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REVIEW ARTICLE

Protecting the radiation-damaged skin from friction: a mini review

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Abstract

Radiation-induced skin reactions are an unavoidable side effect of external beam radiation therapy, particularly in areas prone to friction and excess moisture such as the axilla, head and neck region, perineum and skin folds. Clinical studies investigating interventions for preventing or managing these reactions have largely focussed on formulations with moisturising, anti-inflammatory, anti-microbial and wound healing properties. However, none of these interventions has emerged as a consistent candidate for best practice. Much less emphasis has been placed on evaluating ways to protect the radiation-damaged skin from friction and excess moisture. This mini review analyses the clinical evidence for barrier products that form a protective layer by adhering very closely to the skin folds and do not cause further trauma to the radiation-damaged skin upon removal. A database search identified only two types of barrier products that fitted these criteria and these were tested in two case series and six controlled clinical trials. Friction protection was most effective when the interventions were used from the start of treatment and continued for several weeks after completion of treatment. Soft silicone dressings (Mepilex Lite and Mepitel Film) and Cavilon No Sting Barrier Film, but not Cavilon Moisturizing Barrier Cream, decreased skin reaction severity, most likely due to differences in formulation and skin build-up properties. It seems that prophylactic use of friction protection of areas at risk could be a worthwhile addition to routine care of radiation-damaged skin.

Introduction

Several recent reviews have analysed the effect of topical agents for the prevention and/or management of acute radiation-induced skin reactions.[1–4] Most of these interventions have been products that have moisturising, anti-inflammatory, anti-microbial and/or wound healing properties. Other than perhaps some of the topical corticosteroids none of these interventions has consistently been shown to prevent or reduce the severity of these skin reactions.[1,5,6] Another approach to dealing with radiation-damaged skin is to prevent further damage to the fragile skin by protecting it from friction. Database searches identified only two types of products currently on the market that provide this type of protection by adhering very closely to the creases and folds in the skin and not causing trauma upon removal; these are Safetac-based soft silicone dressings and Cavilon barrier film/cream. This review will describe the structure of the skin, the effect of radiation on the skin and the effect of these two barrier products on acute radiation-induced skin reactions.

Skin structure, turnover and repair

The outer layer of the skin protects the body from microbial, physical and chemical assault, excessive water loss and overheating. The skin is a multi-layered organ consisting of a more superficial epidermis, which confers physical protection, and the dermis which lies directly underneath. The epidermis is made up of many different cell layers grouped into strata. The deepest layer is the stratum basale, which is attached to the basement

membrane directly adjacent to the dermis. Cells of the stratum basale are the epidermal stem cells that undergo regular asymmetrical division to produce another basal stem cell and a keratinocyte, which is pushed towards the skin surface as the basal stem cell continues to divide. Keratinocytes differentiate on their journey towards the cell surface as they become part of the stratum spinosum, stratum granulosum, stratum lucidum and finally the most superficial stratum corneum. The stratum corneum forms the physical part of the skin barrier; it consists of many layers of flattened dead keratinocytes packed with keratin, surrounded by an envelope of cross-linked proteins and lipids and embedded in a lipid-rich extracellular matrix.[7,8] Keratinocytes are normally shed from the epidermis by desquamation; the rate of basal cell division adjusts to the rate of keratinocyte loss to maintain epidermal integrity. In healthy individuals, a newly formed keratinocyte takes 2 weeks to reach the stratum corneum and another 4 weeks to traverse the stratum corneum with the entire epidermis being replaced by new cells every 48 days.[7] Basal stem cell damage is repaired by a change in cell division pattern of adjacent cells; these now divide symmetrically in a plane that is perpendicular to the skin surface, replenishing the stem cell population. If damage to the stratum basale is not too extensive, migration of basal cells from the side into the damaged area reconstitutes the basal layer, which will then replenish the epidermis over time.[8] The dermis provides strength to the skin structure; it is primarily composed of areolar and reticular connective tissue. Damage extending into the dermis is always accompanied by inflammation and leucocyte infiltration to remove damaged cells and debris and promote migration of basal stem cells and fibroblasts into the damaged area. However, with respect to wound healing, inflammation has also been shown to promote scarring.[8–10]

