Polymeric membrane dressings for radiotherapy-induced skin damage

Audrey Scott

Abstract

Radiotherapy is one of the mainline treatments for cancer. One of the side effects associated with radiotherapy includes skin problems, which range from mild (dull erythema and tightening of the skin) to severe (moist desquamation resulting in open wounds that can be very painful associated with sloughy and, in some severe cases, necrosis). The increased use of advanced radical treatments, such as intensity-modulated radiotherapy treatment (IMRT), can also result in a higher number of patients experiencing skin reactions. It is estimated that approximately 87% of patients will experience a moderate-tosevere skin reaction (Harris et al, 2011) An evaluation was undertaken in 20 patients with head and neck cancer following a prescribed treatment of radiotherapy to compare a polymeric membrane dressing (PolyMem®) against the standard treatment. The standard treatment consisted of topical aqueous cream at the start of radiotherapy with the addition of paraffin gauze when moist desquamation occurred. A bespoke evaluation form was completed for a period of 4 weeks or until healed. Patients were asked to complete both qualitative descriptions and numerical scores of pain for symptoms and procedural pain. Analgesia and sleep patterns were logged and, in addition, free text diaries were provided for up to 4 weeks. Common themes were identified and qualitative data analysed.

Key words: Radiotherapy ■ Skin damage ■ Polymeric dressings ■ Best practice

here are numerous factors that affect the severity of radiotherapy-induced skin reactions including the area of the body treated, dose of radiotherapy, number of fractions of radiotherapy delivered, concomitant treatment (i.e. chemotherapy), age and other patient comorbidities. Radiotherapy involves various specialist clinicians who make up the multidisciplinary team. This includes surgeons, oncologists, radiotherapists, the pain team, and hospital and community nurses who are often left to deal with the side effects (Trueman, 2013).

Radiotherapy is specifically designed for each individual patient, taking into consideration the type and location of the tumour, weight and general health. Once prescribed, the delivery dose is normally administered for up to 6 weeks.

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RTOG scales

In the evaluation described in this article, the delivery dose of radiotherapy was considered important with regards to skin damage. The Radiation Therapy Oncology Group (RTOG) acute radiation morbidity scoring criteria (Trueman, 2013) is commonly used to classify the skin reaction ranging from 0-4 (Figure 1). All patients' radiotherapy doses were recorded at the beginning of the evaluation and monitored on a weekly basis. It was assumed that the higher the dose of radiation, the more severe the skin reaction would be. Patients undergoing standard radiotherapy would receive a dose of up to 64Gy in 32 fractions. However, 65Gy in 30 fractions is the standard intensity-modulated radiotherapy treatment (IMRT) dose given to the head and neck patients undergoing radical treatment at the author's organisation. All patients selected for the evaluation had RTOG scales between 1 and 2.5 (Table 1) at the start of the study. One of the most significant findings in this study included the decline in wound pain scores from weeks 1-3, both on the numerical rating description and on Wong and Baker (1988) FACES[®] pain grades listed by clinicians and patients.

While it is unlikely that most skin reactions can be prevented, the aim should be try to prevent them, and when they do occur, to minimise the symptoms. Although wound care dressings have evolved over recent years, many UK radiotherapy departments are using a variety of products recommended in previously published guidelines (Delaney et al, 2005; Hornsby et al, 2005; Truman, 2011). This evaluation has highlighted concerns over products that are potentially contraindicated for use with radiotherapy.

Study objectives

The objectives of this study were to evaluate whether or not a polymeric membrane dressing (PolyMem®, Aspen Medical, Redditch) is effective for the management of patients presenting with an RTOG score of between 1 and 2.5 over a 4-week period. In particular, to assess its performance in the following:

- Improving skin integrity
- Managing dry and moist desquamation
- Relieving pain and inflammation
- Improving quality of life, particularly sleep patterns
- Patients' and clinicians' rated dressing satisfaction and performance as very good; good; satisfactory; or poor.

