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MATRICARIA RECUTITA TEA COMPRESS VERSUS *BRASSICA OLERACEA* OINTMENT FOR PREVENTION OF RADIODERMATITIS IN WOMEN WITH BREAST CANCER

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ABSTRACT

Objectives: To compare the effect of *Brassica oleracea* extract ointment (cabbage ointment) and *Matricaria recutita* (chamomile) tea compresses for the prevention of radiodermatitis in women with breast cancer. **Design:** Randomized controlled trial. **Setting:** Radiotherapy Department of the Hospital Araújo Jorge (Goiania, Brazil). **Subjects**: The sample consisted of women initiating adjuvant radiotherapy for breast cancer. **Interventions**: Participants were randomized into two groups. Group 1 (n=23) received chamomile tea bags to be applied as compresses twice a day at room temperature. Group 2 (n=20) received a 100g tube with cabbage ointment (Debridan®), and instructions to apply the ointment twice a day. Both groups also received a brief educational intervention on general skin care during radiotherapy treatment. **Outcome measures**: Skin was assessed weekly during radiation treatment, using the Radiation Therapy Oncology Group (RTOG) scale. **Results**: All women developed dermatitis during radiotherapy with increasing cases mainly from the 15th session. Erythema was the first sign of radiodermatitis observed in both groups. No difference in the incidence and severity of radiodermatitis between the two treatment groups was observed. **Conclusions:** The effect of Chamomile tea compresses and *Brassica oleracea* ointment were similar in the prevention of acute radiodermatitis in patients with breast cancer.

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INTRODUCTION

Breast cancer patients have benefited from advanced therapeutic approaches increasing not only the chances of cure and survival, but also improved quality of life (Mastrella, 2014). In radiation therapy, despite the positive results reached through illness-focused efforts, the occurrence of side effects still represents a major limiting factor in the treatment since it can cause dose reduction, delay in sessions, or even precipitated ending of therapy (Ferreira, 2017). One of the most common effects of radiation treatment is radiodermatitis, also referred to as radiation dermatitis, radiation-induced skin reactions, or radiation injury. Up to now, no intervention has shown to be efficient and/or effective for the prevention of radiodermatitis in breast cancer patients. The acute form of radiodermatitis emerges in the second and third weeks of treatment, depending on the dosage of radiation delivered. Initially observed characteristics include erythema, edema and pigment changes, which are present in over 90% of breast cancer patients. As it progresses, dry desquamation and moist desquamation develop and occur in more than 30% of breast cancer patients in radiation therapy (Singh, 2016). Many patient and treatment-related factors associate to its severity such as breast size, skin integrity issues (specially related to previous breast cancer surgery), co-morbid conditions, nutritional status, age, skin color, medications, sun exposure, tobacco use, mobility, genetic factors, total radiation dose, type of external beam employed, site of treatment, volume and surface area of irradiated tissue, and different concurrent antineoplastic treatments (Singh, 2016). Radiodermatitis can be evaluated by different tools, and the most frequently used ones, despite the lack of robust data on their reliability and validity, include the Common Terminology Criteria for Adverse Events (CTCAE) and the Radiation Therapy

Oncology Group (RTOG) scale (Wong, 2013). The CTCAE tool was developed by the National Cancer Institute, and the RTOG scale was developed by the European Organization for Research and Treatment of Cancer (Wong, 2013). These skin assessment tools have been available for decades, and the continuous use of these tools have enabled comparison of results between trials conducted world-wide. Continued effort to improve prevention and treatment of radiodermatitis is demonstrated by the constant number of publications. In 2017, four systematic reviews have attempted to identify the best evidence for management of radiodermatitis. A first group of researchers performed a meta-analysis to evaluate the efficacy of topical steroids in breast cancer patients and concluded that corticosteroids reduced the severity of radiodermatitis, reduced pruritus, and improved quality of life (Haruna, 2017). A second group focused the review on semi-permeable dressings and found them beneficial in the management of radiodermatitis (Fernández-Castro, 2017). A third group conducted a review focused on head and neck cancer patients and concluded that there are no differences between topical pharmacological (including botanical medicine) or non-pharmacological interventions for the prevention of acute radiation dermatitis (Ferreira, 2017). Finally, a fourth group reviewed low-level light therapy for radiodermatitis for breast cancer and the results are promising (Robijns, 2017).

