European Journal of Oncology Nursing 17 (2013) 429–435

Contents lists available at SciVerse ScienceDirect

European Journal of Oncology Nursing

journal homepage: www.elsevier.com/locate/ejon

No differences between Calendula cream and aqueous cream in the prevention of acute radiation skin reactions – Results from a randomised blinded trial

Lena Sharp [a,b], Kristina Finnilä [a,c,*], Hemming Johansson [a], Marie Abrahamsson [d], Thomas Hatschek [a,e], Mia Bergenmar [a,e]

[a] Department of Oncology, Radiotherapy, Karolinska University Hospital, SE 171 76 Stockholm, Sweden
[b] Karolinska Institutet, Department of Learning, Informatics, Management and Ethics, SE 171 77 Stockholm, Sweden
[c] Umeå University, Department of Radiation Sciences, SE 901 87 Umeå, Sweden
[d] Regional Cancer Centre, Stockholm-Gotland, Karolinska University Hospital, SE 171 76 Stockholm, Sweden
[e] Karolinska Institutet, Department of Oncology–Pathology, SE 171 77 Stockholm, Sweden

Keywords:
Breast cancer
Radiotherapy
Radiation skin reaction
Skin
Randomised trial
Dermatitis
Patient reported outcomes
Calendula
Aqueous cream

A B S T R A C T

Purpose: The purpose of this blinded, randomized clinical trial was to compare two topical agents (Calendula Weleda® cream vs. Essex® cream) in reducing the risk of severe acute radiation skin reactions (ARSR) in relation to adjuvant radiotherapy (RT) for breast cancer.
Method: The primary endpoint was the difference in proportion of patients with ARSR, assessed with the Radiation Therapy Oncology Group/The Organization for Research and Treatment of Cancer Acute Radiation Morbidity Scoring Criteria (RTOG/EORTC scale) at follow-up. The secondary endpoints included patient reported outcome measures; Quality of Life Questionnaire (QLQ-C30), Sleep disturbances (MOS-sleep questionnaire) and symptoms from the irradiated area (visual analogue scale). Patients' experiences and adherence to the topical agents were also evaluated.
Results: A total of 420 patients were randomised and 411 were analysed. With the exception of previous chemotherapy, the treatment groups were well balanced, both regarding treatment- and patient-related factors. The incidence of severe ARSR (RTOG/EORTC grade ≤ 2) at the follow-up visit was 23% ($n = 45$) in the Calendula group and 19% ($n = 38$) in the Essex group. We found no difference in severe ARSR between the groups at any point of assessment. The patients reported low levels of skin related symptoms and no statistically significant differences between the groups were found.
Conclusions: No differences in ARSR between patients randomised to Calendula or Essex cream was found. ARSR seem to be a relatively limited problem, probably more influenced by treatment related factors than by choice of skin care products in this patient group.
© 2012 Elsevier Ltd. All rights reserved.

Introduction

Acute radiation skin reactions (ARSR) occur in the majority of patients undergoing curative radiotherapy (RT). Some patients experience more severe reactions such as dry and/or moist desquamation but most patients experience mild reactions e.g. erythema (Lopez et al., 2002). The radiation dose, volume, RT technique and previous treatment, such as type of surgery and previous chemotherapy, are factors that might impact the risk for ARSR together with patient-related factors such as body mass index (BMI), smoking status and previous skin damage (Porock et al., 1998; Wells et al., 2004). In a pilot study ($n = 93$) of the frequency of ARSR in patients with breast cancer who underwent adjuvant RT it was shown that 93% developed ARSR, mostly mild reactions. Patient reported low scores on pain and itching (Sharp et al., 2011). Over 80% of the patients reported adherence to the skin care recommendations which included application of a thin layer of Essex® cream, a non-perfumed aqueous cream, on the irradiated area at least two times a day (Sharp et al., 2011).

There is a range of various topical agents and dressings in use for prevention and management of ARSR (Feight et al., 2011; Kumar et al., 2010; Pommier et al., 2004). Corticosteroid products have been tested and investigated but so far, no clear benefits regarding the effect on ARSR has been demonstrated (Feight et al., 2011; Kumar et al., 2010; Miller et al., 2011). However, in a recent randomised double-blinded study, patients in the experimental group

* Corresponding author. Department of Oncology, Radiotherapy, Karolinska University Hospital, SE 171 76 Stockholm, Sweden. Tel.: +46 736 998867.
E-mail address: Kristina.finnila@karolinska.se (K. Finnilä).

1462-3889/$ – see front matter © 2012 Elsevier Ltd. All rights reserved.
http://dx.doi.org/10.1016/j.ejon.2012.11.003

(Mometasone Furoate 0.1%, a potent corticosteroid cream) reported significantly less itching, irritation, persistence or recurrence of skin related problems in comparison with the placebo group (Miller et al., 2011). One of the potential risks in long-term use of corticosteroid products are the thinning of the skin and, to our knowledge, there are no studies focussing on this problem or its consequences (Kumar et al., 2010).

The effects of Aloe vera products have been investigated in randomized controlled trials (RCTs) but failed to show significant benefits in preventing or minimising ARSR (Richardson et al., 2005). However, a study comparing topical Aloe vera gel and aqueous cream showed that patients in the Aloe vera group experienced significantly more pain than patients in the aqueous cream group (Heggie et al., 2002). Other products containing agents such as sucralfate, urea and hyaluronic acid has shown no or limited positive effects in preventing or reducing ARSR (Pardo Masferrer et al., 2010; Pinnix et al., 2012; Wells et al., 2004).

