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Radiation dermatitis

Prospective audit showing improved patient-assessed skin toxicity with use of betamethasone cream for those at high risk of radiation dermatitis



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ABSTRACT

This audit was conducted before and after introduction of a risk-based skincare policy with prophylactic steroids recommended for those at high risk. Comparison of the two cohorts confirmed results seen in trials with significant reduction in redness, itch, discomfort, sleep disturbance, and use of analgesia with the addition of steroids.

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Skin reaction is one of the most common acute side effects of radiotherapy, however it is frequently under appreciated by health care professionals with dis-concordant reporting between patient and health care assessments in a number of phase III trials [1]. This under-recognition of the impact on patients, and possibly because studies are published or presented in less prominent places in journals and at meetings, may explain why there can be delays in implementing the study findings into routine clinical practice.

In Edinburgh Cancer Centre (ECC) for many years the skin care protocol recommended the use of aqueous cream with the addition of 1% hydrocortisone for itch, and if moist desquamation developed, proflavin (a topical anti-septic) during radiotherapy or silver sulfadiazine cream (a topical sulphonamide) on completion of radiotherapy. However, it was clear that these were not the optimal choices, particularly the aqueous cream which is a soap substitute and studies have shown many people are allergic to some of the components [2,3]. Two systemic reviews examined the data on radiotherapy skin care up to end 2011, and suggested a possible benefit for the use of potent steroids, but called for more studies [4,5]. Subsequently two Phase III trials have been published which demonstrated a benefit from the prophylactic use of potent steroids [6,7].

It was therefore proposed that the ECC protocol was up-dated to reflect this evidence, however concerns were raised about the potential toxicity of the use of potent steroids and the increased cost. It was therefore decided to conduct two audits, one before

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and one after the implementation to assess the impact of the change in routine practice

Methods

A new skin care policy was written based on the risk of developing a skin reaction (see Table 1) with the recommendation that all patients at high risk of a skin reaction applied a potent steroid once a day from the start of radiotherapy and for up to two weeks after. Betamethasone valerate 0.1% was chosen as this is the preferred one in the hospital formulary and equivalent potency when compared to 0.1% mometasone furoate (and cheaper). The medium and high risk patients were also given Diprobase as an emollient. This was chosen as it was on the hospital dermatology formulary and there is no clear evidence that one simple emollient is superior to another. A patient information leaflet was also written giving general advice on skin care (see Supplementary information).

For the audit a simple questionnaire was developed asking patients about smoking, diabetes, frequency of washing, type of soap and creams used, and then they were asked to rate on a 1–10 scale their skin redness, itch, discomfort, and pain. They were also asked if they were using any analgesia for their skin, or if the reaction was disturbing their sleep. The patients completed the questionnaire when they attended for their final fraction of treatment and on the telephone two weeks after completion of their radiotherapy. The treatment radiographers also graded the skin reaction on the final fraction according to RTOG toxicity scale.

Two cohorts of patients in the high risk group were invited to participate in the audit, one a month before the change was implemented, and the second, three months later. No formal statistical

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ECC skin care protocol.

(1) Daily washing in warm water with unperfumed soap/shampoo. Evaporate to dry or use cool hair dryer

(2) Use of antiperspirants permitted. Loose fitting clothing encouraged. Reduce shaving and use electric shaver. Keep skin covered from sun

(3) No use of talcum powder, aqueous cream, aloe vera, barrier creams (e.g. zinc oxide), petroleum gel, sun-cream, hair removal creams or waxing. Avoid adhesive dressings if possible

⁽⁴⁾ Swimming allowed for patients at medium and low risk of reaction, but not high risk. No use of jacuzzis

High risk	Medium risk	Low risk	Case by case	
Breast Head and Neck	Palliative 11–15# Radical chest posterior beam	Palliative ≤10# Pelvic VMAT	Brain Sarcoma	
3D CRT pelvis BMI > 35 Any radical treatment with skin bolus	3D CRT pelvis BMI < 35		Lymphoma	
Betamethasone valerate 0.1% to apply $1\times$ per day after RT and Diprobase to use on dry areas	Supplied with Diprobase to apply $2\times$ per day to any dry areas	If reaction develops discuss with consultant (as unexpected)	Plan reviewed and creams provided depending on risk	

power calculation was performed as the aim was to confirm the results of clinical trials could be replicated in day to day clinical practice.