Compared with standard treatment

The standard treatment for radiotherapy-induced skin reactions before this evaluation at Mount Vernon Cancer



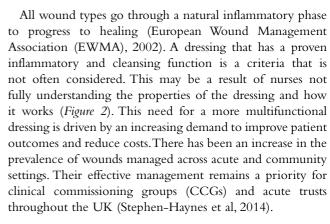
Figure 1. Radiotherapy skin reaction

Table 1. RTOG Acute Radiation Morbidity Scoring Criteria	
Score skin reaction	(Cox et al, 1995)
RTOG 0	No visible change to skin
RTOG 1	Faint or dull erythema; mild tightness of skin and itching
RTOG 2	Bright erythema/dry desquamation; sore, itchy and tight skin
RTOG 2.5	Patchy,moist desquamation; yellow/green exudate; soreness with oedema
RTOG 3	Confluent moist desquamation; yellow/pale green exudate; soreness with oedema
RTOG 4	Ulceration, bleeding, necrosis (rarely seen)

Centre was topical aqueous cream at the start of treatment, with the addition of paraffin gauze for moist desquamation.

A plethora of advanced wound care dressings have been on the market since Winter's (1962) seminal work that stated that wounds heal quicker in a moist environment (Jones, 2005). Clinicians are increasingly expecting dressing manufacturers to meet additional criteria such as the ability to absorb and retain moisture, reduce pain on application and increase wear time. Examples of dressings used in radiotherapy have included:

- Mepitel[®] (Mölnlycke Health Care Ltd)
- AllevynTM (Smith & Nephew UK Ltd)
- Atrauman[®] (Paul Hartmann Limited)
- Aquacel[®] (Convatec Limited).



The dressings used in this evaluation

The non-adhesive PolyMem dressings were used throughout the evaluation and were adapted to suit the patients' needs by the nursing staff following training and support from the local representative, particularly with regards to fixation techniques and wear time. For example, PolyMem Roll Dressing is adapted for neck fixation and secured with a tracheostomy tube holder or fixed using tape.

Cost effectiveness

During this study the amount of cleansing required during dressing changes was documented. PolyMem® contains glycerol and a surfactant F68 that, when activated with wound fluid, negates the need for cleansing and reduced inflammation, thereby saving time and exposure of the skin during dressing changes. The reduction in inflammation promotes comfort and reduces pain, which in turn reduces the amount of medication. Wear time, prescribed analgesia and healing rates were documented. This study demonstrated a reduction over the 4-week period in all of the above. Eight of the patients or their carers felt confident enough to change the dressings themselves, reducing the need for home or hospital visits (Panca et al, 2013). However, further studies would be needed to demonstrate statistical cost savings.

How polymeric membrane dressings work

Polymem is a thin non-adherent polyurethane foam dressing that contains glycerol and surfactant F68. The glycerol and surfactant work in partnership to provide:

- Cleansing of the wound while in situ (*Figure 2*)
- De-sloughing
- Moisturisation of the periwound area



Figure 2. Dressing in situ. Application for head and neck cancer patients (Trueman, 2011)

PRODUCT EVALUATION

- Reduce of inflammation
- Pain relief while in situ (*Figure 2*).

Surfactant F68

Surfactant (F68) helps keep wounds clean and support cell repair along with helping to break the chemical bonds, adhering slough to healthy tissue (Rodeheaver et al, 1975).

Non-toxic wound-cleansing agent (F-68 surfactant) is activated by moisture and gradually released into the wound bed. This reduces interfacial tension between healthy tissue and debris, loosens eschar and necrotic tissue, and supports autolytic debridement—all while keeping the wound bed clean throughout healing (Charalambos, 2012).

Glycerol

Glycerol (moisturising agent), a hygroscopic (capable of easily absorbing moisture) compound helps to regulate moisture levels at the skin's surface, maintains a moist wound-healing environment and prevents the dressing from adhering to the damaged area. Together with other components, it creates a 'water flux' effect within the wound, bringing fluid from the deeper tissues, which contain healing agents such as nutrients and growth factors (Waller and Maibach, 2006).

Glycerine reduces odour. Wound odour can be distressing for patients with skin damage and malodour is often linked to infection (Wounds UK, 2010). The combination of ingredients in Polymem helps to reduce the spread of inflammation, swelling and pain into surrounding areas of undamaged tissue. This helps to prevent further injury and helps the body to repair more effectively (Charalambos and Koulermou, 2010; Davies and White, 2011; Rafter and Oforka, 2013).

