Journal of Radiotherapy in Practice

Journal of Radiotherapy in Practice (2016)
15, 322–333 © Cambridge University Press 2016
doi:10.1017/S1460396916000315

Original Article

Colloidal oatmeal emollient as an alternative skincare approach in radiotherapy: a feasibility study

Rosemary Rudge

Bristol Cancer Institute, Horfield Road, Avon, Bristol, UK

(Received 3 March 2016; revised 28 June 2016; accepted 6 July 2016; first published online 17 August 2016)

Abstract

Aim: To assess the feasibility of a randomised controlled trial (RCT) on patients receiving radical radiotherapy for carcinoma of the anus in order to compare the present skincare advice at the time of the study with an alternative product, Aveeno, used primarily for dermatological and chemotherapeutic-induced skin conditions.

Materials and method: Standardised Radiation Therapy Oncology Group (RTOG) grading and skincare assessments were used primarily to inform on physical reactions within a RCT. A pre-existing morbidity/quality-of-life instrument 'the Head and Neck Radiotherapy Questionnaire', which was validated for use with radiotherapy patients in preceding studies, was adapted for anus patients and formed the secondary basis for data collection. In all, 24 participants undergoing radical radiotherapy for anal cancer were randomised into two arms, Aveeno cream versus Aqueous Cream BP, and reviewed weekly to collect data and perform analysis and Mann–Whitney U non-parametric statistical tests.

Results: RTOG gradings for skin reactions were comparable week by week across the cohorts, with a baseline 100% of participants exhibiting RTOG 0 at week 1 in all areas, through to week 6 where both cohorts had progressed to higher RTOG grades. The Aveeno cohort, however, indicated a p-value approaching significance in regards to epidermal regeneration at follow-up 1 ($p = 0{\cdot}0543$). Questionnaires yielded diminishing responses as treatment progressed correlating with advancing RTOG grades, and exhibited increasing negativity in responses in correlation with advancing RTOG grade exhibited.

Conclusion: The study was the first to recognise colloidal oatmeal as a skincare approach in the radiotherapy setting and recognises the potential benefits of Aveeno in radiation-induced skin reactions. The study determined the RTOG grading system to be robust as a method of evaluation of skin reactions and the questionnaires deemed the quality-of-life assessment to be a necessity in order to address patients' psychological needs in addition to the physical needs.

Keywords: anal cancer; radiotherapy; skincare; skin reactions

Correspondence to: Bristol Cancer Institute, Horfield Road, Avon, Bristol, UK. E-mail: roseyrudge@gmail.com

INTRODUCTION

Despite advances in radiotherapy practice, skin reactions remain one of the most common, and significant problems for patients undergoing treatment.[1,2] It is recognised to impact not only the quality of life for the patient[3,4] but also may lead to delays in treatment or even the cessation of treatment.[5] The importance of skincare in radiotherapy is therefore paramount, as all patients receiving external beam radiation treatment are liable to erythematic reaction as the radiation beam must penetrate the external epidermis and subcutaneous tissues in order to reach the target volume. Erythema is commonly associated with radiation, occurring at doses of 20–40 Gy, with dry desquamation noted at doses of >30 Gy, and moist desquamation reported at doses >40 Gy.[6–8]

Moist desquamation occurs when the basal layer of the skin cannot produce enough cells to replace those lost in the epidermis, proving particularly difficult for patients undergoing radiotherapy as the damage is repeated throughout treatment.[9,10] Patients undergoing radical radiotherapy for anal cancer receive doses totalling up to 60 Gy to the pelvic region. Moist desquamation is reported in almost all cases[11,12] suggesting this cohort might particularly benefit from skincare investigation into radiation effects on skin. It is widely accepted that re-granulation and wound healing is more prevalent in moist environments[12–14] suggesting that as a preventative measure, emollients such as Aqueous Cream (Aqueous Cream BP, BCM Ltd, Nottingham, NG2 3AA, UK) and Aveeno® (Aveeno, Johnson & Johnson Ltd Foundation Park, Roxborough Way, Maidenhead, SL6 3UG, UK) may promote a healing environment and prevent infection.

There is limited research and evidence into skincare after radiotherapy at present, with many centres across the United Kingdom advocating the use of a variety of agents in an ad hoc capacity.[15,16] The Society of Radiographers (SoR) UK Survey of Radiotherapy Skin Care[17] recommends that further evidence and trials, particularly of new products, are required in order to inform current practice and shape national guidelines. The survey stated difficulties throughout the research in unclear methodologies and varied assessment tools leading to inconsistency of care,[17] thus standardising assessment and monitoring could prove beneficial in future skincare guidance.

As many of the reviews call for research into new interventions[18,19] one such product, colloidal oatmeal emollient cream licenced under the name Aveeno, has been reportedly used in the treatment of minor burns and drug-induced rashes.[20,21] As presently advocated for use in chemotherapy-related skin conditions, colloidal oatmeal has been recommended for use due to its molecular mechanisms of anti-inflammatory and anti-histaminic activity.[21] Some research suggests that colloidal oatmeal could be of greater moisturising benefit than the water-based emollients alone, due to the high concentration of starches and β glucans, which retain water more effectively.[22] The beneficial properties of colloidal oatmeal have long been accepted in dermatitis conditions, receiving Food and Drug Administration (FDA) approval for use as studies show good efficacy and no toxicity.[20,23] Avenanthramides, which are naturally found in oat grain, are suggested to be responsible for the release of pro-inflammatory cytokines and histamine, gaining both anti-inflammatory and anti-pruritic properties for the user.[24] It is proposed that the high polysaccharide content of colloidal oatmeal forms a protective seal to aid repair and maintenance of the epidermal barrier.[20] It should, however, be noted that these particular study results, although appearing to cite reputable sources as evidence, should be treated with caution as author bias may be evident as manufacturer sponsorship is alluded to drive the study. With an independent researcher stance, this feasibility study eliminated this element with the double blinding approach.