We did not include the medium and low risk groups as the main driver was to confirm efficacy of routine use of prophylactic steroid cream.

Results

Two-hundred and nineteen patients agreed to participate in the audit. Based on an average of 115 patients in high risk groups treated per month this represents around 95% of potential patients. The characteristics of the patients in the two cohorts are set out in Table 2. There were no statistically significant differences except that in cohort after policy change (C2) there were fewer patients treated with 3D-conformal radiotherapy, and slightly more with volumetrically-modulated arc therapy (VMAT). Though VMAT is associated with lower skin reactions [8] the departmental change was principally the introduction for anal tumours. The breast technique with selected patients having 'field in field' to reduce 'hot

spots' and routine use of VMAT for head and neck patients other than T1 larynx remained unchanged (12/13 in C1 and 11/11 in C2).

In the cohort before the change (C1), 29% were using any cream compared with 96% in C2 ($X^2 p < 0.001$) showing increased compliance with the skin care policy. In C2, 84% used Betamethasone, with 9% Diprobase only, and 4% no cream. The number of patients using non-recommended products (zinc oxide cream, aloe vera, petroleum gel) dropped from four patients in C1 to one in C2.

As set out in Table 3, on their final fraction of radiotherapy, patients in C2 scored lower for itch (mean 1.3 C2 v 3.0 C1 ANOVA p < 0.001) and discomfort (2.2 v 3.3 ANOVA p = 0.009) compared to C1. However, redness and pain was not statistically significant different, though fewer in C2 were using analgesia (9% v 21% X^2 5.2, p = 0.022).

The radiographers also scored the skin reactions lower (C1 Grade 0 = 8%, G1 49%, G2 34%, G3 9% and C2 G0 = 26%, G1 53%, G2 16% G3 5%, X^2 19.4, $p \leq 0.001$), though this was un-blinded as to which cream the patient was using.

All patients were telephoned two weeks following treatment, 185 could be contacted (C1 = 85 and C2 100) and though the scores were generally lower in C2 none reached statistical significance.

Table 2

Comparison Cohort 1 and Cohort 2.

	Cohort 1 <i>N</i> = 112	Cohort 2 <i>N</i> = 107	Comparison (X^2 unless stated)
Treatment site			
Breast	83 (74%)	87 (81%)	p = 0.46
Head & neck/brain	15 (13%)	12 (12%)	•
Pelvis	11 (10%)	6 (6%)	
Other high risk	3 (3%)	1 (1%)	
Technique			
Breast	84	87	<i>p</i> = 0.02
VMAT	12	15	
3D-CRT	16	4	
Mean dose	45.8 Gy (44.3-47-3)	45.8 Gy (44.3-47.3)	ANOVA $p = 0.97$
Diabetes	7 (6%)	8 (7%)	<i>p</i> = 0.79
Smoker	22 (20%)	11 (10%)	<i>p</i> = 0.06
Frequency of washing			
<1	4	5	p = 0.54
1	84	73	
>1	24	29	
Soap			
Unperfumed	97	97	p = 0.40
Perfumed	15	10	
Cream			
None	80 (71%)	4 (4%)	p < 0.001
Aqueous cream	19 (17%)	0	
Diprobase	1 (1%)	10 (9%)	
Betamethasone ± Diprobase	0	90 (84%)	
Hydrocortisone	4 (4%)	1 (1%)	
Other non-perfumed cream	4 (4%)	1 (1%)	
Not recommended product	4 (4%)	1 (1%)	

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