Benefits of PolyMem

PolyMem has been proven to:

- Create an osmotic environment that pulls the fluid from the deeper tissues (Waller and Mailbach, 2006)
- Reduce pain: Evidence suggests that the dressing absorbs sodium ions. Sodium ion production is increased when injury occurs and is required for the action potential during nerve signaling for pain sensation. A local decrease in sodium-ion concentration results in reduced nociception nerve conduction, thus providing pain relief (Ricciardo, 2007)
- Reduce the spreading of inflammation and generally reduce interstitial oedema, resulting in pain reduction (Denyer, 2010)
- Reduce pain as a result of reduced dressing changes (Charlambos and Koulermou, 2010)
- Reduce exudate: The polyurethane membrane matrix wicks away up to ten times its weight in exudate. It will not fragment and leaves no residue in the wound bed. The superabsorbent starch copolymer in PolyMem absorbs and binds the water molecules from the wound fluid, allowing the natural growth factors and nutrients to concentrate in the wound bed (Kim et al, 1999)
- Reduce oedema: Evidence suggests that a cell and tissue oedema cause over granulation. Therefore, a reduction of

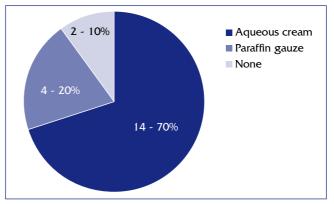


Figure 3. Skin treatment at the start of the study

overall oedemas should reduce this risk (Bateman, 2011; Haik et al, 2011)

Provide an effective barrier: The semipermeable thin film backing provides a liquid barrier while allowing gas (O₂ and CO₂) exchange and maintaining an ideal Moisture Vapour Transmission Rate (MVTR). The film backing allows for visual inspection that determines the need for a dressing change (Bateman, 2011).
 Method

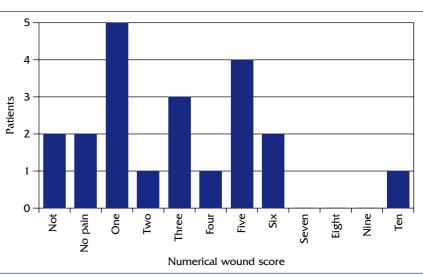


Figure 4a. Wound pain score (not related to dressing proceedure) week 1

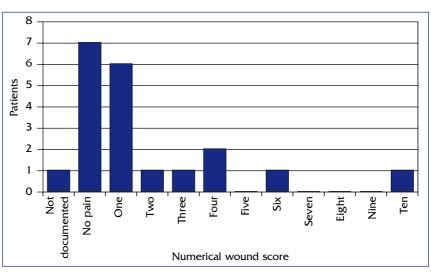


Figure 4b. Dressing pain score week 1

Ltd

The aim of this study was to evaluate whether or not PolyMem was effective in the management of patients presenting with RTOG rates of between 1 and 2.5 by improving skin integrity, managing dry and moist desquamation, relieving pain and inflammation and improving quality of life. Consent was obtained using the Mount Vernon Trust's evaluation protocol. Patients had to be over the age of 18, and competent to give written and verbal consent. Any patient was able to withdraw from the evaluation at any time. A bespoke evaluation form was developed in line with the author's requirements along with support from Aspen Medical Ltd to capture detailed information on the patient's age, gender, radiotherapy dosage, nutritional status, cancer type and location, RTOG rating, wound-pain score and pain at dressing change. The study consisted of baseline details and continued for a maximum of 4 weeks. This timeframe was agreed with the local clinicians involved. Each week, the RTOG rating, wound size, location and description, pain score of wound, pain associated with dressing change and dressing wear time was completed by the clinician (head and neck specialist nurse) applying the dressings.