Associated with these reviews, a number of risks exist, including: risks for prolonged use of topical corticosteroids; elevated costs of wound dressings; the need for specialized training and equipment for laser therapy; and a lack of availability of gold-standard interventions. Considering these risks, the use of natural products, mostly derived from plants, are investigated to provide more options for quality practice. Also, patients receiving radiation therapy are interested in complementary and alternative therapies for radiodermatitis, and many already use them (Gillett, 2012). Botanical medicine (also known as plant-based treatments, phytotherapies, or herbal medicines) have been an important source of medicinal interventions in health care worldwide. They can be used by different routes, and the topical application is important when the problem is the dermal tissue. A literature review on natural actives used for wound management highlights that the effects of botanical therapies on skin care are mainly related to their anti-inflammatory, cell-stimulating, and antimicrobial properties (Ataide, 2018). In Brazil and other Latin American countries, many nursing colleagues report the use of *Matricaria recutita,* commonly known as chamomile, for prevention of radiodermatitis and relief of common-associated symptoms. Chamomile has internal and external anti-inflammatory and antiseptic effects, demonstrated by positive results for treatments of skin problems such as acne, chronic wounds or nail infection (Nogueira, 2005). The most common presentation of this herb is tea, an ancient infusion with soothing and digestive properties (Lucca, 2010). The application of this medicinal plant among women in radiotherapy is generally by tea compresses at room temperature, twice a day. When applied to the skin, chamomile accelerates wound healing, and promotes the elimination of toxins through the skin (Lucena, 2009). Several products are continuously developed by pharmaceutical companies and are tested for the prevention and treatment of radiodermatitis. Some examples of botanical medicine products are Capilen® cream (Stefanelli, 2014), Aloe vera (Rao, 2017), and Calendula (Kodiyan, 2015). A product developed in Brazil, based on the Brassica family of vegetables, popularly known as cabbage, is known for its high healing power, demonstrated in over twenty years of research (Debridan Farma, 2014). The *Brassica oleracea* extract is a powerful emollient that provides an intensive and prolonged hydration, and it has been effective in the prevention of pressure ulcers, and treatment of chronic wounds (Debridan Farma, 2014). The cabbage-derived ointment significantly increases the number of type I collagen fibers when treatment is maintained for longer period of time.[17] No contraindications have been identified with this ointment. Based on results of earlier studies showing the effect on other skin lesions and the lack of contraindications, we hypothesized that cabbage ointment might be effective in preventing radiodermititis. We understand that the development of research is the way to build evidence for the effectiveness of products, providing reduction, relief and even the non-appearance of local signs and symptoms related to the irradiation of the breast. Therefore, the main objective of this research was to compare the effect of chamomile tea compresses and cabbage extract ointment to prevent radiodermatitis in women with breast cancer under radiation therapy.

MATERIALS AND METHODS

This randomized-controlled experimental study was approved by the Research Ethics Committee of the Cancer Fight Association of Goias. Data was collected at the Radiotherapy Department of the Hospital Araújo Jorge (Goiania, Brazil), one of the country's largest radiotherapy facilities serving patients with public and private healthcare coverage.

Sample: A sample of 43 women with breast cancer initiating adjuvant radiotherapy were included. The inclusion criteria consisted of: a minimum age of 18 years, and prescription radiation between 30 and 34 radiotherapy fractions, with a dose of 180-200 cGy per day. The exclusion criteria included: breast reconstruction procedures with prosthesis, tumor infiltration of the skin, or a history of allergy to components of the investigated products (chamomile and cabbage).

