**Author:** J. Wheat, G. Currie and K. Coulter
**Author Address:** jwheat@csu.edu.au
gcurrie@csu.edu.au
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**Abstract:** Acute radiation skin toxicity in breast irradiation occurs in the majority of patients and a variety of topical agents and dressings have been employed in clinical practice, however, there is little empirical evidence to support one protocol for skin care over another. The aim of this investigation was to examine the potential benefits of wheatgrass extract in reducing the severity and delaying the onset of acute radiation skin toxicity in breast irradiation.METHODS: This pilot study was a prospective randomised control trial using one control group employing current best practice (sorbelene cream) and one treatment modification group (wheatgrass extract). Patient recruitment was randomised and blinded to treatment group.RESULTS: A total of 20 'lumpectomy' patients were recruited for the initial pilot phase of this research. The mean weight of the control group was only 67.1 kg compared to 82.4 kg for the experimental group. A bra size greater than 20 was only seen in 14.3% of the control group compared to 50.0% of the experimental group. A cup size greater than or equal to D was only seen in 25% of the control group but 37.5% of the experimental group. The mean planned dose for the experimental group was higher (63.3 Gy) than the control group (59.4 Gy). No statistically significant difference was noted between the control group and the experimental group with respect to the peak ONS rating or time to peak ONS rating for the experimental group. There was a statistically significant improvement in the quality of life of patients in the wheatgrass group (P = 0.014).CONCLUSION: This pilot study demonstrated a trend noted towards decreased severity of acute radiation skin toxicity and increased time to peak incidence which may be strengthened in a larger population. The pilot study provides evidence that wheatgrass offers improved management of the early morbidity associated with breast irradiation.

# MANAGEMENT OF ACUTE RADIATION SKIN TOXICITY WITH WHEATGRASS EXTRACT IN BREAST RADIATION THERAPY: PILOT STUDY.

Janelle Wheat[1], B AppSci (radiotherapy), M MedRadSc, DHlthSc

Geoff Currie[1], M MedRadSc, M AppMngt

Kristine Coulter [2], MIR

[1] School of Biomedical Sciences, Charles Sturt University, Wagga Wagga.

[2] Riverina Cancer Care Centre, Wagga Wagga.

Correspondence:

Janelle Wheat

School of Biomedical Sciences

Locked Bag 588

Charles Sturt University

Wagga Wagga 2678

Australia

Telephone: 61 2 69332750

Facsimile: 61 2 69332866

Email: jwheat@csu.edu.au

Foot line: WHEATGRASS EXTRACT IN BREAST IRRADIATION

**ABSTRACT**

Acute radiation skin toxicity in breast irradiation occurs in the majority of patients and a variety of topical agents and dressings have been employed in clinical practice, however, there is little empirical evidence to support one protocol for skin care over another. The aim of this investigation was to examine the potential benefits of wheatgrass extract in reducing the severity and delaying the onset of acute radiation skin toxicity in breast irradiation.

**METHODS:** This pilot study was a prospective randomised control trial using one control group employing current best practice (sorbelene cream) and one treatment modification group (wheatgrass extract). Patient recruitment was randomised and blinded to treatment group.

**RESULTS:** A total of 20 'lumpectomy' patients were recruited for the initial pilot phase of this research. The mean weight of the control group was only 67.1 kg compared to 82.4 kg for the experimental group. A bra size greater than 20 was only seen in 14.3% of the control group compared to 50.0% of the experimental group. A cup size greater than or equal to D was only seen in 25% of the control group but 37.5% of the experimental group. The mean planned dose for the experimental group was higher (63.3 Gy) than the control group (59.4 Gy). No statistically significant difference was noted between the control group and the experimental group with respect to the peak ONS rating or time to peak ONS rating for the experimental group. There was a statistically significant improvement in the quality of life of patients in the wheatgrass group ($P = 0.014$).

**CONCLUSION:** This pilot study demonstrated a trend noted towards decreased severity of acute radiation skin toxicity and increased time to peak incidence which may be strengthened in a larger population. The pilot study provides evidence that wheatgrass offers improved management of the early morbidity associated with breast irradiation.

## INTRODUCTION

As many as 1 in every 5 people in Western society will undergo radiation therapy during their life time (*1*). The most common side effect of radiation therapy is acute radiation skin toxicity with 95% of patients experiencing an acute skin reaction (*1*). The curative role radiotherapy may be limited by radiation tolerance of normal tissues surrounding the treated volume (*2*). A variety of topical agents and dressings have been employed in clinical practice for acute radiation skin toxicity in breast irradiation despite a lack of empirical evidence to support one treatment over another (*3*). There are no standards of care in the radiotherapy discipline to manage acute radiation skin toxicity (*4,5*). Skin management during radiation therapy should focus on minimising impact / severity and promoting patient comfort / tolerance. Acute radiation skin toxicity is more problematic where there is appositional skin (eg. the inframammary fold) due to more rapid shedding of the stratum corneum (increased moisture, increased warmth, increased friction and lack of adequate aeration) (*1*).

