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The effect of avena sativa cream on dermatitis caused by radiation in breast cancer patients: a pilot study

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Abstract

In this randomized clinical trial study, intended to determine the effect of Avena sativa cream on radio dermatitis in breast cancer patients. The study results revealed that the degree of skin grade has decreased remarkably within the participants of intervention group using the cream containing Avena sativa extract, though this difference was not statistically significant. Moreover, pain, itching, and burning were reported to get ameliorated in all the participants of the intervention group. It should be noted that the difference in the severity of burning variable was demonstrated to be statistically significant (p=0.008, burning). Consequently, The results indicates that utilizing topical ointments containing the Avena sativa extract can be regarded beneficial in order to heal the skin reactions caused by radiotherapy.

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Introduction

Breast cancer is regarded as the most prevalent cancer within the Iranian women, and The findings of studies conducted that more than 50% of the patients suffering from cancer necessitate to be exposed to radiotherapy during the treatment process (Omidvari *et al., 2013)*. Although radiotherapy aims to provide the maximum treatment along with the minimum side effects, more than 95% of the patients suffer from average to severe skin reactions such as edema, erythema, dry and moist desquamation, bleeding, wound, and necrosis (Mc Question, 2006). The pain, burning, and itching as radiotherapy side effects not only produce adverse effects on these patients' life quality, but also they will probably reduce the anti-tumor effects, since the severity of such complications can lead to undesirable interruptions in the radiotherapy treatment process(Omidvari *et al.,2013)*.

Various procedures have been put forward in order to prevent or treat radio dermatitis, among which such procedures as public health, washing the wheal with mild soaps and water, medical plants such as Aloe Vera, Corticosteroids, ointments containing honey and etc (Omidvari *et al.,2013*). Among the various treatments utilized, applying topical Corticosteroids is most focused in treating the acute radiodermatitis. Moreover, both patients and doctors are reluctant to apply Corticosteroids during the radiotherapy due to their probable long-term side effects (Fotuhi *et al.*,2007).

Given that radiotherapy can lead to the skin reactions as the result of the damage of dermal layer of the skin, some other interventions with the fundamental physiological mechanisms may be demanded(Mc Question, 2006), among which complementary and alternative medicine (CAM) can be mentioned.The investigations conducted on the use of complementary therapies in various populations have proposed that these therapeutic procedures are mostly used for chronic diseases such as cancers. In other words, 75% of women suffering from breast cancer have been reported to use complementary therapies (wanchai, *et al.*,2010).

Today, herbal therapies and medical plants compose the most active constitutes of complementary therapy (Ebrahimi, 2011), among which medical plant of oat can be mentioned which is scientifically named as *Avena sativa* L. Oat has benefited a great number of domains such as wound healing, disinfection, and healing skin problems like eczema and pain relief. Overall, the oat bran involves a supply of B-complex, protein, fat, minerals, and soluble fibers of ß-Glucagon (FENG,*et al.*, 2013). In fact, PhytoChemicals have been lately taken into consideration due to their Anti-cancer properties. There are some Phytoestrogen compositions in oat named Lignans, which can reduce the risk of being affected by hormonal diseases such as breast cancer(Nazari, *et al.*,2012).

As a matter of fact, complementary medicine involves one of the integrative aspects of the nursing profession. Moreover, nursing is one of the first professions that has facilitated use of complementary medicine. CAM in nursing aims to provide palliative care, relieve the patient's pain and suffering, increase his comfort, and promote the improvement aspects of the patient encountering life-limiting diseases(Frisch, 2001).

Previous studies have shown that the Avena sativa extract propose its antioxidant and anti-inflammatory properties which can be effective in different types of skin inflammations such as itching, atopic dermatitis, rashes, and Psoriasis (Pazyar, *et al.*, 2012). These positive effects of using this medical plant allowed us to hypothesis that there might have been remarkable influenced of Avena sativa cream on radio dermatitis in breast cancer patients. Therefore, this study intended to determine the effect of Avena sativa extract on skin topical problems caused by radiotherapy in patients suffering from the breast cancer.

Materials and methods

Overal design

The present study is a randomized clinical trial conducted in Shahid Ramazan-zade Radiotherapy Center in Yazd. After obtaining informed consent, 13 patients with breast cancer, who were undergoing radiotherapy treatments with Radiation dose of 40 to 60 Gray, were selected using simple randomization. The study participants were divided into two groups of intervention and control, using table of random numbers and sealed envelopes already prepared.