Radiation-induced skin damage

Different stressors produce different types of skin damage. Mechanical assault can produce lacerations, punctures and abrasions, whereas heat and chemicals burn the skin. Radiation damages the DNA of the skin's stem cells, interfering with normal tissue turnover. Exposure to UVB generates dimers between adjacent pyrimidine bases (particularly thymine) on the DNA which are relatively easily repaired by nucleotide excision repair.[11] Radiation therapy employs high-energy X-rays, gamma rays or electrons that damage the DNA by direct ionisation or by the action of reactive oxygen species (ROS) formed through ionisation of water molecules in the nucleus. DNA damage includes base damage, cross linking of the DNA strands, single-stranded DNA breaks and double-stranded DNA breaks. The latter are the most difficult to repair as there is no undamaged complementary strand to use as a template. Double-stranded breaks are fixed most effectively by homologous repair which occurs during the late S/G2 phase of the cell cycle when sister chromatids or homologous chromosomes are in close proximity and can act as templates. Homologous recombination takes 6–8 h to complete and during this time the damaged cell is very vulnerable to additional damage by friction.[12,13]

The acute damage done to the skin by radiation is uniquely different from all other forms of skin damage. Although only a certain number of basal stem cells are damaged during the first radiation exposure, cells continue to be exposed to radiation on a daily basis for 4–7 weeks. Damaged basal stem cells in the epidermis and fibroblasts in the dermis produce cytokines, which recruit circulating immune cells, such as neutrophils and macrophages. Additional mast cell degranulation and T lymphocyte recruitment all contribute to the inflammatory environment which leads to chronic free radical production in addition to the daily transient free radical storm produced by the radiation treatment. This relentless free radical assault leads to in an increasingly large deficit in basal stem cells, responsible for the radiation-induced side effects.[3,8,14]

The severity of radiation-induced side effects is related primarily to aspects of the treatment regimen, such as the dose per fraction, total dose, use of bolus, size of treatment field, site treated and the use of concurrent chemotherapy. Skin that has received a total dose of 30–40 Gy is at risk of developing moist desquamation, with the higher dose more likely to result in ulceration.[1,3,8,15] The effects of patient-related aspects on skin reaction severity are less clear. Although smoking, chronic sun exposure, obesity and old age have all been linked to more severe skin reactions[1,14,15] these observations have not been consistent across all studies.[16–19]

With respect to location, the worst skin reactions are typically found in the axilla, which is the most likely area to experience a lot of friction due to normal arm movements, the close proximity of items of clothing and a build-up of perspiration. Other areas that are prone to moist desquamation in breast cancer patients are the inframammary fold, particularly of large-breasted women, and other skin folds in obese patients.[20–22] This can not only be attributed to the dose build-up effect of skin folds but also to the fact that these skin folds tend to be moist due to increased perspiration and decreased evaporation. Head and neck cancer patients and anal cancer patients are also likely to develop moist desquamation. Although skin hydration is important for skin homeostasis,[7] an increase in hydration levels does lead to an increase in friction of skin against fabric,

which causes more abrasion damage.[23] In addition, excessive hydration can lead to softening of the skin (maceration), loss of mechanical strength and greater susceptibility to injury.[24]

Preventing additional skin damage

Management of diabetic ulcers, venous stasis ulcers and other slow healing wounds includes measures to reduce breakdown of the wound edges by friction and maceration.[25] However, additional damage to the radiation-damaged skin by friction is not something that has received a lot of attention in the literature. There is no gold standard for the prevention or management of radiation-induced skin reactions as evidenced by a number of review articles in the last few years.[1–4] Although there is evidence that some steroids may have some efficacy,[1,5,6] the vast majority of topical agents investigated do not affect the incidence or the severity of acute radiation-induced skin reactions. A new approach may be needed in the quest to find interventions for radiation-induced skin reactions. Protecting the irradiated skin from friction may be at least as effective as decreasing inflammation.

Methodology

Electronic databases (Medline, Ovid), websites and reference lists were searched, using the keywords radiation therapy, moist desquamation, friction, barrier and protection in the period 1990–2013. Relevant studies proceeded to quality assessment and analysis. Only peer-reviewed prospective studies that used topical agents that prevent mechanical damage or friction were included in this review. Studies that used topical agents that provide a moist wound environment, have anti-inflammatory or specific wound healing properties were excluded.