This study aims to investigate the potential for informing future randomised trials by way of a feasibility study.[18,25] The study aims to pre-test the combined use of questionnaires and Radiation Therapy Oncology Group (RTOG) grading systems[26] in a comparative study of two products, and drawing conclusions as to the efficacy of those methods used to form an evidence base to standardise skincare advice.[27] The study aims to evaluate the feasibility of performing a trial on patients receiving treatment for carcinoma of the anus to compare the current skincare product

https://doi.org/10.1017/S1460396916000315 Published online by Cambridge University Press

advice at the time of study conception, Aqueous Cream, with an alternative product, Aveeno, which is widely used for dermatological conditions.[22,27]

METHOD

Ethical approval was sought from the Ethics Board to ensure patient safety and that the proposal for the study met with the approval of peer review. Participants were randomised into equally sized comparison groups in order to determine the possible reliability of the methods used and simple statistics were used to determine if there is scope for alternative skincare advice with regard to radiotherapy. All eligible participants were targeted (see inclusion criteria in Table 1). Potential participants were given a Patient Information Sheet detailing the study before starting treatment to allow for informed decisionmaking before consenting to the trial and with comprehensive washing and skincare instructions to ensure consistency.

A sample size calculation for ordered categorical data using a 95% confidence interval was used to determine participant numbers required, allowing for drop outs. The calculation demonstrated that 10–12 patients/arm were required to allow for reliable and valid results with a 4·36% high precision percentage decrease/case. The recruitment size and rate was then verified to be feasible with historical footfall from departmental records.

The study was an randomised controlled trial (RCT) distributing participants between two arms, one group routinely using Aqueous Cream BP, the other using Aveeno. All participants were assigned numbers consecutively and randomised into control or test arms by means of distribution by computer-allocated assignment. Both products were prepared and distributed by the Pharmacology Trials Unit (PTU) at the research site to ensure the safety of the blinded products.

Eligible participants were seen in clinic, the Consultant provided information pertaining to the study to the patient at that time to allow time to make an informed decision. The randomisation of patients then occurred at the point of planning to ensure the patient's skin status was assessed before treatment, and participants were given the same washing and cream application instructions (3 × daily at regular intervals throughout the day) irrespective of study arm. All participants were reviewed weekly as per department protocol, and treatment regime including details of concurrent chemotherapy as well as skin assessment was recorded and monitored by a review radiographer. Patients' social background was recorded as part of the data collection using the RTOG grading (Table 2) and anus toxicity assessment sheet modified to include all study data required, as it is documented that social factors such as poor hydration, smoking and poor hygiene[28] may impact on skin integrity. Where the patients' skin deteriorated requiring further intervention such as hydrocolloids or dressings, the point at which these were introduced in the patients' pathway was documented, as with regular review, skin assessment and adherence to the trial requirements. As post radiotherapy treatment is recognised to be the period at which reaction time peaks[29] follow-up with patients at weeks 2 and 4 post treatment was scheduled. Entire repopulation of the epidermis is commonly seen

Table 1. *Inclusion criteria for eligible participants*

Inclusion criteria
Must be >18 years of age
Must have histological confirmation of primary squamous cell carcinoma of the anus
Must be receiving radical external beam radiotherapy, either in dual-phase treatment concomitantly with chemotherapy to a total of 50·4 Gy in 28 fractions over 5·5 weeks, or single-phase radiotherapy alone to a total dose of 60 Gy in 30 fractions over 6 weeks
Must be receiving 6 MV X photons or 10 MV X photons
Must have a tumour diameter of between 2 and 5 cm
No rash or open wounds in the treatment area before commencement of treatment
Must sign the study-specific consent form before randomisation

Table 2. *Standardised Radiation Therapy Oncology Group (RTOG) grades for patients undergoing radiotherapy*

RTOG 0: No visible change to skin
RTOG 1: Faint or dull erythema
RTOG 2a: Tender or bright erythema. Itching may be present
RTOG 2b: Patchy moist desquamation
RTOG 3: Confluent moist desquamation

https://doi.org/10.1017/S1460396916000315 Published online by Cambridge University Press

at 4 weeks post radiotherapy,[30] therefore the final follow-up occurred at week 4, with post treatment follow-up also allowing to gauge if the intensity and severity of the reaction was affected between the two groups. Patients submitted a questionnaire at the reviews to gain insight into their experiences with the products. A written response was chosen for questionnaire dissemination due to the captive nature of the audience targeted in the study attending for radiotherapy.[31] As the study did not require the vast distribution or maximum encompassment discussed by Hek and Moule,[32] it was deemed acceptable in hardcopy format but may require revision if the study were to be repeated or expanded.

The questionnaire was derived from the Head and Neck Radiotherapy Questionnaire, a quality-of-life instrument demonstrated to be a valid measure of acute morbidity in radiotherapy clinical trials, yielding significant results in comparative trials throughout treatment and into post treatment as per this study.[33] The questionnaire was revisited for use with anal carcinoma patients and piloted on Patient Advice and Liaison Service within the study site before use (Appendix 1).

The participants' randomisation was kept from the researcher and investigator by means of a sealed envelope prepared by PTU, only to be opened should the reviewing radiographer deem it necessary in the patients' best interests. Unmarked tubes for each intervention ensured the study was double blinded to both researchers and patients increasing reliability,[34,35] and randomisation ensured anonymity for the participants throughout the process.

