

**STATISTICAL ANALYSIS PLAN**  
**A Pilot Study of Hypofractionated Simultaneous Integrated Boost Radiotherapy in Stage 0, I and III Breast Cancer Patients Objective**

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We conducted a prospective study to assess the safety and feasibility of delivering 15 fractions of simultaneous integrated boost (SIB) radiotherapy for definitive breast cancer treatment.

**Data**

The SIB dataset was queried, and after exclusion and inclusion listed in the selection diagram file. Total 75 cases were included.

Selection and Exclusion Criteria	Sample Size	Excluded
SIB radiotherapy for breast cancer cases	75	-

**Outcome and definition**

1. Skin Thickening Ratio (STRA) Baseline
2. Skin Thickening Ratio (STRA) at 1 year
3. Change in Skin Thickening Ratio (STRA) from Baseline to 1 year
4. Overall Survival was defined as months from the date of radiation ended to death or last seen at Emory.
5. Local Recurrence-free Survival (LRFS) was defined as months from the date of radiation ended to local recurrence or last seen at Emory.
6. Distant Recurrence-free Survival (DRFS) was defined as months from the date of radiation ended to distant recurrence or last seen at Emory.

**Study Cohort and Definition**

1. Concurrent vs. Neoadjuvant
  - a. Concurrent: ADT <= 30 days leading up or within 2 weeks after the RT start date.
  - b. Neoadjuvant: ADT >30 day leading up RT start date.
2. Toxicity Grade Scale  
Grade 1: Mild or pain does not interfere with activity

Grade 2: Moderate or repeated use of nonnarcotic pain reliever > 24 hours or interferes with activity

Grade 3: Severe or any use of narcotic pain reliever or prevents daily activity

### **Statistical Analysis**

Statistical analysis was conducted using SAS Version 9.4, and SAS macros developed by Biostatistics and Bioinformatics Shared Resource at Winship Cancer Institute<sup>1</sup>. Descriptive statistics for each variable were reported. Association between variables of interest and the study cohort were examined using ANOVA for categorical variables and Pearson correlation coefficient for continuous variables. Multi-linear regression between variables of interest and the study outcomes was examined. Variables were selected based on statistical significance on univariate analysis, while accounting for multicollinearity and removing variables with high rates of missing data.