Results

Studies that fitted the eligibility criteria could be grouped under two different types of interventions: Safetac-based soft silicone dressings and Cavilon barrier products. Both types of products closely adhere to the skin, do not cause trauma upon removal and minimise friction damage. Some studies used these barrier products for wounds other than those caused by radiation; these have been mentioned in the review to provide context. With respect to radiation-damaged skin, six controlled clinical trials were identified that investigated the effect of soft silicone dressings[21,22,26,27] and Cavilon barrier products,[28,29] on the incidence and severity of acute radiation-induced skin reactions (Table 1). In addition, two case series[30,31] were identified that focussed mainly on the tolerability of soft silicone dressings. A number of soft silicone dressings from manufacturers other than Mölnlycke are currently on the market; however, these have not been tested in controlled clinical trials.

Soft silicone dressings

Soft silicone dressings have a skin contact layer of a flexible polyamide net coated with soft silicone using the patented Safetac technology from Mölnlycke Healthcare (Gothenburg, Sweden). Silicone is completely inert and adheres gently to intact skin, following its contours and preventing friction of skin rubbing against items of clothing or against skin from other body parts, while providing a moist wound healing environment. The dressings do not adhere to open wounds and can be removed without causing trauma or pain or damaging

Table 1. Overview of the clinical trials that have used barrier products to decrease acute radiation-induced skin reactions.

Product	Control	Patient numbers	Scale	Results	Reference
Mepilex Lite	Aqueous cream	24	RISRAS	30% decrease in erythema	21
Mepilex Lite	Aqueous cream	74	RISRAS/RTOG	40% decrease in overall skin reaction severity	26
Mepilex Lite	Mild salt washes	88	RISRAS	Decrease in moist desquamation healing times from 23 to 16 days	27
Mepitel film	Aqueous cream	78	RISRAS	92% decrease in overall skin reaction severity, decrease in moist desquamation from 26% to 0%	22
Cavilon no sting barrier film	Sorbolene	61	RTOG	Decrease in incidence on moist desquamation from 46% to 33%	28
Cavilon moisturising durable barrier cream	Sorbolene	333	CTCAE v3	No difference between treatment and control arms	29

RISRAS, radiation-induced skin reaction assessment scale; RTOG, Radiation Therapy Oncology Group; CTCAE v3, common terminology criteria for adverse events version 3.

newly formed skin or fragile wound edges. The atraumatic nature of the dressings was demonstrated in two studies that evaluated the use of Mepitel in fixation of skin grafts in children[32] and adults.[33] A large multinational study ($n = 3034$) in patients with leg ulcers, burns, skin tears, pressure ulcers and diabetic foot ulcers showed that Safetac-based soft silicone dressings caused less pain and trauma during dressing changes than hydrocolloids, adhesive foams, surgical dressings and alginates.[34] These dressings have also been used in the management of children with burns[35] and adults with arterial leg ulceration.[36] Soft silicone dressings were first tested on radiation therapy-treated skin of 21 patients in Germany in 1995. Adamietz and co-workers reported that Mepitel did not cause any skin irritation and could be used on intact skin as well as on skin that had developed dry or moist desquamation.[30] Another case series by McBride and colleagues evaluated patient comfort and tolerability of Mepilex Lite dressings in eight breast and eight head and neck cancer patients recruited from two radiation therapy departments in Sweden and Scotland.[31] They reported that the dressings were soothing and well tolerated, did not cause pain on removal and did not negatively affect the healing of moist desquamation.

Three randomised controlled clinical trials conducted in New Zealand by Herst and colleagues have evaluated the efficacy of soft silicone dressings on the incidence and severity of acute radiation-induced skin reactions. Two were intra-patient controlled management trials, applying Mepilex Lite dressings to the breast or chest wall of breast cancer patients after erythema became visible.[21,26] The erythematous area was divided into two equal halves which were randomised to either Mepilex Lite or aqueous cream. Both trials measured skin reaction severity using the validated modified Radiation-Induced Skin Reaction Assessment Scale (RISRAS), which is more sensitive than the more commonly used Radiation Therapy Oncology Group (RTOG)/World Health Organisation (WHO)/ Common Terminology Criteria for Adverse Events (CTCAE) scales and has an additional patient component where patients score the level of pain, burning, itchiness and the effect of the skin reactions on daily life.[31,37] These two management trials showed a significant 30–40% decrease in skin reaction severity in 24 breast cancer patients ($P < 0.001$)[21] and 74 post-mastectomy patients ($P < 0.001$).[26] Although Mepilex Lite dressings decreased skin reaction severity, they did not affect moist desquamation rates. Other disadvantages of Mepilex Lite dressings were that they do not stick well in the axilla, when perspiring or in the shower, have a small bolus effect (0.5 mm)[21] and need to be replaced twice a week.

