.9% (1732/2797) after BCI testing
- Following BCI testing, 15.2% (424/2997) of patients were less fearful or less likely to believe their cancer would return (p<0.0001)

Table 2. BCI Prognostic and Predictive results

	All Patients (N=2797)
<b>BCI Prognostic Risk Category (5-10 years)</b>	
High Risk	1463 (52.3%)
Low Risk	1334 (47.7%)
<b>BCI H/I Predictive Category</b>	
Low Likelihood	1755 (62.7%)
High Likelihood	1042 (37.3%)
<b>H/I Prognostic and Predictive Results</b>	
High Risk/High Likelihood	819 (29.3%)
High Risk/Low Likelihood	644 (23.0%)
Low Risk/High Likelihood	223 (8.0%)
Low Risk/Low Likelihood	1111 (39.7%)

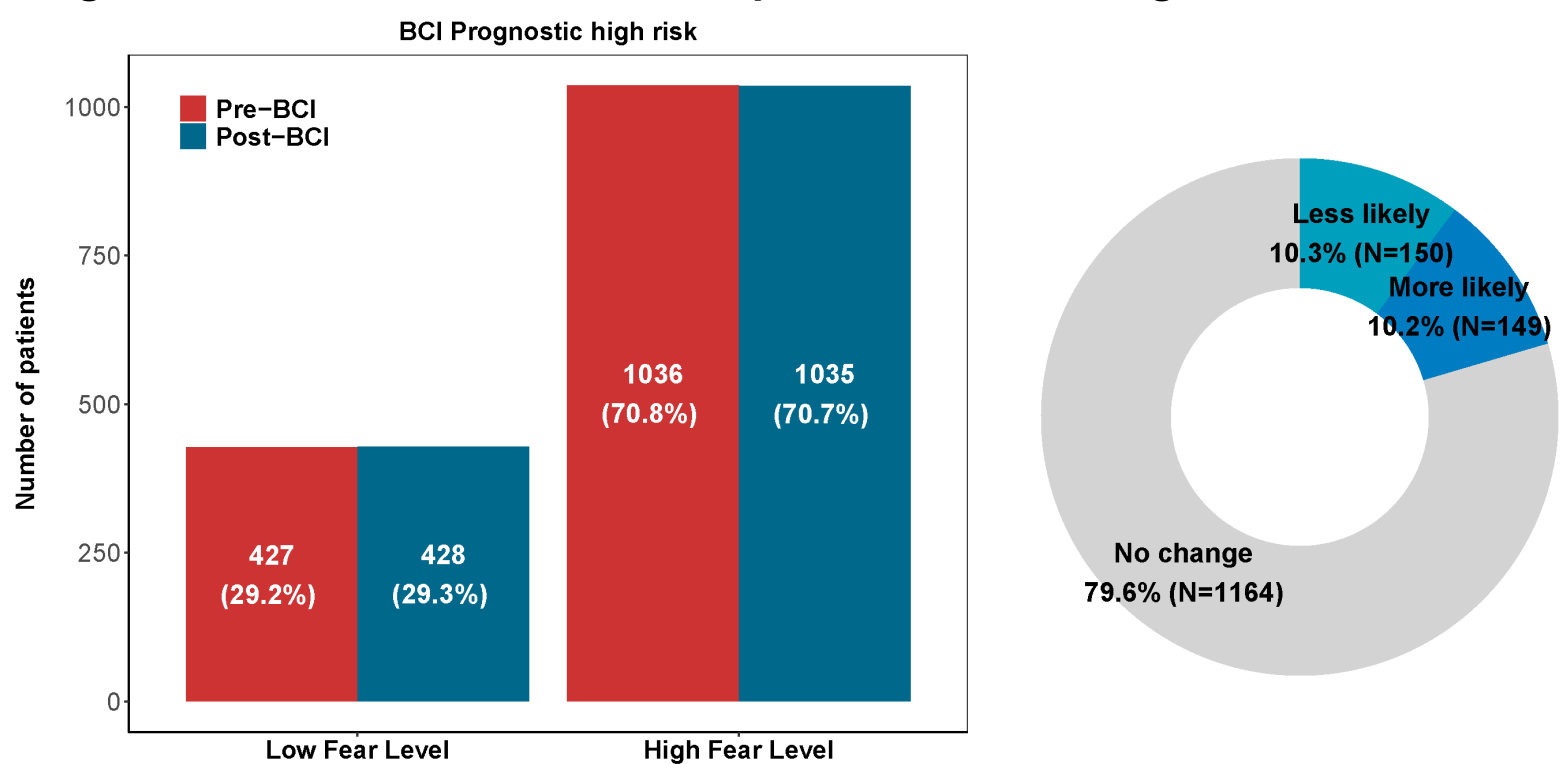
- Combined BCI Prognostic and BCI Predictive results demonstrated a greater number of patients associated with Low Risk/Low Likelihood 39.7% (1111/2797), while 29.3% (819/2797) were associated with High Risk/High Likelihood

Figure 3. Pre- and Post-BCI FCR in patients with BCI low risk



- The percentage of BCI Prognostic low-risk patients having low fear levels increased from 35.8% (477/1334) before BCI testing to 47.8% (637/1334) after BCI testing while high fear levels decreased from 64.2% (857/1334) before BCI testing vs. 52.2% (697/1334) after BCI testing
- Following BCI testing, 20.5% (274/1334) of BCI Prognostic low-risk patients were less fearful or less likely to believe their cancer would recur (p<0.0001)

Figure 4. Pre- and Post-BCI FCR in patients with BCI high risk



- There was no change in high and low fear levels in BCI Prognostic high-risk patients before BCI testing vs. after BCI testing (p=0.9542)

## CONCLUSIONS

- Changes in patient fears of cancer recurrence correlated with BCI test results
- Following BCI testing, BCI Prognostic low-risk patients were less likely to believe their cancer may return
- Compared to baseline levels, patient concerns regarding fear of cancer recurrence are significantly decreased

## REFERENCES AND CONTACT INFORMATION

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