Inclusion & Exclusion criteria

Inclusion criteria included all women with breast cancer who, based on the pathological findings, were first treated with the same dose of radiation (Radiation dose of 40 to 60 Gray, 1.8 to 2 Gray daily, from Saturday to Wednesday lasting for about one and half a month). It is worth mentioning that the participants did not suffer from any kinds of skin lesions. Exclusion criteria involved the following issues: 1. Patients with uncontrolled diabetes, 2. Acquired immunodeficiency syndrome, 3. Active SLE, 4. Scleroderma or rheumatic diseases, and 5. Being allergic to medicinal plants.

Procedure

Thirteen patients participated in the study, seven of whom were exposed to the treatment via applying a cream made of Avena sativa extract, whereas the other participants received a basic cream lacking oat extract. After the construction of the cream, the patients in the intervention group were required to rub it softly on the intended place three times a day_ at 8-hour intervals. One figure unit (FTU) of the cream needed to be rubbed on the place under radiotherapy treatment (Of course, it is worth mentioning that the amount of cream to be used depended on patient' s Body Mass Index (BMI) and extent of the lesion), and the patients were advised to avoid washing the cream place for about three hours. Moreover, the control group were given the cream lacking Avena sativa extract.

It is noteworthy that each FTU is equal to almost 0.5 gram, and thus each $1cm^2$of the intended place receives $2\ mg/cm^2$of the cream. According to FDA standards, the amount of cream to be used on the lesion involves$2\ mg/cm^2$. One FTU is equal to the cream that comes out of a tube with a bore of 5 mm from the joint line to the distal tip of the finger (Maleki *et al.*, 2009).

Data collect

Then, participants' demographic characteristics and skin problems were investigated via a questionnaire which was devised on the basis of Radiation-Induced Skin Reaction Assessment Scale (RISRAS), and RTOG (to determine the degree of radio dermatitis). It is worth mentioning that since they involve standardized questionnaires, the validity as well as the reliability of these two questionnaires have been substantiated earlier. The demographic characteristics explored in the current study consisted of age, menopausal status, type of surgery, the number of chemotherapy sessions, etc., whereas the skin problems entailed Erythema, dry desquamation, grade of skin problems, burning, itching, tenderness, pain and discomfort. These variables were studied at intervals of 10 days after the beginning of treatment (the beginning of general Erythema reaction), and 28 days after the beginning of treatment (dry desquamation). Moreover, the aforementioned variables were scrutinized on the last day of radiotherapy, and two other times after the completion of radiotherapy each one having one week as their interval. Then the gleaned data was analyzed using statistical tests of t-test and chi-square via SPSS software(version 10), taking into consideration α=0.05.

Instructions to Prepare the Avena sativa Cream

The instructions in regard with how to prepare Avena sativa cream was followed as below: first, Avena sativa was got from the medical plant market of Tehran. Then, in order to prepare the oat extract, 100 gram oat should be powdered, and 1000 ml distilled water should be added. Afterwards, a container involving Avena sativa powder and distilled water was to boil for 10 minutes and then was sieved. The extract should get on bain-marie to be condensed. Avena sativa creams of 1%, 2%, 3%, 4%, and 5%were

prepared using a basic cream in order to determine the effective dose of cream. The creams were piloted on the patients, and the beneficial points were observed and recorded. Finally, it was revealed that 4% and 5% creams produced similar effects, and, as a result, the cream containing 4% of oat extract was regarded to be the benchmark.

Results

Sample Characteristics

The study sample consisted of 13 patients suffering from breast cancer based on the pathological results, who were treated with radiotherapy for the first time. The study participants were classified into two groups of intervention (7 patients) and control (6 patients). The mean age of the patients in intervention and control group were 51.14±14./04 and 54.8±18/2, respectively, among which six participants were at the stage of pre menopause, six other of patients experienced after-menopause stage, and one participant had undergone hysterectomy surgery. The average of radiotherapy period of time was 33.8±6/4 days for the intervention group, whereas it was 36.5±5/8 days for the control group.

Within the study sample, seven patients were involved with their lymph nodes as well, and five patients had undergone mastectomy. CAF (Cyclophosphamide, Adriamycin, and 5 Fluorouracil) was considered to be the Chemotherapy regimens for five patients, whereas Taxotere, Adriamycin, and Cyclophosphamide Chemotherapy regimens were prescribed for other six patients.

The Comparison Results between Intervention and Control Groups in Regard with the Study Variables

Several variables were scrutinized in the current study to detect whether there was a significant difference between the intervention and control group including age, menopausal status, right and left breasts, the number of Chemotherapy sessions, lymph node involvement. As a matter of fact, comparing intervention and control groups revealed some results presented in Table 1 as below.