Analysis

Data collected from toxicity assessment sheets were entered into a spreadsheet, and descriptive statistics were used to draw out common themes. Colour coded bar charts denoting the severity of reaction were used to compare the creams and identify trends using Excel and simple coding techniques and Mann–Whitney U tests were applied to give *p*-values. Tabular forms were utilised to provide simple summaries about the quantitative data collected from the questionnaires. The 'free

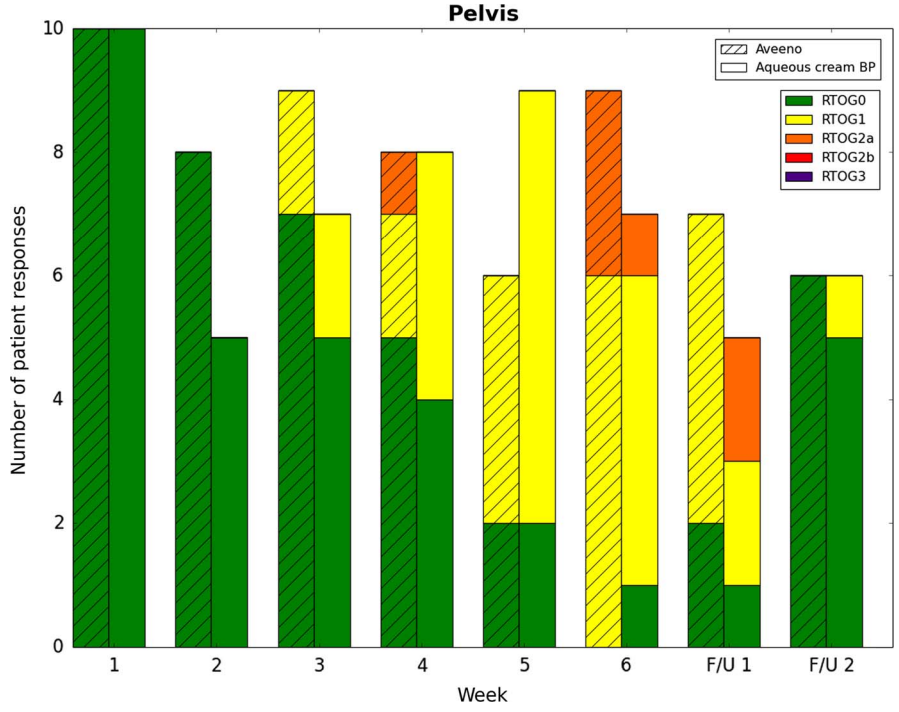

Figure 1. Graphical representation of Radiation Therapy Oncology Group (RTOG) skin reactions week by week for Aveeno (left side) and Aqueous Cream (right side) cohorts side by side for the pelvis region.

https://doi.org/10.1017/S1460396916000315 Published online by Cambridge University Press

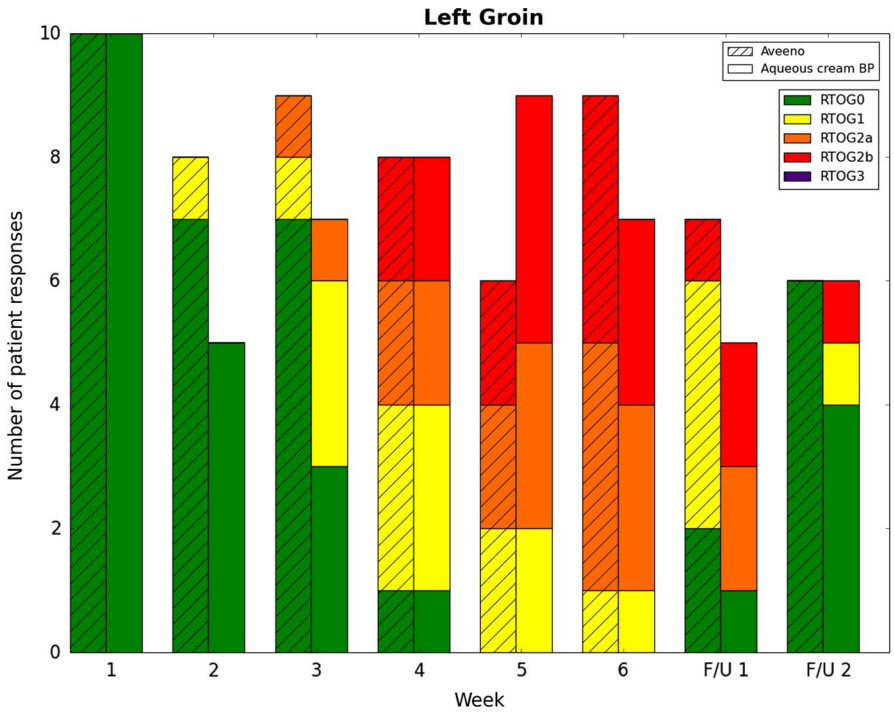

Figure 2. Graphical representation of Radiation Therapy Oncology Group (RTOG) skin reactions week by week for Aveeno (left side) and Aqueous Cream (right side) cohorts side by side for the left groin region.

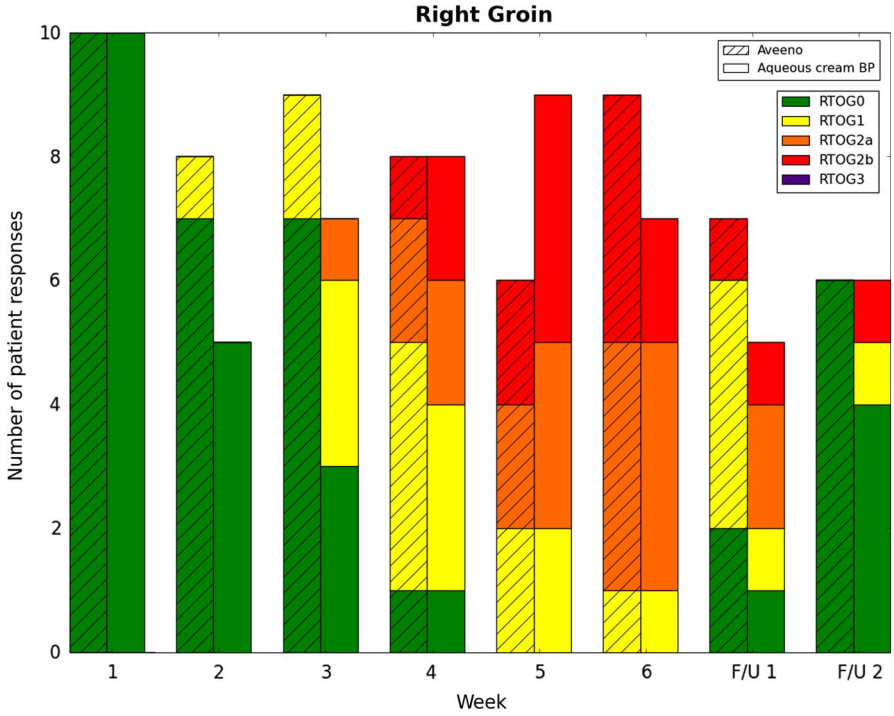

Figure 3. Graphical representation of Radiation Therapy Oncology Group (RTOG) skin reactions week by week for Aveeno (left side) and Aqueous Cream (right side) cohorts side by side for the right groin region.