Even though skin reactions will not be visible until the second week of radiation treatment, basal stem cells will be damaged at the time of the first radiation fraction and at every consecutive fraction after that. Damaged cells need time to heal without sustaining additional damage due to excessive moisture and friction against clothing and skin of other body parts. Applying a protective dressing from the very beginning of treatment is likely to be more effective than applying the intervention once radiation damage is visible.

The third soft silicone clinical trial, therefore, used a different dressing, Mepitel Film, in a prophylactic setting.[22] Mepitel Film is thin, more flexible, adheres better to skin folds, stays on during showering, is transparent, has a negligible bolus effect (0.12 mm) and thus can be left on for 1 or 2 weeks. This trial followed the same randomised inpatient controlled design as the previous two trials and recruited 80 breast cancer patients, 34 of whom had had a mastectomy and 46 patients who had not. The results of 78 analysable patients showed that Mepitel Film completely prevented moist desquamation and reduced skin reaction severity by 92% using the RISRAS scale. The skin covered in aqueous cream developed moist desquamation in 26% of patients. In order to facilitate a direct comparison with other skin trials this trial also reported RTOG skin severity scores. For Mepitel Film-covered skin patches 36% of patients scored grade I and 8% scored grade IIA; however, for cream-covered patches the scores were 28% grade I, 46% grade IIA, 18% grade IIB and 8% grade III. With respect to costs, five strips of Mepitel Film and 10 min nursing time per dressing change cost NZ$60, which was enough to protect the axilla; this figure doubles if the inframammary fold also needs to be covered.[22] It is important to note here that the dose to the skin of the patients in this trial did not exceed 40 Gy. It is likely that at much higher skin doses, prevention of friction will not prevent moist desquamation.

Due to the very visible differences between film and dressings on the one hand and aqueous cream on the other hand, all three trials were limited by the inability to blind either the researcher or the patients to the treatment arms. This is a common limitation of skin trials that use easily discernible topical interventions.

All patients in these three trials were given exit questionnaires that gave them the opportunity to describe their experiences with using Mepilex Lite or Mepitel Film. The vast majority preferred the Mepilex Lite (80%)[26] and Mepitel Film (95%)[22] over aqueous cream and commented specifically on how comforting it was to wear something protective over their skin, that the dressings and film felt protective, decreased pain and itchiness and allowed them to wear normal clothing. Some patients commented that Mepitel Film rolled up at the edges and was visible. With respect to side effects, four out of 78 patients found that the skin under the

Film was itchy and two out of 74 patients reported the same for Mepilex Lite.[26] Itchy skin underneath Mepilex Lite was also reported by McBride et al.[31] for two of their 16 patients.

A fourth randomised controlled trial (RCT) by Zhong and colleagues[27] investigated the effect of Mepilex Lite dressings on wound healing in 88 patients with nasopharyngeal carcinoma who were treated with 60–66 Gy to the neck area and 40 mg/m^2 cisplatin for seven cycles. In this study, patients presenting with moist desquamation were divided into two groups; Mepilex Lite was applied to the wound in the treatment group whereas wounds in the control group were washed with salted water. Time to healing, wound pain, sleep disturbance, appearance and restriction of neck movement were compared between treatments. Skin reaction severity was assessed three times a week using RISRAS. Mepilex Lite dressings significantly improved healing time (from 23 to 16 days; $P = 0.009$) and sleep ($P = 0.005$) and did not affect neck movements or appearance.