A variety of topical preparations have been employed for the care of acute radiation skin toxicity although supporting empirical evidence is sparse. Wheatgrass extract is squeezed from the mature sprouts of wheat (triticum aestivum), is a topical immunomodulator and has been used to boost topical immunity with excellent results demonstrated for promoting healing in burns patients due to re-epithelialisation (dries burns, reduces pain and promotes healing). Wheatgrass extract decreases the inflammatory response (takes heat and pain away), is a substance P inhibitor, stops subcutaneous bleeding and increases the fibroblastic activity of cells (*6*). It is these purported properties that raised interest in the potential for management of acute radiation skin toxicity.

## AIMS AND OBJECTIVES

The aim of this investigation was to examine the potential benefits of wheatgrass extract in reducing the severity, delaying the onset of acute radiation skin toxicity in breast irradiation and improving patient quality of life (QOL) by better management of early skin related morbidity. To this end, the objective of this pilot study was to determine whether there was sufficient evidence of such a relationship that might provide both justification and motivation for a larger multi-centre trial.

## METHODOLOGY

This pilot study was a prospective randomised control trial using one control group employing current best practice (sorbelene cream) and one treatment modification group (wheatgrass extract). Patient recruitment was randomised and blinded to treatment group. The cream was applied three times daily beginning with the commencement of radiation therapy for the duration of the patient's radiation treatment.

Prior to the commencement of radiation therapy and at weekly consultations throughout the radiation treatment, the treatment area was assessed with respect to acute radiation skin toxicity and QOL. Acute skin toxicity was recorded according to the Oncology Nursing Society (ONS) scale (*1*) for acute skin toxicity scale (table 1). The ONS scale was recorded at 4 weeks and 6 months after the completion of the radiation therapy for those patients returning to the centre for follow up.

QOL was assessed using the Spitzer QOL method (SQLI) which has been devised for use in cancer patients as both a self administered and a rater assessed five item categorical questionnaire summed in the Likert format to provide score ranges of 0 to 10 (10 indicating the highest QOL) without subscales (*5*). This study employed the SQLI via rater adminsitered questionnaires to evaluate QOL between the two groups. SQLI has been previously validated and widely accepted within the international radiation oncology profession (*7*).

Table 1: ONS radiation skin reaction scoring system. Adapted from (*1*).

| GRADE | DESCRIPTION |
|---|---|
| **0** | No change. |
| **1** | Faint or dull erythema, follicular reaction. |
| **2** | Bright erythema. |
| **3** | Dry desquamation with or without erythema. |
| **4** | Small to moderate wet desquamation. |
| **5** | Confluent moist desquamation. |
| **6** | Ulceration, haemorrhage or necrosis. |

The statistical significance was calculated using Chi-Square analysis for nominal data and Student's *t* test for continuous data. The $X^2$ Pearson Chi Sqaure test was employed for categorical data with normal distribution and the $G^2$ Likelihood Ratio Chi-Square test for categorical data without normal distribution. The *F* test analysis of variances was used to determine statistically significant differences within grouped data. A *P* value less than 0.05 was considered significant.

This research was approved by the Charles Sturt University Ethics in Human Research Committee.

## RESULTS

A total of 20 ‘lumpectomy’ patients were recruited for the initial pilot phase of this research. All patients satisfied eligibility and exclusion requirements. The mean age of patients was 55.2 years (ranging from 35 to 74 years) and the mean weight was 72.7 kg (ranging from 50.5 to 106 kg). The patient bra size ranged from size 12 to size 38 with cup sizes ranging from B to E. A bras size less than or equal to 20 was noted for 66.7% of patients and a cup size smaller than or equal to C was noted in 66.7% of patients. No correlation was noted between bra size and cup size ($P = 0.538$), bra size and weight ($P = 0.582$) or weight and cup size ($P = 0.431$). The peak ONS rating for each patient occurred, on average, at 4.9 weeks into the radiation treatment with a mean peak rating of 2.7.

The mean age for the control group was 55.3 years compared to 55.0 years for the experimental group ($P = 0.945$). The mean weight of the control group was only 67.1 kg compared to 82.4 kg for the experimental group, although no statistically significant difference was noted ($P = 0.214$). A bra size greater than 20 was only seen in 14.3% of the control group compared to 50.0% of the experimental group ($P = 0.370$). Similarly, a cup size greater than or equal to D was only seen in 25% of the control group but 37.5% of the experimental group ($P = 0.486$). The mean planned dose for the experimental group was higher (63.3 Gy) than the control group (59.4 Gy) ($P = 0.156$). A uniform distribution of patient skin types was also noted ($P = 0.287$) although 100% of dark skin types were contained within the control group.

No statistically significant difference was noted between the control group and the experimental group with respect to the peak ONS rating ($P = 0.316$). There was also no statistically significant difference in the time to peak ONS rating for the experimental group (5.2 weeks) compared to the control group (4.6 weeks) ($P = 0.241$).