Measures: Participants were evaluated weekly from the beginning to the end of radiation therapy. In all evaluations, data was obtained through interviews, clinical examination and consulting the medical records. The primary outcome, radiodermatitis, was assessed using the Radiation Therapy Oncology Group scale (RTOG), which classifies skin toxicity in five degrees, ranging from 0 – no reaction – to 4 – ulceration based on the presence of erythema, edema, dry and/or moist desquamation (Cox, 1995). Each of these characteristics (erythema, edema, dry and/or moist desquamation) can also be classified in 0 – absent – to 4 – severe. Adverse events were evaluated every meeting. Demographic, clinical, disease and treatment-related variables were also assessed and included: age, education level, marital status, skin color, breast volume and presence of ptosis, skin type (dry, normal, oily), Body Mass Index (BMI), current use of tobacco, tumor staging, comorbidities, local pain (numeric scale 0-10), Karnofsky Performance Status (KPS), interval between surgery and radiation therapy, axillary dissection, radiation fields, evaluation of compliance with radiotherapy, and the radiation dose. In addition, patient´s compliance with the intervention they were given was verified by asking them to register daily applications of treatment. A photography of the skin affected by radiotherapy was recorded to double check the evaluation of skin conditions (inter-observer reliability).

Procedures: Patients that agreed to participate in the study, signed the Informed Consent Form, and were randomly assigned to one of the two intervention groups: chamomile and cabbage. Randomization was performed by using opaque envelopes, impeding the researcher to predict the group to which the patient would be allocated. The envelope was opened by two members of the research team and no change was made to patient's allocation after randomization. Group 1 received chamomile tea bags, written instructions on the chamomile tea preparation and the application of tea compresses twice a day at room temperature (once in the morning, and once after radiotherapy). Group 2 received a 100g tube with cabbage ointment (Debridan®), and instructions to apply the ointment twice a day (once in the morning, and once after radiotherapy). The treatments were offered free of charge to all research participants. In addition to the experimental product, both groups received a brief educational intervention on general skin care during radiotherapy treatment that included the following information: wash the breast during a shower, preferably with mild soap, without rubbing the irradiated area; avoid direct sunlight for up to 6 months; avoid powders and creams that were not recommended by the nurse or doctor; and avoid the use of bra, tight clothing or synthetic fabric. The instructions on general skin care were carried out at the first assessment, both verbally and in a booklet format, and reinforced in subsequent evaluations.

Analysis: Analyses were performed using SPSS version 24. Baseline characteristics were compared using the chi-square test or likelihood ratio, and analysis of variance (ANOVA). The comparison between groups was performed using Mann-Whitney test, and intra-group comparison was performed using a pairwise Wilcoxon test with Bonferroni correction as post-hoc test for a Friedman test. For all tests, P values of < 0.05 were considered statistically significant.

RESULTS

Twenty-three women were in the group treated with Chamomile tea compress (Group 1), and 20 women were in the group treated with cabbage ointment (Group 2). The average age was 52.1 years, and most women had not completed elementary school (n= 25; 58.1%). More than half of the participants had medium breast volume (n=24; 55.8%), and the same proportion did not have breast ptosis. The mean BMI was 27.4 Kg/m^2 (SD= 4.8), 25.6% (n=11) of the participants had cancer in clinical staging 3 or 4, and in average they had surgery for breast cancer 6 months prior to radiation therapy. Overall, the groups were homogeneous regarding demographic, clinical and treatment variables (Table 1), except for skin color (more women with white skin on the cabbage group), and breast ptosis (more women with breasts ptosis on Chamomile group). The mean dose of radiation was similar between groups (Figure 1). Figures 2 and 3 illustrate the occurrence of the signs of radiodermatitis during radiation therapy. The first sign of radiodermatitis observed in both groups was erythema. Most patients started to present erythema around the 15th session, but it was observed as soon as in the first week of treatment for a few women. The occurrence of erythema within the Chamomile group significantly increased from the baseline assessment and 5th session to the 15th session onwards, and from the 10th session to the 20th session onwards. The occurrence of erythema within the cabbage group significantly increased from baseline assessment, 5th session and 10th session to the 20th session onwards. Erythema was similar in both groups throughout therapy. Dry desquamation was the second characteristic of radiodermatitis observed.