Cavilon no sting barrier film/cream

The wound margin of exudating chronic wounds, such as diabetic foot ulcers and deep venous stasis ulcers, is continually exposed to excess moisture which leads to local maceration, delay in healing, wound enlargement and can be very painful. Water impermeable barrier films or creams underneath wound dressings stabilise wound margins and facilitate healing. There are four classes of barrier products: petrolatum, zinc oxide paste, hydrocolloids and film-forming liquid acrylates.[25] One of these liquid acrylates is Cavilon No Sting Barrier Film (NSBF) from 3M (3M Global, St. Paul, MN, USA) which is sprayed onto intact or damaged skin to form a long-lasting waterproof barrier. It protects the skin from wound fluids, body wastes, perspiration and friction.[38,39] Schuren and colleagues conducted a systematic analysis comparing the effect of NSBF, petrolatum, zinc oxide and hydrocolloids on peri-wound protection.[25] Although the quality of the clinical research was generally poor with very small patient numbers and very short, if any, follow-up times, the review found no difference in peri-wound protection between the different barrier products. Petrolatum and zinc oxide were difficult to remove and interfered with the function of other dressings. NSBF had the advantages of being transparent, easy and quick to apply and remove without causing pain [25] and was cost effective.[28,40–42]

Two intra-patient controlled clinical trials, both conducted by Graham and colleagues in Australia,[28,29] investigated the effect of Cavilon products on the incidence and severity of acute radiation-induced skin reactions. In the first trial, the post-mastectomy chest wall of 61 patients was divided into a lateral and medial compartment at the start of radiation treatment and randomised to either NSBF or sorbolene cream (aqueous cream plus 10% glycerine).[28] Products were applied from the start of radiation until 2 weeks after completion of treatment. Patients were assessed weekly for skin reaction severity (using RTOG skin scores), pain and pruritus (using a 5-point Likert scale questionnaire) for up a total of 12 weeks. The study showed that NSBF significantly reduced the incidence of moist desquamation (from 46% to 33%; $P = 0.049$). Moist desquamation was treated with hydrocolloid dressings. Skin reaction severity was significantly lower in favour of NSBF; 54% of skin compartments covered with film and 75% of skin compartments covered with sorbolene had RTOG scores of >2 ($P = 0.002$). In addition, pruritus, but not pain, was significantly reduced in the skin treated with NSBF ($P = 0.012$). Costs per patient would be very similar between the NSBF and sorbolene if moist desquamation dressings and nursing time were to be included (AUS $145).[28]

These results were very promising. However, as with the three previous clinical trials, this study was also limited by its lack of blinding. In order to circumvent this limitation, the authors conducted a large ($n = 333$) double-blinded multicentre follow-up RCT with a slightly different formulated Cavilon Moisturizing durable barrier cream (MDBC), which was indistinguishable from the sorbolene cream.[29] Like the previous trial, the post-mastectomy chest wall was divided into a lateral and medial compartment and interventions used from the start of radiation therapy till 2 weeks after completion of treatment. Patients were seen once a week for up to 12 weeks to score skin reaction severity (CTCAEv3), pain and pruritus (5-point Likert score questionnaire). As with the first trial, skin reactions in the lateral compartment were significantly more severe than in the medial compartment but unfortunately there was no difference in moist desquamation incidence (55% for both arms), skin reaction severity, pain or pruritus between the two treatment arms. The authors suggest that the failure of the larger double-blinded trial to differentiate between the barrier cream and sorbolene was due to the fact that the acrylate terpolymer used to make the cream was different from that used to make the film. In addition, the film caused a build-up of material on the skin when applied two (medial compartment) or three (lateral compartment) times a week whereas the cream did not cause a clinically detectable build-up with daily application, indicating that this protocol did not deliver the level of friction protection that the film did in the first trial.[29]

Concluding Remarks

From the results of the trials described in this mini review it seems that prophylactic protection of vulnerable areas such as the axilla and inframammary fold in breast cancer patients, may prevent or at least decrease the severity of radiation-induced moist desquamation in breast cancer patients, enhancing their quality of life as well as minimising treatment breaks. With respect to silicone dressings, only Mepitel Film can be left on during radiation therapy because of its insignificant bolus effect. However, it is important that Mepitel Film is applied correctly; different pieces of Film must not overlap and the Film must be applied with the patient in treatment position, so the shape of the breast is not altered in any way.

Overall, the prophylactic use of friction protection of areas at risk could be a worthwhile addition to routine skin care during radiation therapy.

Conflict of Interest

The author has no conflict of interest to declare.

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