No statistically significant difference was noted between the two groups with respect to QOL (SQLI) pre treatment ($P = 0.855$). The experimental group (wheatgrass) demonstrated a general trend toward improved QOL against the control group (tables 2 and 3). Moreover, the improved QOL demonstrated a statistically significant improvement in the experimental group across all weeks combined ($P = 0.014$).

Table 3: SQLI QOL rating for each group against the weeks of radiotherapy.

| WEEK | CONTROL GROUP MEAN SQLI RATING (MEDIAN) | EXPERIMENTAL GROUP MEAN SQLI RATING (MEDIAN) | P VALUE |
|---|---|---|---|
| 1 | 9.8 (10) | 9.9 (10) | 0.493 |
| 2 | 9.4 (9.5) | 9.8 (10) | 0.139 |
| 3 | 9.6 (10) | 9.5 (10) | 0.754 |
| 4 | 9.6 (10) | 9.9 (10) | 0.135 |
| 5 | 9.3 (9) | 9.9 (10) | 0.049 |
| 6 | 9.3 (9) | 9.7 (10) | 0.305 |
| **OVERALL** | **9.5 (10)** | **9.8 (10)** | **0.014** |

Table 4: Distribution of SQLI QOL rating for each group (all weeks combined).

| SQLI RATING | CONTROL GROUP PROPORTION | EXPERIMENTAL GROUP PROPORTION |
|---|---|---|
| 1 | 0 | 0 |
| 2 | 0 | 0 |
| 3 | 0 | 0 |
| 4 | 0 | 0 |
| 5 | 0 | 0 |
| 6 | 0 | 0 |
| 7 | 0 | 0 |
| 8 | 3.9% | 5.4% |
| 9 | 40.4% | 10.7% |
| 10 | 55.8% | 83.9% |

## DISCUSSION

While no statistically significant differences were noted between groups with respect to demographic data, several key factors for acute radiation skin toxicity had greater incidence in the experimental group. The wheatgrass group exhibited a higher mean weight, greater proportion of large breasted patients and a higher planned dose (all known to increase radiation skin toxicity) while the control group contained the only patient with a darker skin type (protective effect for radiation skin toxicity). The lack of a statistically significant difference in time to peak ONS rating and difference in the actual severity (peak ONS) may have been masked by compounding of these factors.

This pilot study did, however, demonstrate a trend in the wheatgrass cohort towards decreased severity of acute radiation skin toxicity and increased time to peak incidence. This is an important observation because it supports a potential role for improving patient compliance and, thus, success of therapy in patients susceptible to severe or early onset of acute radiation skin toxicity.

The wheatgrass group also demonstrated improved QOL in this patient cohort. The lack of significant trend for the ONS time to peak provides an argument that improved QOL may be both related to delayed severity of acute radiation skin toxicity and independently achieved due to improved management of skin morbidity.

## CONCLUSION

Topical herbal preparations for the management of acute radiation skin toxicity have the potential to decrease acute and late morbidity, improve short and long term QOL, improve tolerance and, thus, improve treatment outcomes. This pilot study revealed a trend towards increased time to peak incidence of acute radiation skin toxicity and improved QOL in the wheatgrass group despite unfavourable distribution of potential confounders. Thus, the investigation provides sufficient evidence to justify a larger multi-centre randomised trial.

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## REFERENCES


1. Porock, D, Nikoletti, S & Kristjanson, L 1999, Management of radiation skin reactions: literature review and clinical application, *Plast Surg Nurs*, vol. 19, no. 4, pp. 185-192.
2. Lopez, E, Nunez, M, Guerrero, M, del Moral, R, de Dios Luna, J, del Mar Rodriguez, M, Valenzuela, M, Villalobos, M & Ruiz de Almodovar, J 2002, Breast cancer acute radiotherapy morbidity evaluated by different scoring systems, *Breast Cancer Res Treat*, vol. 73, no. 2, pp. 127-134.
3. Porock, D & Kristjanson, L 1999, Skin reactions during radiotherapy for breast cancer: the use and impact of topical agents and dressings, *Eur J Cancer Care*, vol. 8, no. 3, pp. 143-153.
4. Blackmar, A 1997, Radiation-induced skin alterations, *Medsurg Nurs*, vol. 6, no. 3, pp. 172-175.
5. Fisher, J, Stevens, R & Scott, C 1998, Phase III randomised study comparing best supportive care to biafine as a prophylactic agent for radiation-induced skin toxicity for women undergoing breast irradiation, Radiation Therapy Oncology Group (RTOG), viewed 16 June 2004, <http://www.rtog.com/>
6. Seibold, R 1991, Cereal grass, Keats Publishing Inc.
7. Spitzer, W, Dobson, A, Hall, J, Chesterman, E, Levi, J, Shepherd, R, Battista, R & Catchlove, B 1981, Measuring the quality of life of cancer patients: a concise QL-index for use by physicians, *J Chronic Dis*, vol. 34, no. 12, pp. 585-597.