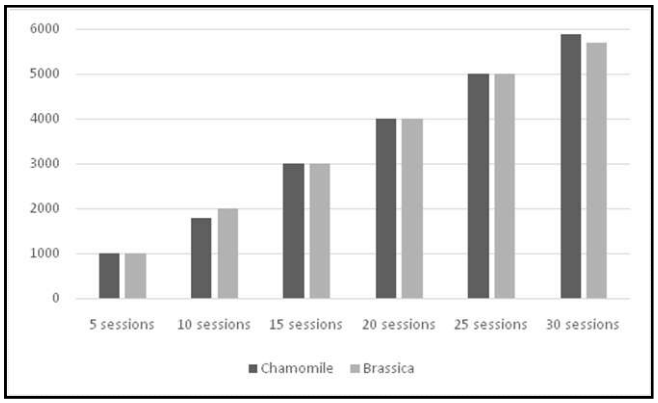

Figure 1. Average cumulative radiation dose in cGy per intervention group

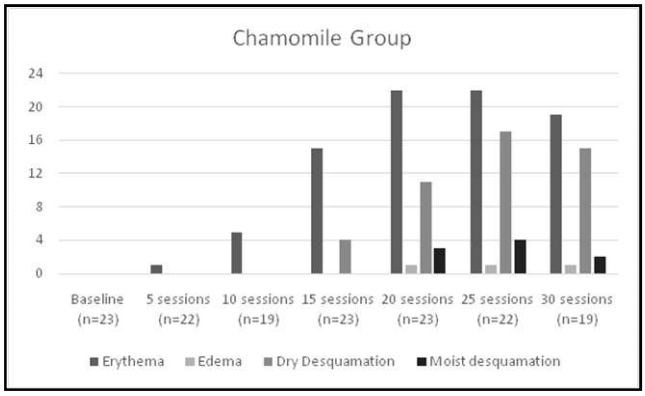

Figure 2. Signs of radiodermatitis in the Chamomile group during radiation therapy

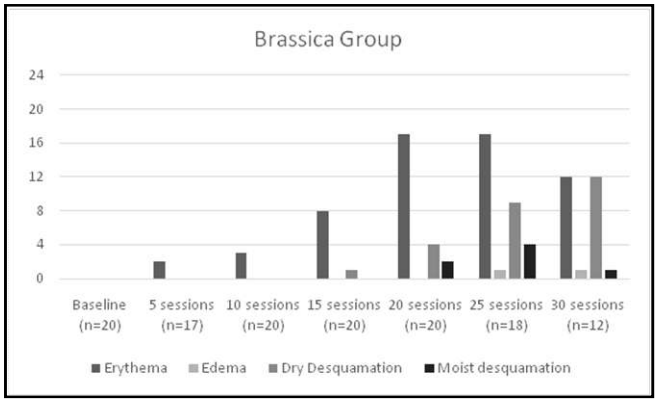

Figure 3. Signs of radiodermatitis in the Brassica group during radiation therapy

It was first seen around session 15 but was more common around session 25. Within the Chamomile group, dry desquamation increased significantly during the 20th session. Within the cabbage group, dry desquamation increased significantly around the 25th session. Although no significant difference was identified between groups, more women treated with Chamomile started to present dry desquamation earlier in radiation therapy. Moist desquamation was observed later in radiation treatment, starting around the 20th session and was seen in similar number of women in both groups. There was no significant increase in the moist desquamation within groups.

Table 1. Characteristics of participants by intervention group for prevention of radiodermatitis

