Introduction

- Response Evaluation Criteria in Solid Tumors (RECIST) criteria are used to measure tumor response in breast cancer clinical trials but require disease to be measurable on imaging
- Invasive lobular carcinoma (ILC) of the breast forms diffuse lesions which are more difficult to measure (Figure 1)

Research Questions

- What is the prevalence of the use of RECIST in breast clinical trials?
- Are there differential enrollment rates by tumor histology and stage?

Methods

- Proportion of interventional, stage IV clinical trials that utilize RECIST using clinicaltrials.gov
- Analysis of tumor histology and stage for patients included in the UCSF Clinical Trials Management System (CTMS) vs. UCSF Cancer Registry (2000-2018)

Results

- Of 146 actively-recruiting interventional trials for stage IV breast cancer 71.2% require measurable disease
- Early-stage disease: no difference in proportion of ILC enrolled in clinical trials compared to registry (Figure 2)
- Stage IV disease: significantly lower proportion of ILC enrolled in clinical trials compared to registry (9.2% vs. 17.9%, p=0.005)

Conclusions

- Patients with metastatic ILC were significantly less likely to be enrolled in clinical trials.
- Requirements for measurable disease may contribute to decreased trial enrollment.
- Enrollment criteria should be modified for ILC.

Question:
Are patients with lobular breast cancer (ILC) underrepresented in clinical trials?

Answer:
Patients with metastatic ILC are less likely to be enrolled in clinical trials compared to those with metastatic invasive ductal carcinoma (IDC). Requirements for measurable disease may reduce trial eligibility.

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Figure 1: Histopathologic differences between IDC (left) and ILC (right). ILC has non-cohesive, diffuse growth due to the lack of adhesion protein E-Cadherin

Figure 2: Proportion of Patients with Invasive Lobular Carcinoma in the UCSF Cancer Registry versus the OnCore Clinical Trials Management System (CTMS), Stratified by Stage. *Two sample test of proportion: p = 0.005