STRATAXRT FOR THE PREVENTION OF BREAST RADIATION DERMATITIS: A PILOT STUDY

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BACKGROUND AND AIM

- Radiation dermatitis (RD) is a common side effect of breast radiation therapy (RT).
- Silicone-based products have been used for the prevention of RD and show efficacy.
- Previous literature has different findings on the use of StrataXRT for prevention radiation dermatitis (RD) in breast cancer.

- **Aim:** to assess the feasibility and efficacy of StrataXRT.

METHODS

This pilot study consisted of five cohorts:

1. Large breast (supine), local RT
2. Large breast (prone), local RT
3. Any size breasts, locoregional RT
4. Local chest wall RT alone
5. Locoregional chest wall RT

Primary endpoint: RD grade as assessed using the Common Terminology Criteria for Adverse Events (CTCAE).

Secondary endpoints:

- Presence of moist desquamation
- Patient- and clinician-reported skin assessments
- Patient quality of life (QoL)
  - Skindex-16
- Patient satisfaction

RESULTS

- 45 patients receiving RT to the breast or chest wall were enrolled and two withdrew, leaving 43 evaluable.
- The group treated in the prone position had the best results.
- Cohort 4 reported the highest (worst) mean overall QoL score at 28.5, and cohort 2 had the best at 10.3.

Table 1. Patient and treatment characteristics

Description	Total (n=45)
Mean age, years (range)	56 (35, 82)
Smoking history, n (%)	
Never	38 (84.4%)
Previous	5 (11.1%)
Current	2 (4.4%)
Smoking history, n (%)	
I	0 (0.0%)
II	14 (31.1%)
III	7 (15.6%)
IV	15 (33.3%)
V	6 (13.3%)
VI	3 (6.7%)
Histology, n (%)	
Ductal	40 (88.9%)
Lobular	2 (4.4%)
DCIS only	3 (6.7%)
Lympho-vascular invasion, n (%)	
Yes	19 (42.2%)
No	25 (55.6%)
Unknown	1 (2.2%)
Biomarkers, n (%)	
ER positive	43 (95.6%)
PR positive	36 (80.0%)
Her-2 positive	7 (15.6%)
Systemic treatment, n (%)	
Prior Chemotherapy	25 (55.6%)
Hormonal therapy	16 (35.6%)
Trastuzumab	7 (15.6%)
Radiation therapy dose, n (%)	
4005 cGy/15 fractions	43 (95.6%)
5000 cGy/25 fractions	2 (4.4%)
Sequential boost, n (%)	
Received boost	17 (37.8%)
200 cGy per fraction	1 (5.9%)
250 cGy per fraction	16 (94.1%)
Bolus, n (%)	
Received bolus	3 (6.7%)

Figure 1. Skindex-16 Scores at Baseline, 2-week FU, and 3-month FU

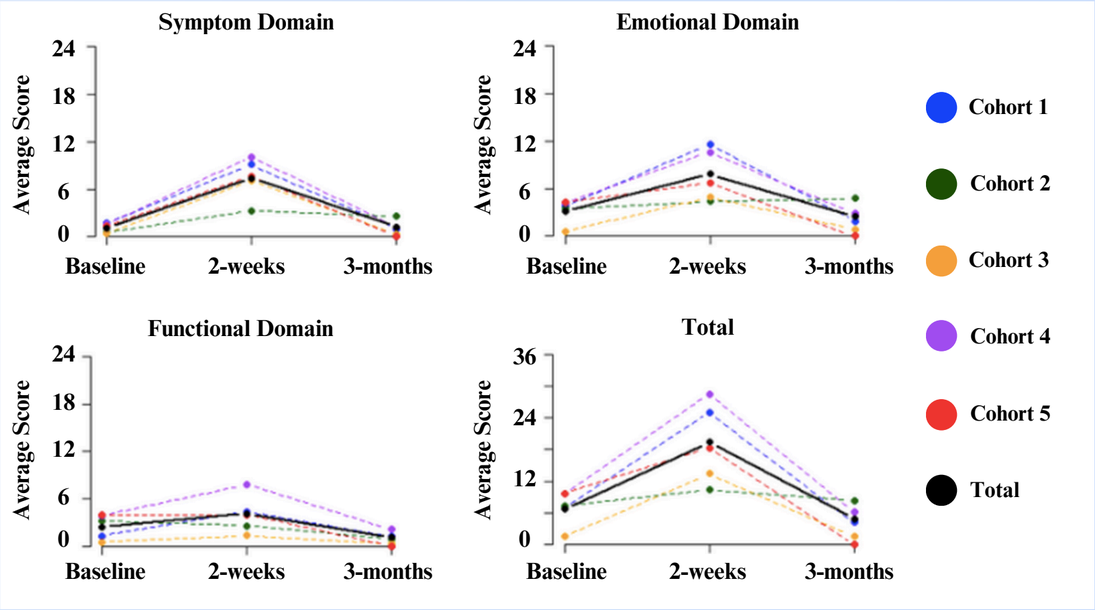

Table 2. Incidence of Radiation Dermatitis (CTCAE) and Moist Desquamation (MD)

Description	Total (n=43)	Cohort 1 (n=10)	Cohort 2 (n=10)	Cohort 3 (n=9)	Cohort 4 (n=11)	Cohort 5 (n=3)	Mepitel Film* (n=251)	Standard Care* (n=125)
CTCAE grade, n (%)								
0	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	28 (11.2%)	2 (1.6%)
1	27 (62.8%)	5 (50.0%)	9 (90.0%)	4 (44.4%)	7 (63.6%)	2 (67.7%)	184 (73.3%)	66 (52.8%)
2	14 (32.6%)	5 (50.0%)	1 (10.0%)	5 (55.6%)	3 (27.3%)	0 (0.0%)	32 (12.8%)	40 (32.0%)
3	2 (4.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	1 (33.3%)	7 (2.8%)	17 (13.6%)
Moist desquamation, n (%)								
Yes	10 (23.3%)	3 (30.0%)	1 (10.0%)	3 (33.3%)	2 (18.2%)	1 (33.3%)	20 (8.0%)	24 (19.2%)
No	33 (76.7%)	7 (70.0%)	9 (90.0%)	6 (67.7%)	9 (81.8%)	2 (67.7%)	231 (92.0%)	101 (80.8%)

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CONCLUSION

- StrataXRT is effective in preventing grade 3 RD in patients.
- Promising results were observed within the prone cohort regarding skin toxicities and patient QoL.
- No patients had allergic reactions to StrataXRT and the gel was well-tolerated by patients, with minimal impacts on QoL.
- Further research:
  - RCTs to evaluate StrataXRT
  - Cost-effective analysis

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