https://doi.org/10.1017/S1460396916000315 Published online by Cambridge University Press

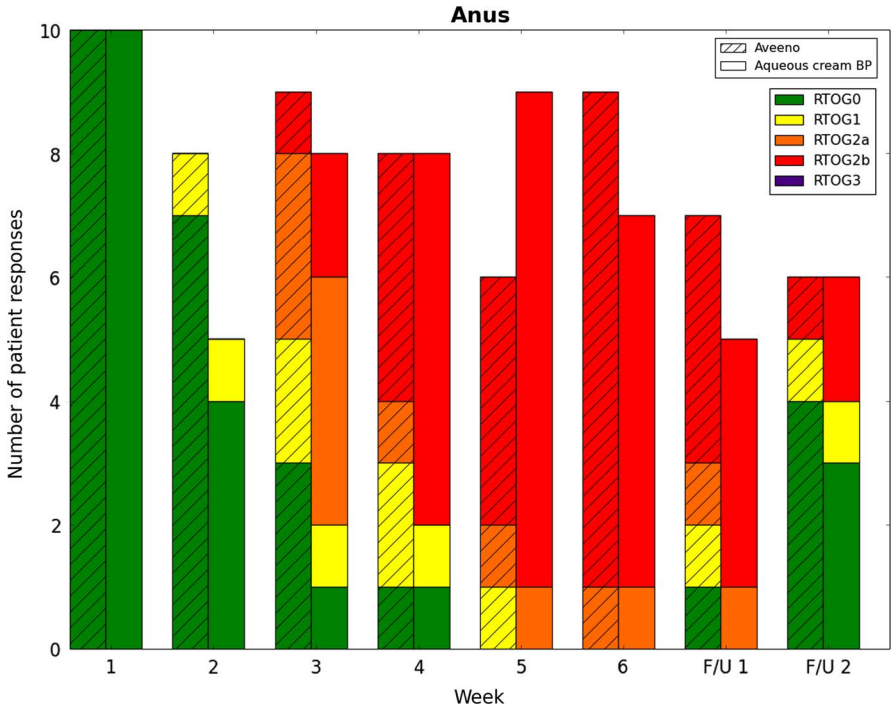

Figure 4. Graphical representation of Radiation Therapy Oncology Group (RTOG) skin reactions week by week for Aveeno (left side) and Aqueous Cream (right side) cohorts side by side for the anus region.

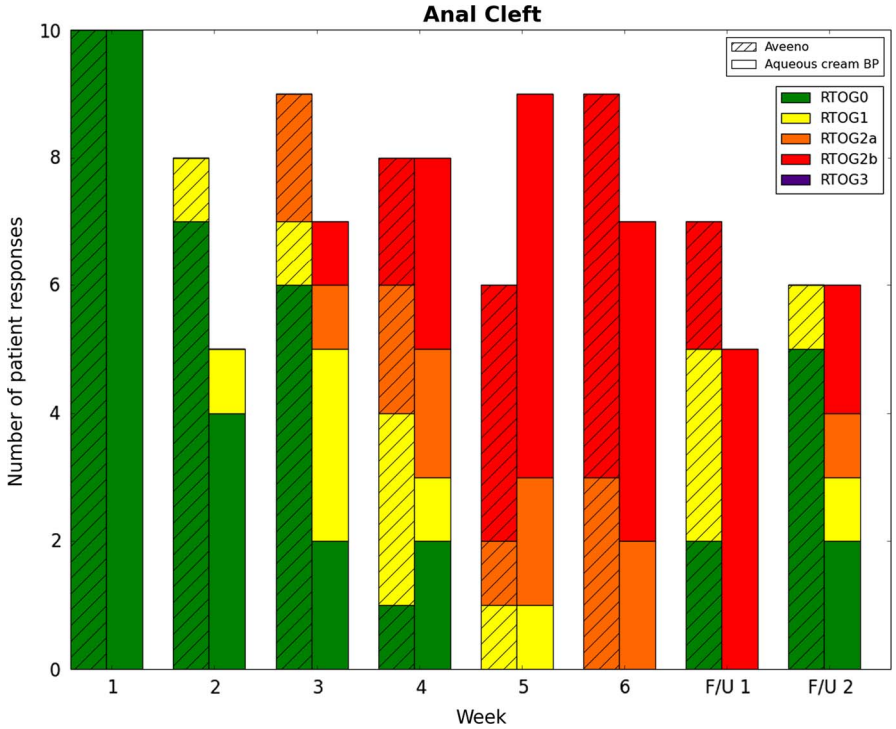

Figure 5. Graphical representation of Radiation Therapy Oncology Group (RTOG) skin reactions week by week for Aveeno (left side) and Aqueous Cream (right side) cohorts side by side for the anal cleft region.

https://doi.org/10.1017/S1460396916000315 Published online by Cambridge University Press

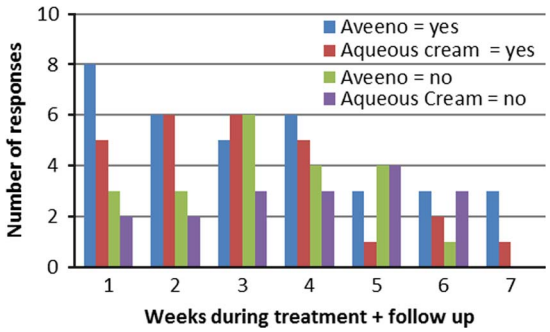

Figure 6. Graphical representation of responses to the quality-of-life section of the questionnaire by participants: 'Have you felt good about yourself this week?' as responded positively and negatively week by week for Aveeno and Aqueous Cream cohorts side by side.