Patient involvement

Patients were provided with a diary to keep a daily record of their wound-pain score using both a numerical scale and the Wong and Baker Face scale (Wong and Baker, 1988). The numerical pain score ranged from 10 (most severe pain) to 0 (no pain). The Wong and Baker tool was designed primarily for children using six faces ranging from happy to sad depending on how the patient experienced pain. Patients were provided with information leaflets about the evaluation and which products were being evaluated. The nursing team explained how to complete the forms as patients were recruited into the evaluation, logging whether the pain was related to the cancer or dressing change. Pain medication and sleep patterns were recorded by the patients themselves but sleep patterns were also monitored by staff. The patients were asked to complete a personal 'free-text diary' during the evaluation. The comments provided a unique insight into how patients were coping on a daily basis. Themes related to the dressing included pain reduction, dressing conformability and comfort.

Results

A total of 20 patients were recruited consisting of 17 men and 3 women, with a mean age of 56.8 years. All patients had a primary diagnosis of head and neck cancer and 30% of patients had a primary diagnosis of squamous cell carcinoma of the larynx. Although all patients were given aqueous cream to use from the start of their treatment, only 16 (80%) had either aqueous cream or parrafin gauze prior to the application of the Polymem dressing (*Figure 3*).

The majority of patients in this study did not show any signs of radiotherapy-induced skin reaction before 5 days of treatment. This is because skin damage does not present when the first dose is given; it can take anywhere from 5 days to 3 weeks to develop (Trueman, 2011). The author predicted that patients receiving higher doses of radiotherapy would have a higher RTOG skin reaction. The majority of patients (55%) in this study received a dose of 65Gy in 30 fractions.

All patients enrolled into the evaluation had various RTOG radiotherapy-induced skin grading scale damage. A total of 13 patients (65%) presented with an RTOG score of 2; five patients (25%) with an RTOG score of 2.5; and two patients (10%) with an RTOG score of 1. No patients were rated as 3 or 4 in this study.

It has long been established that good nutrition aids healing (EWMA, 2008). The nutritional status of patients entering this study was found to be important, particularly as some were receiving nutritional supplements via tube or percutaneous endoscopic gastrostomy (PEG). Eight patients (40%) were considered to have good nutritional status, using the Malnutrition Universal Screening Tool 'MUST' (Elia, 2003), while seven (35%) were being fed via a PEG system. Patients that appeared to have compromised nutrition had a higher RTOG rating. Further investigation would be required to establish if this was statistically significant.

Improved healing rates

According to the patients' notes and clinical observations, the PolyMem dressing in both dry and moist desquamation demonstrated a reduction in skin reactions within the first week of treatment. Eight patients had healed within a week. One patient withdrew after 2 days, as he could not tolerate any dressings on his neck, finding them to be restrictive. Five patients' skin had healed by week two. Two patients had healed and two had stopped using the dressing but no reason was documented by week three. The remaining two patients at week four continued with the PolyMem dressing and their notes stated that the skin was improving but not quite healed. Overall, 15 (75%) patients' skin reactions had healed.

Patient diaries

Patient diaries provided valuable insight into the challenges for patients being diagnosed with head and neck cancer and managing radiotherapy treatment. Patients were asked to measure pain scores, in both symptomatic pain and pain on dressing changes to observe skin condition once desquamation was diagnosed. Figure 4 shows patient-reported pain both in relation to wound pain (Figure 4a) and dressing-related pain (Figure 4b) after the first week. Patients were also asked to record how long the dressings remained in place and when and by whom they were changed. Sleeping patterns were recorded over a 24-hour period. It is appreciated that stress, pain and prognosis will always have an impact on a patient's ability to sleep. Initially, two patients recorded no sleep but as the evaluation time extended, sleep patterns improved. How significant these findings were for these patients would be difficult to accurately measure as there are so many variables that will affect the way in which patients find rest.

Tissue types

Skin damage does not present immediately (Hornsby et al, 2005; Harris et al, 2011; Trueman, 2011). However, all patients entering the study had an RTOG score of 1–2.5 (moist desquamation). Patients entered the evaluation when the skin broke down, i.e. 4–5 days after treatment commenced as this was the criteria set out by the clinicians.