The effects of skin care products containing *Calendula officinalis* (marigold plant) on ARSR in patients with breast cancer were investigated in a RCT (Pommier et al., 2004). Patients in the experimental group, treated with Calendula cream had a statistically significant lower incidence of severe ARSR, pain and treatment interruptions in comparison with the patients in the control group, treated with trolamine. These promising results called for further investigations. Therefore, we conducted a randomised, blinded study to test whether skin care using topical *Calendula officinalis* was superior to aqueous cream in reducing the risk of severe ARSR in patients with breast cancer treated with adjuvant RT. Secondary aims were to compare patient reported symptoms from the irradiated area (pain, burning, tenderness, pulling and itching), quality of life and sleeping disturbances between two skin care regimens. In addition, patients' experiences and adherence to the topical agent were evaluated.

Patients and methods

This two-armed, blinded, randomised phase III trial was designed to test whether Calendula Weleda® cream (Weleda AG, Sweden) was superior to aqueous cream in reducing the risk of severe ARSR in patients with breast cancer treated with adjuvant RT. Calendula Weleda® cream was compared to Essex® cream (Schering-Plough), an aqueous cream without parabenes, meeting the requirements of a basic moisturizing cream to be used on a daily basis during the course of, and after RT. Essex® cream is currently the recommended standard skin care treatment at the RT unit, Department of Oncology. Calendula Weleda cream contains extracts of marigold plant (*Calendula officinalis* 10%), wool fat and sesame oil. It has received approval from the Swedish Medical Products Agency for symptomatic treatment of minor skin inflammations, such as sunburn or acne. Both products contain no perfume or colouring agents. The study was approved by the Regional Ethical Review Board, Stockholm (2009/4:7), EudraCT nr: 2009-018188-29.

Patients

Between February 2011 and March 2012, consecutive eligible women with breast cancer at the RT Unit, Department of Oncology, Karolinska University Hospital were randomly assigned to receive Calendula Weleda® cream or Essex® cream for skin care during RT. Eligibility criteria were age $\geq$18 years, previously treated with partial/modified radical mastectomy and scheduled to begin external RT. Previous RT to the same area, reduced cognitive ability, severe general health problems and language barriers were reasons for ineligibility.

Radiotherapy

Treatments were fractioned in 2 Gray (Gy) five days a week up to 50 Gy or 2.66 Gy five days a week up to 42.56 Gy. All patients under the age of 40 years received an additional boost of 16 Gy, 2 Gy per fraction. The treatment was given with photons 6 megavolt (MV) and sometimes 6 MV in combination with 15 MV or 18 MV.

Inclusion procedures

An information letter about the study was sent to patients together with the first appointment at the RT unit. Potentially eligible patients received further information from the RT-nurses at the first visit. Patients who met the study criteria were asked whether they wanted to participate in the study. The following variables were registered for patients who accepted to participate, after signing the informed consent but before randomisation; surgery (radical vs. partial mastectomy), treatment area (fields covering the breast, chest wall, axillary and/or supraclavicular lymph nodes), body mass index (BMI), seroma after surgery (yes/no), breast implants (yes/no), chemotherapy previous to RT (yes/no), on-going hormone therapy (yes/no) and smoking status (self reported and carbon monoxide, CO, in expired air). Patients also completed two questionnaires, EORTC QLQ-C30 and MOS-sleep (described below).

The randomisation

Computerised randomisation, based on a permuted block technique was used and performed at the Regional Cancer Centre (RCC) in Stockholm. Stratification was made for type of surgery (partial or radical modified mastectomy). An accredited pharmacy was responsible for the packaging of allocated skin care treatments. The computerised randomisation of patients was performed after checking the above-mentioned variables, ensuring the fulfilment of the study criteria.

Skin care

Patients were instructed to apply a thin layer of the assigned cream twice a day, starting at the onset of RT and continuing until two weeks after final RT session, or until the ARSR was healed. It was emphasized that application should include the whole treatment area including the armpit and shoulder/back area in patients treated with modified radical mastectomy. Patients were also advised to not apply the cream within two hours of their RT in order to avoid possible build-up effect. Daily washing with perfume-free soap and tap water was recommended and patients were strongly advised to refrain from using of other topical agents in the irradiated area.

Instruments and points of assessments

Assessments by health care providers

ARSR were evaluated by the RT nurses using the Radiation Therapy Oncology Group/The Organization for Research and Treatment of Cancer Acute Radiation Morbidity Scoring Criteria (RTOG/EORTC scale) (Cox et al., 1995) at the first and final RT sessions, and at the follow-up visit five to seventeen days after final RT. The scale grades ARSR from 0 to 4, Table 1. The RTOG/EORTC scale is a frequently used instrument for assessing ARSR, with good intra- and inter-observer concordance compared with three other scoring systems (Lopez et al., 2002).

دانلود مقاله

http://daneshyari.com/article/2649474

- ✓ امکان دانلود نسخه تمام متن مقالات انگلیسی
- ✓ امکان دانلود نسخه ترجمه شده مقالات
- ✓ پذیرش سفارش ترجمه تخصصی
- ✓ امکان جستجو در آرشیو جامعی از صدها موضوع و هزاران مقاله
- ✓ امکان پرداخت اینترنتی با کلیه کارت های عضو شتاب
- ✓ دانلود فوری مقاله پس از پرداخت آنلاین
- ✓ پشتیبانی کامل خرید با بهره مندی از سیستم هوشمند رهگیری سفارشات