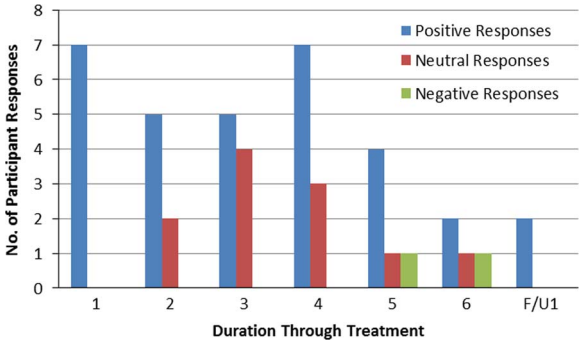

Figure 7. 'Free comments' section of questionnaires quantified into positive, neutral and negative responses week by week throughout treatment for Aveeno cohort.

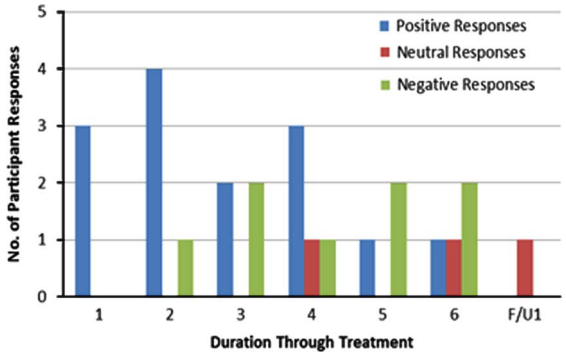

Figure 8. 'Free comments' section of questionnaires quantified into positive, neutral and negative responses week by week throughout treatment for Aqueous Cream BP cohort.

comments' section of the questionnaires were quantified into positive, negative and neutral to provide at a glance response themes (Figures 1–8).

RESULTS

The research took place between February 2014 and January 2015. The recruitment rate included 95% of attendees to the study site. During this period 24 patients were recruited and consented into the study. Three participants were withdrawn, either due to non-compliance or own wishes, of those remaining there were seven males and 14 females with birth years ranging from 1933 to 1981, with a mean age of 61·5 years. The cohort division was 11 participants in the Aveeno cohort and ten participants in the Aqueous Cream cohort.

Questionnaire responses

In total, 168 questionnaires were distributed, and 100 responses were received for analysis (60% return rate). The response rate decreased throughout treatment progression, with the first 4 weeks yielding 17–20 responses, the final weeks' 5 and 6 comprising of 13 and ten responses, respectively, then four responses by follow-up. The feedback from the questionnaires all indicated a positive response to using creams as part of a skincare regime on the whole, and initial responses in the 1st week were 100% positive in both cohorts with regard to application and soothing of skin reactions. Responses were categorised into positive, negative and neutral responses, and key themes were identified to assess the response to the cream (Figures 7 and 8). Overall, Aveeno participants 'free comments' (total = 45 responses) rated positively in 71% of responses, 25% were neutral and 4% were negative, compared with the Aqueous Cream 'free comments' (total = 25 responses), which rated positively in 56%, neutral in 12% and negatively in 32% of responses. At week 1 100% of responses to both creams were positive, with 'easy to apply' and 'cooling and calming' comments consistently occurring in both cohorts. By week 3, Aveeno responses were predominantly positive (70%) with comments specifically identifying benefits such as 'used after each bout of diarrhoea to soothe anal area which worked effectively' and 'clearing soreness and calming down itching' but also inclusive of more ambiguous comments (30%) such as 'easy to use but leaves slight film on skin'. Conversely, at week 3 50% of responses positively advocated Aqueous Cream, and 50% negatively

https://doi.org/10.1017/S1460396916000315 Published online by Cambridge University Press

commented on the cream 'does nothing to help burning sensation'. At week 5 most responses to Aqueous Cream had become negative (66%) and neutral (33%), comments such as 'cream does not seem to help' and 'no ease up' were identified as themes by this point. Comparatively, Aveeno responses were remaining 67% positive, ranging from 'good, soothing, relaxing', 'helps tightness in skin' and 'whichever cream it is it seems the best for skin as it is sensitive and helping with the soreness' to the more ambiguous responses (22% neutral and 22% negative) 'cream seems to be working for about 1 hour then sore and burning again'. By week 6 both creams were reported to 'make little difference' as the skin had deteriorated to the point of requiring complex dressings and hydrocolloids in both cohorts. At follow-up, comments were fewer due to the decreased response rate (four responses total), 100% of Aveeno participants exhibited positive responses such as 'cream continues to be a comfort' and 'healing nicely, cream applied on new skin really helps the tightness feeling – feels as if it has really helped', whereas 100% of the Aqueous Cream responses were ambiguous 'use different gel on weeping skin/groins cream is only useful in stopping underwear sticking to skin on buttocks'. It should be noted that the RTOG grades for the two cohorts differed considerably in some regions by follow-up which may affect comments on the creams (both groins RTOG = 0 in Aveeno cohort, Aqueous Cream RTOG = 0–2b) as it is documented that experiencing pain may impact psychological outlook.[10,36]

Skincare assessment

The baseline statistics indicate minimal external factors such as smoking or alcohol consumption, although it is questionable whether these responses are truly indicative or a reflection of the participants' fear of judgement by a healthcare professional.[34] Although both cohorts were evenly matched, participant numbers varied weekly making the data difficult to compare effectively. Due to limited participant numbers, and therefore limitations in statistical power, it is difficult to assess clearly whether there is any clear benefit of one cream over another. However, within the limits of the feasibility study, the results show there is a difference in median response between the two creams in most regions at follow-up but generally no statistical significant difference between the two cohorts throughout treatment duration. The Mann–Whitney U non-parametric tests (ran using GraphPad Prism 6 software) were used for all time points and all regions. At follow-up 1 (2 weeks post radiotherapy) there is an almost significant ($p = 0{\cdot}0543$, Mann–Whitney U test statistic 5) difference in response between the Aveeno and Aqueous Cream cohorts in favour of Aveeno in the anal cleft region. Follow-up 2 (4 weeks post radiotherapy) in the anal cleft also shows a trend towards significance ($p = 0{\cdot}106$, Mann–Whitney U test statistic 7·5).

