Assessment of STRATAXRT and Aqueous Cream's Impact on Skin Toxicity in Head and Neck Radiotherapy Using CTCAE: A Comparative and Inter-rater Agreement Study

Authors: Wen Xin ER, Siew Peng HENG, Yee Shing SIAU, Janupreya MALLIAH

Affiliation: Sunway Medical Centre, Bandar Sunway, Malaysia

INTRODUCTION

Radiation-induced dermatitis(RD) is a prevalent side effect in head and neck radiotherapy that can affect quality of life of patients. It can range from mild erythema and dry desquamation to more severe conditions such as moist desquamation, skin necrosis or ulceration [1]. Topical agents such as STRATA XRT and aqueous cream (with or without steroids) are commonly used to reduce the severity of RD though their relative efficacy remains under investigation.

This study aimed to evaluate skin reaction severity using the Common Terminology Criteria for Adverse Events (CTCAE) over the course of radiotherapy, and to assess consistency between nursing assessments and regrading performed by a single oncology medical officer (OMO).

METHODS

Participants: Twenty-eight NPC patients receiving 33-fraction IMRT or VMAT

Materials: StrataXRT (n=14) & Aqueous cream (n=14)

Procedure: Both groups were examined weekly by nurses using CTCAE v5.0 over 7 weeks. A single OMO retrospectively regraded the same timepoints based on clinical documentation, yielding 223 paired grading entries.

Data Analysis: Cohen's kappa measured inter-rater agreement, and repeated measures ANOVA assessed toxicity progression across treatment groups.

RESULTS

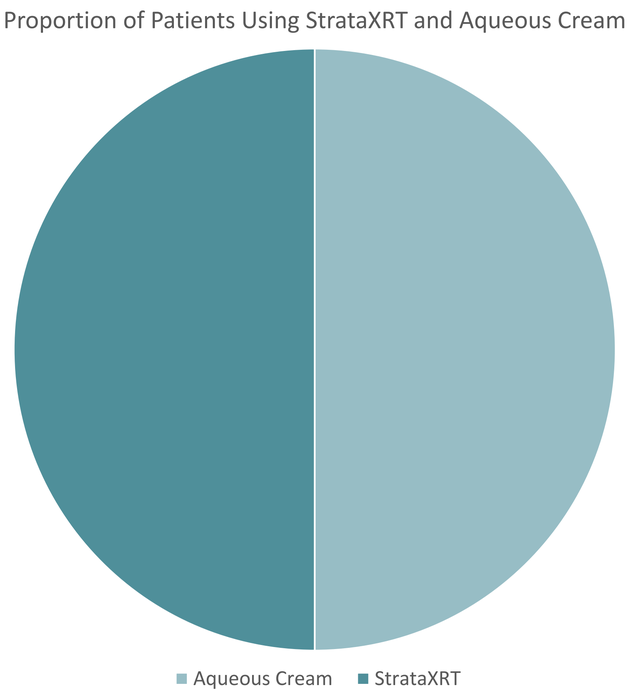

Figure 1: Proportion of Patient Using StrataXRT and Aqueous Cream

In this study, 28 patients was enrolled and yielded 196 paired assessments.

Out of the196 paired assessments, 111 (56.6%) were concordant, while 85 (43.4%) differed. Cohen's kappa showed moderate agreement ($\kappa = 0.51$; 95% CI: 0.43–0.59; $p < 0.001$).

Mean CTCAE grade was significantly lower in StrataXRT users (1.53 ± 0.51) compared to aqueous cream users (1.94 ± 0.45; $p = 0.038$).