However, had it been used earlier, it may have prevented or reduced the incidence. This may be something to explore in a future study. The tissue types were documented over the 4-week period of the study by the nurses at Mount Vernon. Some patients were rated using three or more categories; for example, dry, flaky, macerated, sloughy and crusting skin, particularly in more severe examples. Interestingly, the severity of the skin reaction appeared to be more directly related to the nutritional status of the patients (Kemp, 2001; Cartwright, 2002), rather than the radiotherapy dosage. This was indicated by those patients receiving PEG feeds, or those patients that had mucositis.

Wound cleansing

Two of the patients' records had not documented the amount of cleansing required, whereas 13 patients (65%) had their skin irrigated by nurses to clean it before dressing change. By week three, only six patients required cleansing, as the majority of patients had healed.

Pain

Polymeric membrane dressings have been used successfully for patients with skin reactions graded RTOG 2 and above, both during and after treatment (Trueman, 2011). Similarly, research has demonstrated that sodium ions contribute to the body's pain response and that polymeric membrane dressings absorb these ions from the outer layers of the epidermis (Kahn, 1999), thus helping to ameliorate background (somatic) pain (Beitz et al, 2004; Davies and White, 2011).

In this study, analgesia and sleep patterns were considered important elements of measurement. Clinicians were asked to complete a numerical pain score that was disease-specific and then related to dressing changes both on entry to, and during, the evaluation. Patients were encouraged to take an active role in this evaluation and were provided with a diary to keep a daily record of their wound pain score using both numerical and Wong and Baker (1988) scales. This included description of pain such as sharp/stabbing or burning. Patients were asked to record whether they felt the pain was related to disease or dressing change. Patients were also asked to document any analgesia taken, and this was related to the World Health Organization (WHO) analgesic ladder (WHO, 1986).

One of the most significant findings in this study was the rapid decline in wound pain scores between weeks one and three, both on the numerical rating description and the Wong and Baker (1988) pain grades as listed by clinicians and patients. It must be remembered that by week one, eight patients had already healed, and one had withdrawn, leaving a total of 11 patients. *Figure 5* shows patients' mean self-reported pain scores.

Analgesia

In 1986, the WHO presented the analgesic ladder as a framework that physicians could use when developing treatment plans for cancer pain. Using this tool, patients were asked to record the time and type of analgesia taken and whether it had an impact on perceived pain and pain management. Based on individualised patient assessment, the majority of patients took a combination of codeine,

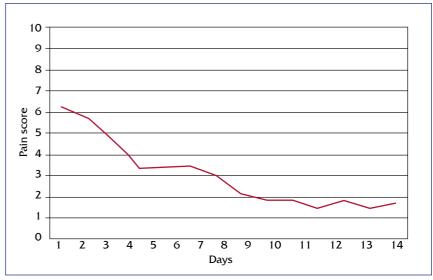


Figure 5. Mean patient pain score

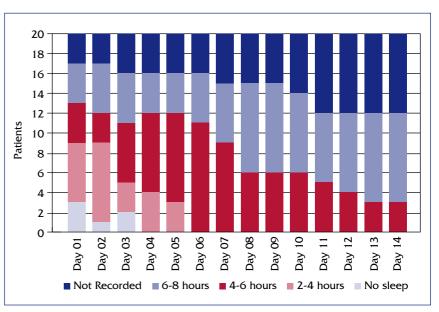


Figure 6. Patient diary sleep patterns

cocodamol and paracetamol during the first 14 days. Only 4 took opiates. It was interesting to note that after 2 weeks, 11 patients had healed and did not continue to document their medication.

This does necessarily mean they were not taking it but it was outside of the study remit to investigate this beyond recording patient documentation. It was also not possible to establish whether the use of the dressing reduced the need for analgesia, which was a key part of the evaluation. However, when comparing the notes with the patient free-text diaries, the information gathered supported the conclusion that the dressing had an impact on both a reduction in pain and healing rates. Patients reported a specific reduction in wound pain and increased comfort when using the dressing. Therefore, it can be assumed that these reports are a direct result of the dressing and not any analgesia patients may have been taking. However, this evidence could have perhaps been made more robust through the use of more probing questions.