DISCUSSION

Studies by Kedge et al.[25] and Wells[37] contend that there is no significant difference between Aqueous Cream and more expensive creams for prophylactic use, however, the post epidermal regeneration results in this study could indicate otherwise, although a larger scale RCT would be required to support this. In the light of the Medicines and Healthcare Products Regulatory Agency[38] safety update refuting the use of Aqueous Cream as an emollient since the advent of the study, the study shows Aveeno to be a viable alternative emollient for comfort, demonstrating no detrimental qualities within the limitations of the pilot study.

Studies conducted by Gosselin et al.[39] and McQuestion[4] state that there is little evidence to suggest benefit in the prophylactic use of different emollients such as Aqueous Cream and other creams in reducing the occurrence of skin reactions during treatment other than patient comfort. Conversely, studies by Heggie et al.[40] and Glean et al.[15] positively advocate the use of emollients such as Aqueous Cream in reducing skin reactions such as dry desquamation and delaying skin breakdown. The week by week results indicate no significant difference between the two cohorts during treatment, but without a control 'no cream' arm the assertion of actual benefit cannot be proven, as it was deemed unethical to withhold treatment, whereas Aqueous Cream was routinely dispensed at the time of the study. As the SoR skincare guidance[41] has since been updated recommending that at present no product can be supported or refuted based on current evidence, and further

https://doi.org/10.1017/S1460396916000315 Published online by Cambridge University Press

recommending research designs of 'no intervention' be utilised, a wider RCT developing a 'no intervention' arm is presently more viable in order to assess benefit effectively.

Heggie et al.[40] and Glean et al.[15] also state emollient benefit in pain relief as well as delayed skin reaction, and therefore the combined approach of RTOG grading scores and quality-of-life questionnaires afford a fuller picture of the physical and psychological needs of these individuals. The quality-of-life question 'have you felt good about yourself in the last week?' elicited a mixed response (Figure 6), and appeared more dependent on the individual than the point at which they were through treatment or cream assigned. The extremities of responses indicate the need to monitor patient wellbeing and ability to cope. The need for both approaches is exemplified by the inconsistency in scaling the frequency of response,[36,42,43] however, a more simplistic approach to gauging patient wellbeing would improve evaluation. The yes/no approach followed by a numerical graphic rating scale incurred confusion, for example, those who had rated 'yes' they had felt good about themselves at a scale of 3, is difficult to compare to one who rated themselves 'no' to feeling good about themselves at a scale of 5. The inference of negativity provides useful information to address patient concerns, but from an evaluative stance, a sliding visual analogue scale of emotional wellbeing might prove more effective in both gauging patients' status and prove simpler for assessment. By week 6 most respondents' comments indicate both creams make 'little difference' or 'does not seem to help'. All participants indicated pain levels on high end and majority experiencing itching and dryness by this point.

In total, 17% of patients declared a preference at the consenting stage for Aveeno before commencement, indicating a potential bias, with 12% of overall patients suggesting they knew which cream they were allocated during the study due to the consistency and prior awareness of the cream. This may have led to participants answering according to their perception of allocation. It is recognised that it is difficult to get complete subjectivity,[31] but reiterated importance of blinding the study to get impartial results such as those obtained by Gosselin et al. (2010)[39] for future guidance. The comments appear to be favourable for the use of creams as an active method of hydrating and soothing the skin, potentially due to participants wanting to exert a sense of control in a situation otherwise out of their own hands.[10,44] This supports the suggestion in research that by feeling instrumental in actively taking responsibility for an aspect of their health patients were being positively proactive in their own care.[39,45]

The most recent publication by the SoR in 2015[41] recognises that although some studies deem skincare products to be ineffective in reducing skin reactions, the element of therapeutic benefit in bringing comfort and symptom amelioration should not be discounted.[39,40] Throughout the free comments the notion of 'soothing' and providing relief at times of discomfort such as bouts of diarrhoea it was indicated that the creams afforded symptom alleviation. The Aveeno cohort seemed to find on-going relief in this respect but as the sample size was too small to draw such conclusions it could be wholly subjective to the individual in these qualitative responses.[42] Many researchers discuss the difficulties of data collection and response rate[28,31] deeming the process as time consuming with issues in eliciting participant response, and therefore clear instructions for the return of the questionnaires at the regular weekly reviews was put in place to rectify this. Unfortunately, not all questionnaires were returned at the review sessions, suggesting this method of dissemination remains not without difficulty, as response rate declined rapidly throughout the study duration. A definite decline in response rate was recorded as the treatment duration progressed.