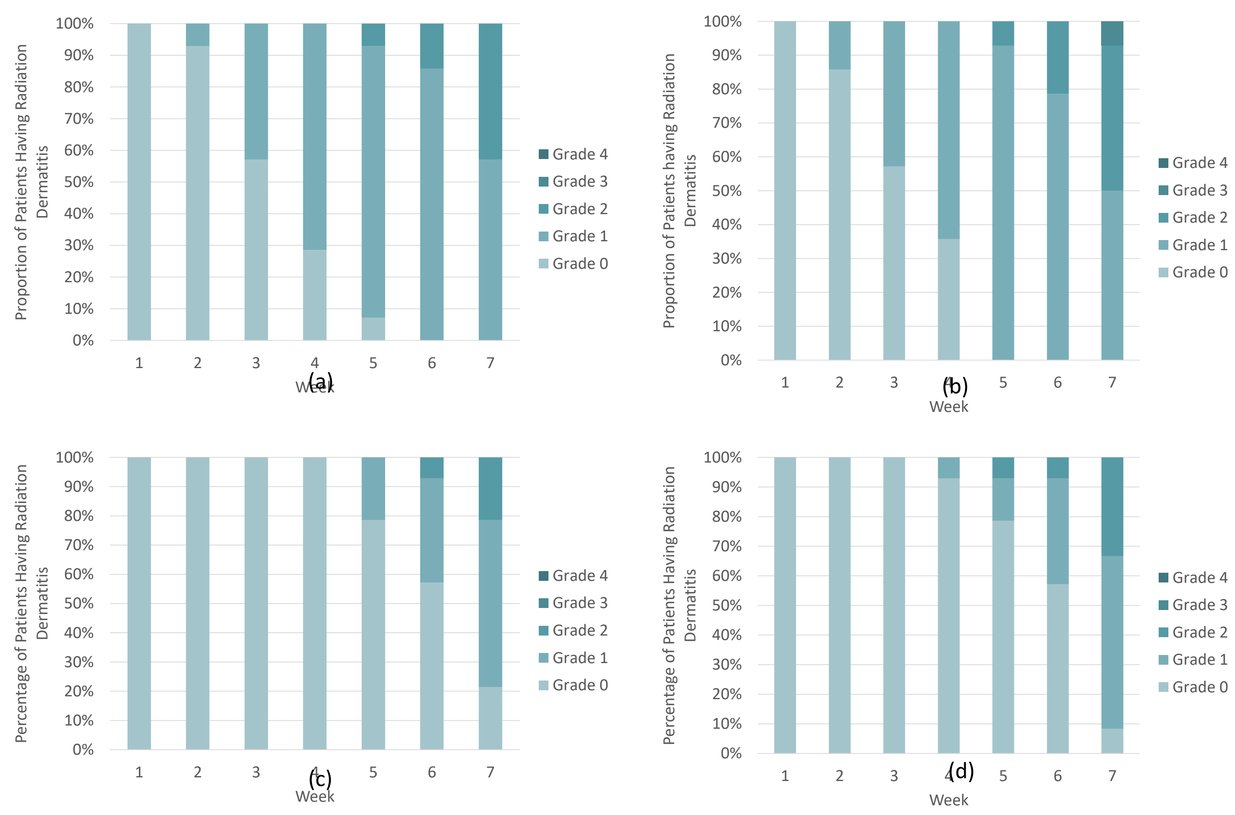

Figure 2: Weekly Skin Toxicity Assessment of Patients Using (a) Aqueous Cream and assessed by MO (b) StrataXRT and assessed by MO (c) Aqueous Cream and assessed by nurses (d) StrataXRT and assessed by nurses.

Moreover, there is no significant difference in the time to onset of ≥ 2 RD in both groups ($p>0.5$) and the number of patients developing RD ($p>0.5$) except in Week 2 while peak skin toxicity occurred in Week 6 in both groups of patients. Grade 2 reactions were observed in 64.3% of patients by Week 6, with more frequent higher-grade reactions in the aqueous cream group.

DISCUSSION

Other studies showed StrataXRT is good in reducing RD in patients receiving breast radiotherapy. However, the prescription in breast radiotherapy is 40-50Gy/15-25# which is different from head and neck radiotherapy [2-4]. Our study focuses on head and neck patients and shows StrataXRT had lower peak CTCAE skin toxicity compared to aqueous cream.

Limitations of this study included the non-standardization of the usage of StrataXRT among patients as some of them might apply it too thick or thin. This might affect the treatment outcomes if patients applied StrataXRT exceeded the thickness recommended.[5]

CONCLUSION

Findings supports StrataXRT as a more effective prophylactic agent. Moderate grading agreement was observed between nurses and the regrading OMO, with the most divergence during peak toxicity. Standardized CTCAE training and objective assessment tools are recommended for consistent grading.

REFERENCE:

1. Radiation dermatitis | DermNet (dermnetnz.org)
2. Chan, R.J., Blades, R., Jones, L., Downer, T.R., Peet, S.C., Button, E., Wyld, D., McPhail, S., Doolan, M. and Yates, P., 2019. A single-blind, randomised controlled trial of StrataXRT®–A silicone-based film-forming gel dressing for prophylaxis and management of radiation dermatitis in patients with head and neck cancer. *Radiotherapy and Oncology*, *139*, pp.72-78.
3. Kennedy, S.K., Gojsevic, M., Rajeswaran, T., Zhang, L., Kuszaj, O., Day, M., Karam, I., Vesprini, D., Leung, E., Szumacher, E. and Rakovitch, E., 2024. StrataXRT for the prevention of acute radiation dermatitis in breast cancer: a pilot study. *Supportive Care in Cancer*, *32*(10), p.670.
4. Omidvari, S., Eskandari, Z., Nasrollahi, H., Ahmadloo, N., Ansari, M., Hamedi, S.H., Khanjani, N., Kadkhodaei, B., Mosalaei, A. and Mohammadianpanah, M., 2022. The investigation of prophylactic effect of StrataXRT gel on radiation-induced dermatitis in breast cancer patients: a randomized clinical trial. *Middle East Journal of Cancer*, *13*(2), pp.293-298.
5. Suzuki, T., Ohira, S., Ogita, M., Ohta, T., Nozawa, Y., Minamitani, M., Hayashi, T., Saegusa, S., Imae, T., Ueyama, T. and Katano, A., 2025. Dosimetric effect of silicone-based gel on skin surface during volumetric modulated arc therapy for breast cancer. *Journal of Applied Clinical Medical Physics*, p.e70070.