The Comparison Results between Intervention and Control Groups in Regard with the Pain, itching& burning

Analysis of data showed that In both the intervention and control groups, a severe pain was reported in all patients' breasts and armpits; though, no participants experienced tenderness. Also, On the 28th day of the treatment, three patients in the intervention group were reported to suffer from a little itching which was gradually alleviated within5 days. However, in the control group, the number of little itching patients grew from 2 to 5 in a week interval, who were reported to have little or average itching(table 4).

Regarding the burning variable, one of the participants in the intervention group experienced it on the 12th day which was eliminated by the 17th day. On the other hand, in the control group, three patients were reported to be suffering on the 8th day, which was gradually increased to the average degree, and on the 35th day, near the end of the treatment, all the patients in the control group were reported to suffer from burning. Overall, the patients considered the little or average effect of these problems on their daily activities (table 4).

Finally, the study results revealed that, the degree of skin grade has decreased remarkably within the participants of intervention group compared to the those of control group, using the cream containing Avena sativa extract. It is worth mentioning that such a difference between the two groups was not statistically significant which can be attributed to the insufficient number of the participants. Moreover, pain, itching, and burning were reported to get ameliorated in all the participants of the intervention group who received cream of Avena sativa extract. It should be noted that the difference in the severity of burning variable was demonstrated to be statistically significant (p=0.008, burning).

Discussion and conclusion

The existing studies conducted on Avena sativa extract propose its antioxidant and anti-inflammatory properties which can be effective in different types of skin inflammations such as itching, atopic dermatitis,

rashes, and viral infections (Pazyar & *et al*., 2012). In another study conducted by Fowler *et al*, utilizing moisturizers or cleansers containing colloidal Avena sativa extract was revealed to produce substantial effects on healing of eczema, atopic dermatitis, itching, and dry desquamation.

Table 1. The Comparison Results between Intervention and Control Groups in Regard with the Study Variables.

Groups		Intervention Count Percent%	Control Count Percent%	p-value
Variables				
Menopausal status	Before Menopause	3 50%	3 50%	./4
	After Menopause	3 50%	3 50%	
	Hysterectomy	1(100)	0	
Total		7(100)	6(100)	
Lymph node involvement	Yes	5(71/4)	2(28/6)	./5
	No	2(40)	3(60)	
Total		7(100)	6(100)	
Breast	Left	4(66/7)	2(33/2)	./5
	Right	3(42/9)	4(57/1)	
Total		7(100)	6(100)	
The number of chemotherapy sessions	6	3(50)	3(50)	./3
	8	3(50)	3(50)	
	16	1(100)	0	
Total		7(100)	6(100)	
Age	30-40	2(28/5)	1(16/6)	./3
	40-50	2(28/5)	3(50)	
	Age>50	3(42/8)	2(33/3)	
Total		7(100)	6(100)	

*Fisher's Exact Test was statistically applied to analyze the study data.

As far as the authors of the present study were concerned, no special product has hitherto been made from Avena sativa in regard with its antioxidant and anti-inflammatory properties to decrease itching and inflammation. Therefore, this study intended to prepare a topical cream in order to be used in the reactions caused by radiotherapy. As a matter of fact, this cream was produced to alleviate the itching and inflammations caused by radiotherapy in women suffering from the breast cancer. The study findings revealed that within the intervention group, pain, itching, and burning were reported to get ameliorated in all the participants. It should be noted that the difference in the severity of burning variable was demonstrated to significantly decrease which is in line with those findings of Fowler. In that study, applying moisturizers or cleansers containing colloidal Avena sativa extract could result in amelioration of itching and dryness caused by dermatitis. On the other hand, in the control group who received the placebo (the cream lacking the extract), itching and burning gradually started from the 8th day, and on the 35th day (near the end of the treatment) approximately all the patients were suffering from the phenomena.

Table 2. The Comparison Results between Intervention and Control Groups in Regard with the Grade of Skin Problems Caused by Radiotherapy.

	pre-Treatment Skin Grade			Skin Grade 10 Days After the Beginning of Treatment			Skin Grade 28 Days After the Beginning of Treatment			Skin Grade On The Last Day of The Treatment		
Grade of the Skin Problems	0	1	2	0	1	2	0	1	2	0	1	2
The Sample Number in the Intervention Group	7	0	0	6	1	0	0	5	2	0	2	5
The Sample Number in the Control Group	6	0	0	5	1	0	2	3	1	0	3	3
*p-value	-			1/000			./755			./592		

