Effects of a topical henna preparation in preventing and reducing the severity of radiation dermatitis in breast cancer patients: a randomized double blind clinical trial

Shaghayegh Kamian[1], Ghazaleh Heydarirad[2], Mozhgan Mehriardestani[3], Mansour Lesan[4]

1. PhD, Assistant professor of radiation oncology, Department of radiation oncology, Imam Hossein hospital, Shahid Beheshti University of medical sciences, Tehran, Iran, **Email**: shkamian@sbmu.ac.ir
2. PhD, Assistant Professor of traditional Medicine, Traditional medicine and materia medica Research Center, School of traditional medicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran
3. PhD, Assistant Professor of traditional pharmacy, Department of traditional pharmacy, School of traditional medicine, Tehran University of Medical Sciences, Tehran, Iran
4. MD, Department of radiation oncology, Imam Hossien hospital, Shahid Beheshti University of medical sciences, Tehran, Iran

Introduction

Breast cancer patients who receive radiotherapy develop acute skin complications which known as radiation dermatitis (RD) during radiotherapy or shortly after it. This research aimed to evaluate the efficacy of a topical topical henna preparation (HP) in preventing and reducing the severity of RD in breast cancer patients.

Materials and methods

In this research, 43 patients were allocated into two groups, those received the topical henna preparation (HP) twice daily (experimental group, n= 20) or those received placebo (control group, n= 23) twice daily for six weeks. Participants were instructed to spread intervention preparation on the surfaces of the irradiated areas after radiotherapy and before bedtime. Intervention was started since the first session of radiotherapy.

Severity of RD symptoms set as the outcome measure. RD grade was evaluated weekly based on RTOG grading system for 6 weeks. Patients were monitored weekly during radiotherapy for the side effects of intervention and grade of dermatitis.

Results

No significant differences with regard to age, breast size, total dose of radiotherapy, and number of days from the end of chemotherapy till the start of radiotherapy were observed between the two groups (P Value>0.05) (table 1).

Table 1: Demographic and radiotherapy variables in two groups

Variable	Group	Mean	P Value
Age (year)	Case	49.10±10.44	0.325
	Placebo	45.87±10.47	
Total dose of radiotherapy	Case	61.16±1.92	0.912
	Placebo	61.22±1.57	
Breast size (cc)	Case	1107.25±370.41	0.852
	Placebo	1086.57±351.24	
Number of days *	Case	34.25±13.78	0.434
	Placebo	31.52±8.62	

*Number of days from the end of chemotherapy till the start of radiotherapy

The results in table 2 showed that in the HP group, the most grade of RD was 0 and 1 until the fourth week of radiotherapy; while, in the placebo group 8.69% of patients had grade 2 RD from the third week. In the HP group, grade 2 RD was reported in 25% of patients from the fifth week of radiotherapy.

As well, in the HP group only 10% of patients in the fifth and sixth weeks of radiotherapy had grade 3 RD, while in the placebo group, 26.09% of patients had grade 3 RD in the same times.

Table 2: Grade of dermatitis grade during the time in two groups

Group	Grade of dermatitis	third week	fourth week	fifth week	sixth week
Drug	0	16(%80)	10(%50)	5(%25)	4(%20)
	1	4(%20)	10(%50)	10(%50)	10(%50)
	2	0(%0)	0(%0)	5(%25)	4(%20)
	3	0(%0)	0(%0)	0(%0)	2(%10)
placebo	0	10(%43.48)	2(%8.70)	0(%0)	0(%0)
	1	11(%47.83)	13(%56.52)	8(%34.78)	4(%17.39)
	2	2(%8.69)	8(%34.78)	9(%39.13)	13(%56.52)
	3	0(%0)	0(%0)	6(%26.09)	6(%26.09)
P Value		0.039	0.001	0.007	0.004

Discussion

The HP could reduce the severity of RD within 6 weeks. The use of HP delayed the onset of grade 2 RD for 2 weeks and grade 3 RD for 1 week compared to the placebo group. In the case group, the volume of the breast that received 107%, 110% and the percentage of the total breast volume that received 110% of the radiotherapy dose was significantly higher than the placebo group (P = 0.043, p=0.014 and p=0.49, respectively).

There are a few studies on various types of topical henna formulations for dermatitis, which all have significant positive results that are compatible with this study (1, 2). henna has anti-inflammatory, analgesic, antimicrobial, and wound healing effects (1). Lozza et al. study revealed that lawsone activates the aryl hydrocarbon receptor (AhR) transcriptional program and modulates skin homeostasis. AhR mediated signals have an essential role in the regeneration and recovery of skin during continuous exposure to environmental harmful agents (3). Therefore, it seems that HP can be effective in both preventing and healing RD.

Conclusion

Henna is an inexpensive and accessible herbal medicine that seems be effective in preventing and reducing the severity of RD in patients with breast cancer, so, it could be considered as a suitable complementary therapy for improvement of RD.

The authors confirm they had no conflicts of interest in this study and they did not receive any funding.

Reference

1. Niazi M, Mehrabani M, Namazi MR, Salmanpour M, Heydari M, Karami MM, et al. Efficacy of a topical formulation of henna (*Lawsonia inermis* L.) in contact dermatitis in patients using prosthesis: A double-blind randomized placebo-controlled clinical trial. Complementary Therapies in Medicine. 2020:102316.

2. Hosseini SV, Tanideh N, Kohanteb J, Ghodrati Z, Mehrabani D, Yarmohammadi H. Comparison between Alpha and silver sulfadiazine ointments in treatment of Pseudomonas infections in 3rd degree burns. Int J. Surg. 2007;5(1):23-6.

3. Lozza L, Moura-Alves P, Domaszewska T, Crespo CL, Streata I, Kreuchwig A, et al. The Henna pigment Lawsone activates the Aryl Hydrocarbon Receptor and impacts skin homeostasis. Sci rep. 2019;9(1):1-21.