CONCLUSION

Although the data amassed were vast, the limited sample size excludes any representation of a population, but does indicate trends in determining the feasibility of different aspects of the methods of data collection. Throughout research many studies lament the lack of quality studies evaluating skincare solutions in radiotherapy,[16,27,46] the study

https://doi.org/10.1017/S1460396916000315 Published online by Cambridge University Press

evaluated the RTOG grading system using simple descriptive statistics determining it to be robust and comparable as a method of recording and evaluating skin reaction and severity, with limited room for misinterpretation. The quality-of-life method of using questionnaires indicated a need for quality-of-life assessment in review to address patient concerns and emotional wellbeing in addition to the physical requirements, but greater clarity in eliciting response should be determined. The study indicated participants' desire for being proactive in skincare and the potential for other products to be of benefit in radiotherapy skin reactions. The SoR[41] recognises a reluctance to investigate the effectiveness of new products, as such this study is the first to recognise colloidal oatmeal in the treatment of radiation-induced skin reactions, but does so solely in a limited feasibility capacity to address the primary need for sound evaluation methods in order to determine the efficacy of any product. In order for significant results to drawn regarding the benefits of post treatment epithelial regeneration, larger clinical trials would need to be conducted.

Acknowledgements

The author thanks all patients who took the time to participate and S. Griffiths for her support and help in reviewing and data collection. The author thanks Dr. J Selfe and A. Brown for assistance with statistical analysis and coding support, and also thanks Dr. S. Falk and S. Willis for their support and mentorship.

Financial support

This research received no specific grant from any funding agency, commercial or not-for-profit sectors.

Conflicts of Interest

None.

References

1. Harsolia A R, Kestin L L, Grills I et al. Intensity modulated radiation therapy results in a significant decrease in clinical toxicities when compared to conventional wedge based radiation therapy. Int J Radiat Oncol Biol Phys 2007; 68 (5): 1375–1380.
2. Naylor W, Mallett J. Management of acute radiotherapy induced skin reactions: a literature review. Eur J Oncol Nurs 2001; 5 (4): 221–233.
3. Barkham A M. Radiotherapy skin reactions and treatments. Prof Nurs 1993; 8 (11): 732–736.
4. McQuestion M. Evidence-based skin care management in radiation therapy. Semin Oncol Nurs 2006; 22 (3): 163–173.
5. Aistars J. The validity of skin care protocols followed by women with breast cancer receiving external radiation. Clin J Oncol Nurs 2006; 10 (4): 487–492.
6. Harris R. Skin Care in Radiation Therapy. New Orleans, LA: ASRT, 2002.
7. Bernier J, Bonner J, Vermorken J et al. Consensus guidelines for the management of radiation dermatitis and coexisting acne-like rash in patients receiving radiotherapy plus EGFR inhibitors for the treatment of squamous cell carcinoma of the head and neck. Ann Oncol 2008; 19 (1): 142–149.
8. Byun H J, Lee H J, Yang J I et al. Daily skin care habits and the risk of skin eruptions and symptoms in cancer patients. Ann Oncol 2012; 23 (8): 1992–1998.
9. Denham J, Hauer-Jensen M. The radiotherapeutic injury–a complex 'wound'. Radiother Oncol 2002; 63: 129–145.
10. Bolderston A, Lloyd N S, Wong R K et al. The prevention and management of acute skin reactions related to radiation therapy: a systematic review and practice guideline. Support Care Cancer 2006; 14 (8): 802–817.
11. Kim S, Jary M, Mansi L et al. DCF (docetaxel, cisplatin and 5-fluorouracil) chemotherapy is a promising treatment for recurrent advanced squamous cell anal carcinoma. Ann Oncol 2013; 24 (12): 3045–3050.
12. Hymes S R, Strom E A, Fife C. Radiation dermatitis: clinical presentation, pathophysiology, and treatment. J Am Acad Dermatol 2006; 54 (1): 28–46.
13. Kumar S, Juresic E, Barton M, Shafiq J. Management of skin toxicity during radiation therapy: a review of the evidence. J Med Imaging Radiat Oncol 2010; 54 (3): 264–279.
14. Wickline M M. Prevention and treatment of acute radiation dermatitis: a literature review. Oncol Nurs Forum 2004; 31 (2): 237–247.
15. Glean E, Edwards S, Faithfull S et al. Intervention for acute radiotherapy induced skin reactions in cancer patients: the development of a clinical guideline recommended for use by the College of Radiographers. J Radiother Pract 2001; 2: 75–84.
16. Harris R. Guidelines for grade iii radiotherapy skin reactions. Prague: ESTRO, 2002.
17. Harris R, Probst H, Beardmore C et al. Radiotherapy skin care: a survey of practice in the UK. Radiography 2012; 18 (1): 21–27.
18. Salvo N. Prophylaxis and management of acute radiation-induced skin reactions: a systematic review of the literature. Curr Oncol 2010; 14 (4): 94–112.
19. Cumming J, Routsis D. Are improvements needed in the management of severe acute skin reactions following

completion of breast radiotherapy? A discussion of some possible service options. J Radiother Pract 2009; 8: 11–16.