*Chi-Square was statistically applied to analyze the study data

In another study conducted by Cerezo *et al.*, the effect of a herbal gel containing Aloe Vera, Chamomile, and Oatmeal was investigated on the prevention and treatment of the patients suffering from rectal or gynecological pelvic tumor who were exposed to radiotherapy. This study finding revealed that grade 3 dermatitis was observed only in 10% of the patients participating in the intervention group, whereas, that of the control group was 45%. Moreover, the obtained results demonstrated that grade 2 dermatitis was detected in only one patient (5%) in the intervention group after being provided with the dose of 27-30 gray, while, 13 patients (65%) in the control group were suffering from such a problem. Similarly, in the present study, utilizing the Avena sativa extract cream lead to a significant decrease of skin grade in the intervention group compared to those patients in the control group who received the placebo. However, due to the insufficient number of the participants in the sampling, the difference between the two groups was not considered to be statistically significan

Table 3. The Comparison Results between the Intervention and Control Groups in Regard with Erythema Severity**.**

	The pre-prescription severity of erythema			The severity of erythema 10 days after the prescription			The severity of erythema 28 days after the prescription			The severity of erythema on the last day of the treatment		
Type of erythema	Normal skin	Mild erythema	Bright erythema	Normal skin	Mild erythema	Bright erythema	Normal skin	Mild erythema	bright erythema	Normal skin	Mild erythema	bright erythema
The sample number in the intervention group	7	0	0	6	1	0	0	3	4	0	2	5
The sample number in the control group	6	0	0	5	1	0	1	2	3	0	0	6
P-value	-				./731	-		./587	./617		./563	./269

*Chi-Square test was statistically utilized to analyze the study data.

Roy *et al.* conducted a study exploring the effect of washing of the lesion caused by radiotherapy with soap and water. The study results revealed that incidence of moist desquamation was observed in 34% of the patients who did not wash the radio-caused lesion with soap and water, versus 14% of the patients in the soap-washing group. In addition, in another study conducted by Olsen *et al.* the effect of Aloe Vera gel was investigated on the patients undergoing radiotherapy in head, neck, and breast positions. The study findings demonstrated a significant difference in the beginning of skin reactions. In another study, it was revealed that the use of edible curcumin (it involves a natural phenol combination that can be found in curcumin) can result in decreasing the effect of radio dermatitis in patients undergoing radiotherapy on their breasts. Some other studies explored the effect of different types of corticosteroid ointments, lotions, and creams, as well. It was revealed that these material own adverse side effects, besides their medical merits (Mc Question, 2006). Glees *et al.* stated that a significant difference was observed between 1% Hydrocortisone and Clobetasol butyrate creams in regard with the severity of skin reactions. Despite these findings, these creams are not recommended as the first line drugs, since 94% of the patients using Hydrocortisone cream, and 88.5% of those applying Clobetasol butyrate cream suffered from average and severe skin reactions.

Since the herbal products are generally regarded as healthy, utilizing the topical products produced from Avena sativa extract can be effective in healing such skin reactions as eczema, atopic dermatitis, itching, dry desquamation, and even viral infections. On the

other hand, it was revealed that various studies have hitherto been conducted exploring the effect of Aloe Vera gel, topical honey, washing the radiotherapy position with mild soap, and different creams types on healing the radio dermatitis in patients suffering from cancer. Despite mentioning the positive influence of Avena sativa, no study have hitherto been conducted in order to explore its effect on healing and prevention of radio dermatitis. Therefore, conducting this study appears to be necessitated determining the effect of Avena sativa extract on radiotherapy side effects in patients suffering from breast cancer.

Table 4. The Comparison Results between the Intervention and Control Groups Regarding Variables of Tenderness, Itching, Burning, Change in Daily Activities, and Dry Desquamation.

variables		From the beginning of the treatment until 10 days after the prescription			From 10th day to 28th day after the prescription			From the 28th day until the last day of the treatment		
		Low	average	severe	Low	average	severe	Low	average	severe
Pain & tenderness	intervention	-	-	-	-	-	-	-	-	-
	control	-	-	-	-	-	-	-	-	-
p- value		-			-			-		
Itching	intervention	**0**	**0**	**0**	**3**	**0**	**0**	**0**	**0**	**0**
	control	**0**	**0**	**0**	**2**	**0**	**0**	**4**	**2**	**0**
p- value		-			1/000			./005		
burning	intervention	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**
	control	**3**	**0**	**0**	**3**	**1**	**0**	**4**	**1**	**1**
p- value		./070			./339			./005		
Changes in daily activities	intervention	-	-	-	**2**	-	-	**1**	**1**	**0**
	control	-	-	-	**1**	-	-	**5**	**0**	**0**
p- value		-			1/000			./050		
Dry desquamation	intervention	0			1			3		
	control	0			0			2		
p- value		-			./538			./587		

*Chi-Square test was statistically utilized to analyze the study data.

Although the results obtained in the current study confirm utilizing medical products containing Avena sativa extract, the insufficient number of participants in the study sample should be taken into consideration in interpreting the results.

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