Neoadjuvant chemotherapy is widely used to downstage breast cancers prior to surgery. All patients were treated with anthracycline and/or taxane-based neoadjuvant chemotherapy. Pathological complete response (pCR) was defined as the complete disappearance of the primary tumour and axillary lymph nodes.

Methods

Pathological and clinical assessment

Clinical assessment of the primary tumour and lymph nodes was made using bi-dimensional caliper measurements of the primary tumour and axillary nodes. Sonographical assessments of the primary tumour and lymph nodes were performed regularly. Immunohistochemical staining was performed for ER, PR, HER-2 and Ki67. Fluorescence in situ hybridization (FISH) was used to confirm HER2 positivity.

We analyzed data retrospectively/prospectively on 103 breast cancer patients undergoing neoadjuvant chemotherapy.

Pathological complete response (pCR) was defined as the complete disappearance of the invasive cancer in the breast and absence of tumour in the axillary lymph nodes. Ethics approval was obtained from Pharma-Biotia, Pretoria, South Africa (ethics committee working according to the South African Ethics regulations).

NCSS software version 11 for Windows (USA) was used for statistical analyses.

Univariate Analysis

Receiver-operating characteristic (ROC) curve analysis was used to determine the optimal cut-off point for Ki67, CD8+ cytotoxic T cells, CD3+ T cells and Immunoscore.

A prespecified bioinformatics algorithm was used to generate a numerical index (Immunoscore) and analytic cut-offs. Immunoscore assay assesses the density of CD8+ cytotoxic T cells and CD3+ T cells of resected or biopsied cancer samples and performed on FFPE tissue slides.

Immunoscore was applied to tumours with invasive margin and was adapted when no invasion was identified on the specimens.

Introduction

Background

Neoadjuvant chemotherapy is widely used to downstage breast cancers prior to surgery.

Pathological complete response (pCR) rate is a strong predictor of outcomes for breast cancer patients.

Immunoscore

The Immunoscore assay is the first standardized immune-based assay for classification of breast cancer (Fleuret et al., 2016). It assesses the tumour immune response by measuring inter- and peritumoral T cell infiltration in formalin-fixed paraffin-embedded (FFPE) tissue sections.

Originally developed for colon cancer indications, it is intended to be widely used in solid cancer indications for diagnostic and prognostic purposes, as well as a pharmacodynamic biomarker during drug development processes. As a first clinical observation in breast cancer, we assessed the Immunoscore in a cohort of 103 breast cancer patients, that previously received neoadjuvant chemotherapy.

Results

Table 1. Patient Characteristics.

Table 2. Univariate Analysis - Significant factors associated with pCR.

Table 3. Median cell density in patients with pCR vs non-pCR patients.

Table 4. Logistic regression analysis.

Conclusions

- ER+/HER2+ biomarker and Tumour Immunoscore and tumour size are independent prognostic factors of pCR in patients with early breast cancer undergoing neoadjuvant chemotherapy.