20. Alexandrescu D T, Vaillant J G, Dasanu C A. Effect of treatment with a colloidal oatmeal lotion on the acneiform eruption induced by epidermal growth factor receptor and multiple tyrosine-kinase inhibitors. Clin Exp Dermatol 2007; 32: 71–74.
21. Sur R, Nigam A, Grote D et al. Avenanthramides, polyphenols from oats exhibit ant-inflammatory and anti-itch activity. Arch Dermatol Res 2008; 300 (10): 569–574.
22. Kurtz E S, Wallo W. Colloidal oatmeal: history, chemistry and clinical properties. J Drugs Dermatol 2007; 6: 167–170.
23. Talsania N, Coffild A, Orpin S D. Colloidal oatmeal lotion is an effective treatment for pruritus caused by erlotinib. Clin Exp Dermatol 2008; 33 (1): 108.
24. Cerio R, Dohil M, Jeanine D, Magina S, Mahé E, Stratigos A J. Mechanism of action and clinical benefits of colloidal oatmeal for dermatologic practice. J Drugs Dermatol 2010; 9: 1116–1120.
25. Kedge E. A systematic review to investigate the effectiveness and acceptability of interventions for moist desquamation in radiotherapy patients. Radiography 2009; 15 (3): 247–257.
26. Cox J, Stetz J, Pajak T. Toxicity Criteria of the Radiation Therapy Oncology Group (RTOG) and the European Organisation for Research and Treatment of Cancer (EORTC). Int J Rad Oncol Biol Phys 1995; 31: 1341–1346.
27. Russell N. A Review of the Management of Skin Reactions. Barcelona: ESTRO, 2010.
28. Russell N S, Knaken H, Bruinvis I A et al. Quantification of patient to patient variation of skin erythema developing as a response to radiotherapy. Radiother Oncol 1994; 30 (3): 213–221.
29. Hopewell J W, Van Der Kogel A J. Pathophysiological mechanisms leading to the development of late radiation-induced damage to the central nervous system. Front Radiat Ther Oncol 1999; 33: 265–275.
30. Wells M, MacBride S. Radiation skin reactions. Support Care Radiother 2003; 8: 135–157.
31. Creswell J W. Educational Research Planning, Conducting and Evaluating Quantitative and Qualitative Research, 2nd edition. Upper Saddle River, NJ: Pearson Education, 2005.
32. Hek G, Moule P. Making Sense of Research: An Introduction for Health and Social Care Practitioners, 3rd edition. Sage Publications, 2007.
33. Browman G P, Levine M N, Hodson D I et al. The head and neck radiotherapy questionnaire: a morbidity/quality-of-life instrument for clinical trials of radiation therapy in locally advanced head and neck cancer. J Clin Oncol 1993; 11 (5): 863–872.
34. Baker T L. Doing Social Research, 2nd edition. New York: McGraw-Hill Inc., 1994.
35. Kunz R, Vist G E, Oxman A D. Randomization to protect against selection bias in healthcare trials. Cochrane Database Sys Rev 2007; 2: 1–33.
36. Royal College of Radiographers. Summary of Intervention for Acute Radiotherapy Induced Skin Reactions in Cancer Patients. London: CoR, 2000.
37. Wells M, Raab G, MacBride S, Bell N, Mackinnon K, Munro A. Prevention and management of radiation skin reactions: a randomised controlled trial of skin care approaches in patients with breast, head and neck and anorectal cancer. EJC Suppl 2003; 1 (5): S207.
38. Medicines and Healthcare Products Regulatory Agency. Drug safety update. Aqueous cream: may cause skin irritation. https://www.gov.uk/drug-safety-update/aqueous-cream-may-cause-skin-irritation. Accessed on 25th March 2012.
39. Gosselin T, Schneider S, Plambeck M A et al. A prospective randomized, placebo-controlled skin care study in women diagnosed with breast cancer undergoing radiation therapy. Oncol Nurs Forum 2010; 37 (5): 619–626.
40. Heggie S, Bryant G P, Tripcony L et al. A phase III study on the efficacy of topical aloe vera gel on irradiated breast tissue. Cancer Nurs 2002; 25 (6): 442–451.
41. Society of Radiographers. Skin care advice for patients undergoing radical external beam megavoltage radiotherapy. http://www.sor.org/learning/document-library/skin-care-advice-patients-undergoing-radical-external-beam-megavoltage-radiotherapy-0. Accessed on 10th February 2015.
42. Greene J C. Mixed Methods in Social Enquiry. San Francisco, CA: Jossey-Bass, 2007.
43. Everest T. Resolving the qualitative/quantitative debate in healthcare research. Med Pract Rev 2014; 5 (1): 6–15.
44. Gosselin T, Schneider S et al. A prospective randomized, placebo-controlled skin care study in women diagnosed with breast cancer undergoing radiation therapy. Oncol Nurs Forum 2010; 37 (5): 619–626.
45. Miller R. Implementing a survivorship care plan for patients with breast cancer. Clin J Oncol Nurs 2008; 12 (3): 479–487.
46. Wells M, Macmillan M, Raab G et al. Does aqueous or sucralfate cream affect the severity of erythematous radiation skin reactions? A randomised controlled trial. Radiother Oncol 2004; 73 (2): 153–162.

APPENDIX 1

Patient Self-Assessment Questionnaire

I Patient ID number _____

II Date of Assessment _____

III Patient Name _____

https://doi.org/10.1017/S1460396916000315 Published online by Cambridge University Press

(Insert the number of weeks since previous questionnaire) _____ weeks ago, you answered a questionnaire designed for people who have received radiation treatment for anal cancer. Please repeat the questionnaire today to find out how the treatment has been affecting you and how you are coping with skincare during the past week.

Please think about how your skin has felt and how you have got on with the cream provided.

1. Have you had any pain or soreness in the treatment area in the last week?

Yes, (continue to part b)
No

Part b *How TROUBLESOME was this for you*?

A great deal
A lot
A fair amount
Somewhat
A little
Hardly any

2. Have you had any dryness of your skin, where it was treated, in the last week?

Yes, (continue to part b)
No

Part b *How TROUBLESOME was this for you?*

1. A great deal
2. A lot
3. A fair amount
4. Somewhat
5. A little
6. Hardly any

3. Have you had any itching or irritation of the skin, where it was treated, in the last week?

Yes, (continue to part b)
No

Part b *How TROUBLESOME was this for you?*

1. A great deal
2. A lot
3. A fair amount
4. Somewhat
5. A little
6. Hardly any

4. Have you had any swelling of the skin, where it was treated, in the last week?

Yes, (continue to part b)
No

Part b *How TROUBLESOME was this for you?*

1. A great deal
2. A lot
3. A fair amount
4. Somewhat
5. A little
6. Hardly any

5. Have you felt good about yourself, in the last week?

Yes, (continue to part b)
No

Part b *How OFTEN did you feel this way?*

1. A great deal of the time
2. A lot of the time
3. A fair amount of the time
4. Some of the time
5. A little of the time
6. Hardly any of the time

6. Free space for comments on the cream used, ease of application, tactility etc.

Taken from the validated HNRQ: 'The head and neck radiotherapy questionnaire: a morbidity/quality-of-life instrument for clinical trials of radiotherapy in locally advanced head and neck cancer'[33]

https://doi.org/10.1017/S1460396916000315 Published online by Cambridge University Press