42 (69%) patients, respectively. In 16 patients (26%), the receptor status was unknown. Adjuvant chemotherapy or hormonotherapy was administered in 8 (13%) and 7 (12%) patients, respectively. Postoperative RT with a median total dose of 50 Gy (1.8-2.0 Gy/fraction; range, 44-70 Gy) was given in 40 patients.

Results: With a median follow-up of 79 months (range, 6-285 months), 5-year overall and disease-free survival (DFS) rates were 94% (95% confidence interval [CI]: 88-100%) and 82% (95% CI: 71-93%), respectively. Five-year locoregional control rate was 95% (95% CI: 89-100%). There were only 4 patients with local relapse who were all salvaged successfully, and 4 other patients developed distant metastases. According to the Common Terminology Criteria for Adverse Events v3.0, late toxicity consisted of grade 2-3 cutaneous fibrosis in 4 (10%) patients, grade 1-2 edema in 2 (5%), and grade 3 lung fibrosis in 2 (5%). In univariate analyses, the outcome was influenced neither by the type of surgery nor the use of postoperative RT. However, positive receptor status had a negative influence on the outcome. Multivariate analysis (Cox model) revealed that negative ER ($p = 0.006$) or PR ($p = 0.04$) status was associated with improved DFS.

Conclusions: ACC of the breast is a relatively indolent disease with excellent local control and survival. The prognosis of patients with ACC is much better than that for patients with other breast cancers, especially those who are ER and PR negative. The role of postoperative RT is not clear. More aggressive treatments may be warranted for patients with positive receptor status.

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2010 Comparison of Provider Assessed and Patient Reported Outcome Measures of Acute Skin Toxicity during a Phase III Trial of Mometasone Cream versus Placebo during Breast RT from the North Central Cancer Treatment Group (N06C4)

R. C. Miller[1], D. J. Schwartz[2], J. A. Sloan[1], P. C. Griffin[3], R. L. Deming[4], J. C. Anders[5], P. J. Atherton[1], C. L. Loprinzi[1], K. N. Burger[1], J. A. Martenson[1]

[1]Mayo Clinic College of Medicine, Rochester, MN, [2]Minneapolis Radiation Oncology, P.A., Minneapolis, MN, [3]Upstate Carolina CCOP, Spartanburg, SC, [4]Iowa Oncology Research Association CCOP, Des Moines, IA, [5]Wichita Community Clinical Oncology Program, Wichita, KS

Purpose/Objective(s): The NCCTG conducted a two-arm, double blind randomized trial to evaluate the effect of 0.1% mometasone furoate cream (MFC) on skin-related toxicity in patients receiving breast RT. Analysis of the provider assessed (PA) primary endpoint did not reveal a difference in the mean maximum grade of radiation dermatitis (MFC 1.2 vs. Placebo 1.3, $p = 0.18$). However, two patient reported outcome (PRO) measures, the Skindex-16 (less itching (p=0.008), irritation ($p = 0.01$), persistence/recurrence ($p = 0.02$), & annoyance ($p = 0.04$)) and the Skin Toxicity Assessment Tool (STAT) (less burning ($p = 0.02$) and itching ($p = 0.002$)), showed reductions in skin toxicity symptoms in patients receiving MFC. PA toxicity monitoring using the CTCAE showed lower toxicity in the MFC arm ($p = 0.04$), primarily due to reduced pruritus ($p = 0.005$). A comparison of the CTCAE, the Skindex-16, and STAT instruments was performed to assess the relationship between PA toxicity and PROs.

Materials/Methods: 176 patients with DCIS/invasive breast cancer receiving RT to the breast or chest wall were randomized from 09/07 to 12/07 to apply MFC or placebo cream once daily during RT. Toxicity was assessed at baseline and weekly during RT. Skindex-16 responses were averaged as per the scoring algorithm, resulting in a total score and three subscale scores (Function, Symptom and Emotion). Pearson correlation coefficients (PCC) were used to compare toxicity reported between CTCAE skin toxicity, Skindex-16 scores, and STAT symptom questions.

Results: Skindex-16 and STAT PRO comparison with PA CTCAEs revealed little correlation between symptoms with the exception of CTCAE pruritus in relation to the Symptom subscale (PCC 0.54), CTCAE pruritus in relation to STAT itching (PCC 0.74), and CTCAE radiation dermatitis in relation to STAT erythema (PCC 0.64). In contrast, comparison of the PRO measures with one another revealed a relationship between the total Skindex-16 score in relation to STAT burning (PCC 0.64), itching (PCC 0.57), and tenderness (PCC 0.57) and the Symptom subscale in relation to STAT burning (PCC 0.69), itching (PCC 0.66), and tenderness (PCC 0.60). Symptom subscale questions of burning, hurting, and irritation had at least a moderate correlation with STAT reported burning, itching, and tenderness (range 0.52-0.71). Skindex-16 itching had a high correlation with STAT itching (PCC 0.70).

Conclusions: PRO measures provided a comprehensive assessment of patient perceived skin toxicity. The Skindex correlated with STAT questions, but both had little correlation with the CTCAE. Inclusion of PRO measures should be strongly considered in the design of clinical trials assessing RT skin toxicity.

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2011 Comparison of Acute Skin Reaction between Short Course and Conventional Fractionation Radiotherapy in Breast Conserving Therapy with Skin Dose Measurement

K. Karasawa, S. Ozawa, S. Yamaguchi, K. Ito, A. I. Saito, H. Izawa, H. Hirowatari, T. Furuya, C. Kurokawa et al.

Juntendo University, Tokyo, Japan

Purpose/Objective(s): We have conducted a clinical trial to evaluate the short course whole breast irradiation to be equally effective and safe with conventional fractionation. In this study, we compared acute skin reactions in both arms with film dosimetry.

Materials/Methods: The patients with stage 0 to II of breast cancer, after lumpectomy or quadrantectomy with sentinel lymph node biopsy or axillary node dissection, positive lymph nodes less than 3, and no concurrent chemotherapy were eligible for this study. Prior to the treatment, all patients were explained about the two treatment schedules and decided by the patient's free selection. The short course irradiation (SCI) consisted of 43.2Gy/16f to the whole breast with additional tumor bed boost of 8.1Gy/3f for positive or less than 5mm surgical margins. The conventional course irradiation (CCI) consisted of 50Gy/25f to the whole breast with additional tumor bed boost of 10Gy/5f for positive or less than 5mm surgical margins or 6Gy/3f in negative surgical margins which has been our standard of care. All breasts were irradiated with 4 MV photon, tangential fields using electronic tissue compensation. The acute adverse effects were observed weekly during treatment and 1 and 2 week after the