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Hyaluronic acid versus simple emollient for the management of radio-induced skin toxicity: results of an open-label, phase III trial

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Background: To avoid the late skin complications efficious treatment of the early radio-induced epithelitis is needed. The treatment of radio-induced early skin reactions is usually disappointing. Hyaluronic acid is one of the most recent topical products used in this indication, and providing interesting preliminary results.

Materials and Methods: Breast cancer patients with grade 1−2 radio-induced epithelitis during postoperative radiotherapy were eligible. They were randomised to receive either hyaluronic acid (A) or simple emollient (B). The primary endpoint was the clinical evaluation of the erythema (success *versus* failure). Secondary endpoints were the evaluation of skin colorimetry, pain, and quality of life.

Results: Two-hundred patients were enrolled (A = 99, B = 101). Seventy-three patients (36.5%) stopped prematurely the treatment without difference in the reason of treatment interruption. Ninety-five patients per treatment arm were evaluable. There were 23 failures (24.2%) in the hyaluronic acid arm, and 32 (33.7%) in the simple emollient arm (p = 0.15). Among risk factors of delay in healing, body mass index and size of epithelitis were independently associated with failure to local treatment. The relative reduction of colorimetric levels was 20.4% in hyaluronic acid group, and 13% in simple emollient group (p = 0.46). According to the quality of life assessment, there was a trend in a lower level of pain in patients receiving hyaluronic acid (p = 0.053).

Conclusion: The present study showed no significant difference between hyaluronic acid and simple emollient in the treatment of acute radio-induced epithelitis, even if there was a trend to an improvement in pain and skin colorimetry.

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A novel skin assessment tool for inflammatory breast cancer (IBC)

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Background: IBC is an aggressive carcinoma representing 1 to 6% of all invasive breast cancer. IBC has distinct clinical, pathological, and molecular features from other types of BC. IBC is characterized by a rapid onset of diffuse skin erythema and edema resulting in a pitted appearance (peau d'orange), tenderness, induration, and warmth of the involved breast. IBC is designated as non-measurable according to RECIST and there exists no standardized skin assessment tool. For this reason, the IBC Skin Assessment Tool (IBSAT) was created. The IBSAT incorporates the following disease manifestations: the presence and extent of plaques and nodules, grade of erythema, induration/Peau d'orange, and ulceration. Response criteria are based upon changes in size and/or grade of the disease manifestations.

Methods: The IBSAT was retrospectively applied to EGF103009, a phase II study of lapatinib in 153 pts with relapsed or refractory IBC [Kaufman 2009]. Three investigators independently assessed digital photos of 17 pts for all recorded timepoints (range: 2−12 months) and assigned a response of complete (CR), partial (PR), stable (SD), progressive (PD), or unknown. Unknown assessments were imputed as appropriate based on the assessments at previous and subsequent timepoints. In addition, timepoints following a PD assessment were treated as PD. PD concordance was calculated as the % of assessments in agreement with respect to PD and non-PD, both by pt and by time point. Pairwise PD concordance was calculated among the 3 investigators and between each of the 3 investigators vs. the independent review that was done as part of the EGF103009 study. Response concordance was calculated as the % of assessments in agreement with respect to response (CR/PR) and non-response by pt.

Results: PD concordance between pairs of investigators was good both by pt (71%, 71%, 88%) and by timepoint (86%, 79%, 90%). Similarly, PD concordance between each investigator and the independent reviewer was high by pt (94%, 88%, 63%) and by timepoint (85%, 77%, 77%). Response concordance was 94%, 94%, and 88% between pairs of investigators and 88%, 88%, and 81% between each investigator and the independent reviewer.

Conclusion: The IBSAT provides a reproducible means to assess cutaneous disease in IBC. This skin assessment tool is being prospectively applied in an ongoing phase III study in pts with recurrent Her2+ IBC.

References

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The clinical significance of the estrogen receptor beta expression for endocrine therapy in patients with estrogen receptor alpha-negative and progesterone receptor-positive breast carcinoma

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Background: Estrogen receptor (ER) is the key therapeutic target in breast cancer. ERβ has recently been identified to be distinct from ERα. In contrast to ERα, the functions of ERβ in breast cancer are still unclear. We sought to determine whether the expression of ERβ can be used as a predictive marker for endocrine therapy for patients with ERα-negative breast cancer.

Materials and Methods: Formalin-fixed, paraffin-embedded tumor specimens from 52 patients with ER-/PR+ invasive breast cancer were immunostained for their ERβ expression. These patients were treated with adjuvant tamoxifen. The results were correlated with various clinicopathological variables and the follow-up data. The expressions of p53 and HER-2/neu were also analyzed and correlated with the ERβ status.

Results: An ERβ expression was observed in 53.8% (28/52) of the breast cancer samples. There was no correlation between the ERβ expression and the other clinicopathologic factors (age, tumor size, histologic type, nodal status, histological grade, stage, therapeutic modality, progesterone receptor (PR) expression, p53 expression and HER-2/neu expression). Recurrence was present in 7.7% (2/26) of the patients whose tumors had an ERβ expression, as compared to the presence of recurrence in 36.4% (8/22) of the patients whose tumors had no ERβ expression ($p < 0.05$). The patients with ERβ negative-tumors revealed lower disease free survival rate than those with ERβ positive-tumors ($p < 0.05$). Of the 52 patients, 10 (19.2%) were p53 positive, and 11 (21.2%) were HER-2/neu positive. No significant correlations were observed between ERβ and p53 or HER-2/neu.

Conclusions: These results suggest that ERβ might be a predictive marker of a response to endocrine therapy in patients with ER-/PR+ invasive breast cancer, although this needs to be confirmed by additional studies.

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Histological assessment of ductal carcinoma in situ size in the absence of specimen slice radiology

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Background: Accurate assessment of size and adequacy of excision of Ductal Carcinoma in Situ (DCIS) can be challenging. We have no ready access to specimen radiology and therefore rely on widely sampling specimens with a pre-operative diagnosis of DCIS. While this may result in an increase in laboratory workload, we believe that this provides an accurate assessment of DCIS size and margins. We therefore performed this review of our DCIS cases to assess correlation of histological with mammographic size, and its relation to the need for re-excision.

Materials and Methods: All cases of DCIS from Breast Screening Program from 2004 to May 2008 were identified. The maximum dimension of DCIS was retrieved from the histology report and compared with the mammographic dimension. The slides were reviewed for cases with greater than 10 mm discrepancy.

Results: 62 cases of DCIS were identified. 28 (45% of the total 62) showed <10 mm difference between histological and mammographic size. 27 (44%) had a histological size >10 mm more than the mammographic size, while seven (11%) had a mammographic size >10 mm more than the histological size. As a first procedure 60 (97%) underwent wide