	Chamomile compress (n=23)		Brassica ointment (n=20)		Statistical test; p value
Age in years / mean (SD); min-max	50.9 (10.1); 38.4 – 74.3		53.4 (13.2); 32.6 – 77.0		t=-0.719; p= 0.476
	n	%	n	%	
Level of education					LR (3, N=43) =1.360; p= 0.715
Illiterate	12	52.2	13	65.0	
Elementary school	03	13.0	03	15.0	
Middle school	05	27.7	02	10.0	
High school/College	03	13.0	02	10.0	
Marital Status					X^2 (1, N=43)= 0.637; p= 0.544
Married	12	52.2	08	40.0	
Single/Divorced	11	47.8	12	60.0	
Skin color					LR= 7.461; p= 0.024*
White	05	21.7	12	60.0	
Brown	17	73.9	08	40.0	
Black	01	4.3	00	00	
Breast volume					LR (3, N=43)=7.125; p= 0.069
Small	2	8.7	6	30.0	
Medium	12	52.2	12	60.0	
Large	9	39.1	2	10.0	
Breast ptosis	14	60.9	5	25.0	F; p= 0.031*
Skin type					LR (2, N=43)=1.135; p= 0.567
Dry	5	21.7	3	15.0	
Normal	15	65.2	12	60.0	
Oily	3	13.0	5	25.0	
Comorbidities					LR (4, N=43) = 5.688; p=0.276
None	13	56.5	12	60.0	
$\geq$ 1	10	43.5	8	40.0	
Pain (baseline)					F; p= 0.590
No	22	95.7	18	90.0	
Yes	01	4.3	02	10.0	
BMI classification					LR (2, N=41)= 5.648; p=0.075
Underweight	11	47.8	03	15.0	
Normal weight	07	30.4	11	55.0	
Overweight	04	17.4	05	25.0	
Tobacco					F; p= 0.610
No	20	87.0	19	95.0	
Yes	03	13.0	01	5.0	
KPS					LR (1, N=43)= 1.272; p= 1.000
100%	22	95.7	20	100	
Tumor staging					LR (3, N=41)= 4.976; p= 0.237
1	6	26.1	4	20.0	
2	12	52.2	8	40.0	
3	3	13.0	6	30.0	
4	0	0	2	10.0	
Interval surgery-radiotherapy in months / mean (SD); min-max	6.9 (4.0); 38.4 – 74.3		6.3 (3.8); 32.6 – 77.0		t= 0.550; p= 0.585
Axillary Dissection	16	69.6	14	70.0	F; p= 1.000

*Significant difference between groups;BMI – body mass index; KPS – Karnofsky Performance Status; t= Independent sample test; LR = likelihood ratio; F= Fisher's Exact Test

Table 2. Comparison of the preventive effect of interventions on radiodermatitis by intervention

RTOG criteria	Chamomile compress	Brassica ointment	p
Baseline (no radiation)			
0	23 (100%)	20 (100%)	
5 sessions			
0	21 (95.7%)	15 (90%)	0.473
1	01 (4.3%)	02 (10%)	
10 sessions	1800	2000	
0	14 (73.9%)	17 (90%)	0.181
1	05 (26.1%)	03 (10%)	
15 sessions			
0	09 (43.5%)	12 (70%)	0.073
1	14 (52.2%)	08 (30%)	
20 sessions			
0	01 (4.3%)	03 (25.0%)	0.180
1	19 (78.3%)	15 (60%)	
2	03 (17.4%)	02 (15%)	
25 sessions	5000	5000	
0	0	01 (10.0%)	0.934
1	18 (60.9%)	14 (50.0%)	
2	04 (34.8%)	04 (40.0%)	
30 sessions			
0	0	0	0.672
1	17 (63.2%)	11 (72.7%)	
2	02 (36.8%)	01 (27.3%)	

One patient in each group was excluded from the research because their radiodermatitis evolved to grade 3, and the team decided to implement a different therapy between the 25th and 30th radiotherapy sessions. All women (100%) developed radiodermatitis during the course of radiotherapy (Table 2). In terms of RTOG score, no significant difference was observed between the groups during the progression of radiotherapy. It is noteworthy that most women on the Chamomile group started to present grade 1 radiodermatitis around the 15th session, while on the Cabbage group, most women developed grade 1 radiodermatitis around the 20th session. In the Chamomile group, the increase in RTOG scores was significant in the 15th session onwards compared to baseline and 5th session assessments. In the Cabbage group, the increase in RTOG scores was significant in the 20th session and 25th session compared to the baseline and 5th session assessments. Local pain is not considered a criterion for rating radiodermatitis, however it was assessed during this study because of the understanding that chamomile's anti-inflammatory effect could provide relief from pain. Baseline assessment revealed that one patient in the Chamomile group and two patients in the Cabbage group had local pain, and the intensity of pain was not different between the groups. Though an increase in pain during radiation therapy was observed especially around the 20th and 25th session, there was no difference between groups. In general, research participants were compliant to radiation therapy. Two women on the Chamomile group and 3 women on the Cabbage group missed one session each. Overall, they showed good adherence to the proposed interventions. Moreover, there was no allergic reaction or other adverse event related to the investigated products.