KEY POINTS

- All patients undergoing radiotherapy will develop some degree of skin reaction
- The challenge for the radiotherapy team at Mount Vernon continues to be reducing skin damage where possible and encouraging healing in costeffective ways
- Patient involvement through completing the free-text diaries gave real insight into patients' experience
- This study details the benefits of using advanced wound dressings such as PolyMem[®] in the management of radiotherapy-induced skin damage

Sleep patterns

Sleep patterns are rarely considered in dressing evaluations. Being diagnosed with cancer can have a psychological impact on the patient and their family, and sleep is an important process that aids healing and is often linked to pain and stress (Espie et al, 2008). Patients with moist desquamation can often report itchy, burning, painful wounds and this can lead to a reduction in sleep. Therefore, the author felt that if the dressings were able to reduce inflammation and pain, sleep patterns would improve. This was confirmed by patient diaries. By day six, all patients that maintained the pain diaries were sleeping 4-8 hours within a 24-hour period (Figure 6). It should also be noted that none of the patients were taking sleeping tablets or engaging in relaxation techniques, so their improved sleep can be seen to be a direct result of the dressings. They were also not prescribed anything else that could have affected their wound healing. This record was reflected in the free-text diaries.

Free-text diaries

The information gained from the free-text diaries gave valuable insight into patients' experience. A total of 13 diaries were returned. The majority of patients were men with a mean age of 56. The author felt that these relatively young patients were keen to be part of the evaluation and to take an active role in the choice of dressings applied. The main emerging themes (in addition to the pain diary scores) include descriptions of:

- Improvement in the skin
- Cooling effects when in situ
- Pain reduction.

The comments made by patients related to adaption of the dressing and who applied it. The three women in this study all completed the diaries and documented their feelings more openly than the men, for example:

Patient 5, day 3: 'Bad in myself today, mostly weeping and sleeping, but neck feels a little better, left the dressing on'

Patient 11, day 3: 'When the dressing is removed within a short space of time, the burn dries and hurts like hell, when the dressing is applied the relief is almost instant and the pain drops to 0'.

Patient 11 commented about drying of the skin and a

burning feeling. This is expected with a reaction of RTOG 2 onwards. The neck also feels hot to touch. Previous dressings did not alleviate this; however, all patients in this study reported an immediate relief of this symptom. This is a result of the unique properties linked to PolyMem, which allow it to bathe nerve endings, reducing nociceptors' response to inflammation by protecting the skin from air moving over the exposed nerve endings. Also, it is worth noting that patient 11 did not have any additional analgesia to cover this time period so the pain relief appears to be a direct result of the dressing.

Discussion

Patient diaries were invaluable, providing great insight into the quality of life for these patients. Common themes were:

- Increased sleeping hours
- Dramatic reduction in pain during wear time of the dressing
- Increased healing rates when compared with the standard treatment
- Patient and carers were able to change the dressings.

Actively encouraging patients to take part in this project has given the author valuable insight into the importance of involving patients from the start of any study. This is reflected in UK health policy, which has recently begun to focus on giving patients more choice in both the treatment and management of their conditions (Department of Health (DH), 2012). The relatively low mean age of the patients who took part in this study was felt by the author to be an important factor in their willingness and ability to play an active role in this evaluation of the polymeric membrane dressing PolyMem.

Limitations

Only a small number of patients were recruited, 20 in total. The standard treatment was withdrawn owing to improved patient outcomes in pain reduction and healing with the evaluated dressing. This study was limited to only head and neck cancer patients undergoing either standard radiotherapy treatment or IMRT. Further studies will need to be undertaken to support any significant statistical improvement in other anatomical areas of the body. The patients were a relatively young population sample, which could have possibly had an impact on healing ability of the skin.

Conclusion

The advantages of using advanced wound dressings for the treatment of patients presenting with radiotherapy-induced skin damage has been shown in this small study. In direct response to the evaluation, the use of aqueous cream and paraffin gauze for head and neck cancer patients (RTOG 2 and above) has been replaced by the polymeric membrane dressing (PolyMem) at Mount Vernon Cancer Centre. Polymem proved to have a:

- Considerable reduction in pain and inflammation
- Improvement in sleep patterns
- Improved healing rates
- Improved quality of life for the patient.

This work forms part of an ongoing multicentre study to validate the efficacy of PolyMem within radiotherapy.

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