DISCUSSION

A variety of products is used in the prevention and treatment of radiodermatitis in women with breast cancer during radiotherapy. Considering the lack of a gold standard for the prevention of this common skin toxicity, new products are developed and investigated. Up to now, to the best of our knowledge, no literature had presented results on cabbage ointment for the prevention of radiodermatitis. This study provides different perspectives for the management of radiodermatitis. On one hand, since all patients developed radiodermatitis during radiation therapy, this study shows that we still have not discovered a definite preventive measure for radiodermatitis, thus, encouraging the pursuit for alternative treatments and care interventions. Converging to our perspective, literature review showed lack of clear evidence of effective treatment for skin toxicity related to radiation, highlighting the fact that a realistic goal would be to delay and reduce signs and symptoms of skin reactions (Feight, 2011). On the other hand, despite the absence of significant difference between groups in this study, the subjective perception of the researchers that toxicity tends to emerge later in the group with better skin hydration (Cabbage) compared to the group with more anti-inflammatory and soothing effect (Chamomile), the results suggest that these different mechanisms of action indicate that the products could be used in different phases of the toxicity evolution. It is important to mention that the therapeutic effects of chamomile are notorious and studies with different concentrations and product presentations may offer benefits not yet fully known. A true control group has been suggested to compare the results of these interventions *versus* no intervention at all. However, clinical experience has clearly shown the benefits of skin care compared to no intervention. In addition, studies that report skin toxicity following radiation without skin interventions show overall higher severity of skin lesions (Brunt, 2006). No published reports were found on the cross-cultural adaptation, validity and reliability of the RTOG criteria used to assess radiodermatitis. Thus, although commonly used, it is possible that the lack of significant results could have been related to the instrument used to measure the main outcome variable.

Nurses must consider not only effectiveness of a product when intervening with diverse socio-cultural women's background, but also cost and ease of use. Chamomile tea compress has a low cost (approximately US $3.00 for the entire treatment) and is easily found in markets. The Cabbage ointment (Debridan®) has significantly higher cost (approximately US $37.00 for the entire treatment) and is sold in specific drugstores. Acknowledging recent published papers on radiodermatitis, we understand that despite the limitations, the main contribution of our study was to present one more option of a topical agent associated with usual skin care instructions (Feight, 2011 and Hemati, 2012). Moreover, the linkage between evidence-based practice and the theory underlying skin care, and pathophysiology of radiodermatitis, in fact, demands individualized care and knowledgeable professionals who will assess, diagnose, and intervene with these patients (Dendaas, 2012). Yet, understanding that studies like this have disadvantages, such as the common impossibility of determining statistical significance of effectiveness due to small sample size, is the way oncology nurses are critically thinking about their practice and participating in the construction of evidence for quality assistance (Cope, 2015).

Conclusions

We conclude that the effect of Chamomile tea compresses and cabbage ointment were similar in the prevention of acute radiodermatitis in patients with breast cancer. The incidence of radiodermatitis was 100% and the severity of radiodermatitis assessed by RTOG scale ranged between grades 1 and 2. Future studies that include a follow-up after the end of radiation treatment and investigation of associated factors, might show more benefits of each investigational product.

Author Disclosure Statement: Each and every one of the authors involved in this paper has no financial relationship with the organization that donated both products used for the interventions in this study. Therefore, no competing financial interests exist. All primary data is under our power/control and we agree to allow the journal to review the data if requested.

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