

Comparative Evaluation of Efficacy and Safety of Herbal Preparation vis-a-vis Beclomethasone Cream on Radiation Induced Skin Injury in Head and Neck Carcinoma Patients Receiving Radiotherapy or Chemoradiation in Oncology Department at a Tertiary Care Hospital

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ABSTRACT

Introduction: Radiation mitigators are the compounds which can minimize or ameliorate post irradiation-toxicity provided they are administered before the onset of toxic symptoms. Hence, there is an urgent need to prevent harmful effects secondary to ionizing radiations.

Material and Methods: Sixty patients of Head and neck carcinoma more than 18 years of age of either sex and willing to give informed consent were included in the study. In Group-1, 30 patients received the Beclomethasone cream that was topically applied from the day-1 of radiotherapy till 4-weeks after completion of radiotherapy, whereas In Group-2, 30 patients received the local application of the herbal paste from the day-1 of radiotherapy till 4-weeks after completion of radiotherapy.

Results: For measuring radiation-induced reactions, non-parametric test like chi-square test was applied and number of patients in different grades was calculated as per RTOG-criteria. Similarly for measuring radiation-induced mucosal reactions, chi-square test was applied and number of patients in different grades was calculated as per RTOG-criteria.

Conclusion: Present study revealed a marked beneficial

effects of herbal paste containing *Azadirachta indica*, *aloe vera*, *Ocimum sanctum* and *Curcuma longa* on radiation induced skin injury in patients with Head and neck carcinoma as compared to topical Beclomethasone cream.

Key-words: Beclomethasone Dipropionate Cream, Free Radical Scavengers, Ionizing Radiation, Radiation Mitigators, Polyherbal Paste.

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Article History:

Received: 07-11-2018, Revised: 02-12-2018, Accepted: 29-12-2018

Access this article online	
Website: www.ijmrp.com	Quick Response code 
DOI: 10.21276/ijmrp.2019.5.1.004	

INTRODUCTION

In 1902, it was documented that ionizing radiation causes skin injury. Ionizing radiation, now a days is a favoured treatment modality for various types of cancer. Therefore radiation skin injury remains a major hurdle. This type of skin and mucosal injury is termed as radiation dermatitis. It is usually seen in about 95% of patients receiving radiation therapy for cancer, and ranges from mild erythema to moist desquamation and ulceration. Ionizing radiation is not only a concern for cancer patients, but also a public health concern because of the potential for radiological event. Radiations are commonly categorized as ionizing or non-ionizing. The term ionizing radiation applies to any radiation that carries energy to ionize atoms or molecules. They break the chemical bonds and liberate electrons from atoms or molecules. The common source of ionizing radiation are radioactive materials and X-rays from medical radiography examinations.^{1,2}

There is ever growing research to discover effective and less toxic radioprotective agents. This lead to increasing interest on natural compounds from dietary ingredients and medicinal herbal plants. The crude extracts of these plants constitute several effective radioprotective drugs. They also act as antioxidants and significantly prevent the cellular damage in terms of lipid peroxidation, free radical scavenging activity and protein oxidation. The ability of certain substances to provide protection against the damaging effects of ionizing radiation was first published in 1949.³ The first report on in vivo radioprotection was reported by study done by Patt et al,⁴ where pre-treatment with amino acid, cysteine was shown to increase survival of irradiated rodents. Later on studies showed that aminothiols compounds like cysteine and cysteamine have a structure most favourable for radioprotection and the Sulfhydryl moiety in these compounds are

crucial for their radioprotective property.⁵ However, these compounds are too toxic at their radioprotective doses produce serious side effects.

Radiation results in the formation of reactive oxygen species (ROS), reactive nitrogen species (RNS) and also the generation of other free radicals. Because of the presence of unpaired electrons, free radicals are capable of altering all biological molecules including lipids, DNA, and proteins. The health effects resulting from exposure to ionizing radiation can be divided into two categories namely Probabilistic and deterministic. The probabilistic health effect may take several years to develop after radiation exposure, while deterministic effects like cataract induction, hematologic deficiencies, erythema, skin injury and infertility occurs at high doses of radiation. Exposure to high amount of ionizing radiation can also results in damage to the hematopoietic, gastrointestinal, reproductive and central nervous systems. Thus there is always an impending need for good radioprotective agents. Many chemical compounds have been screened for their radio protective potential. These synthetic compounds show toxicity at their optimum protective doses. To reduce the toxic effects of synthetic compounds, there is a need to explore the new compounds. The use of natural compounds for improving health has increased in present time. Therefore, it is quite desirable that the choice of alternative radioprotective agents could be from plants origin. But, their use as radioprotective agents needs scientific evaluation and validation. Natural radioprotective agents could be more successful and cheaper than synthetic compounds.⁶ An ideal radioprotective agents should have the following properties like possessing free radical scavenging activity by upregulating m-RNAs of antioxidant enzymes such as catalase, glutathione transferase, glutathione peroxidase, superoxide dismutase^{6,7}, preventing radio oxidative damage, facilitating DNA and cellular repair, immuno modulatory action, facilitating revival of damaged and affected organs, promoting the recovery of hematopoietic and immune functions,⁸ compaction of DNA,⁹ triggering the DNA repair enzymes, detoxifying the radiation induced reactive species,¹⁰ delay of cellular division and inducing hypoxia in the tissues,¹¹ reduction in lipid peroxidation and elevation in non-protein sulphhydryl group.

Topical corticosteroids have been shown to have an anti-inflammatory effect in radiation dermatitis and, therefore, are commonly prescribed to treat this condition. It has been found that radiation exerts acute and chronic effects due to excessive production of eicosanoids namely prostaglandins, prostacyclin, thromboxanes and leukotrienes. These mediators may be responsible for vasodilatation, increased vascular permeability, thrombosis and chemotaxis seen after radiation exposure. Glucocorticoids are known to inhibit eicosanoid synthesis by interfering with phospholipase A2. Several studies have shown that administration of glucocorticoid inhibit the effects of radiation in humans.^{12,13}

In our study, Aloe vera, Azadirachta indica, Curcumin longa and Ocimum sanctum were studied to test their radioactive potential.

ALOE VERA

Aloe barbadensis (Mill.) belongs to family Liliaceae and commonly known as Aloe vera. Aloe leaf contains two basic components, pulp (gel) and latex. Aloe gel (AG) is a clear mucilaginous substance produced by parenchymal cells located in

central region of the leaf. AG is composed mainly of water (99%) and mono and polysaccharides (25% of dry weight of the gel). The most common monosaccharide in AG is mannose -6-phosphate and most common polysaccharides are called gluco-mannans.¹⁴ The prominent gluco-mannon is named as acemannan. AG significantly stimulates collagen synthesis in dermal wound in rats.¹⁵ Mannose-6 phosphate was found to be responsible in wound healing in man.¹⁶ Thereafter, various biological properties of Aloe have been reported by several workers. Topically applied Aloe gel can help in healing of radiation burns.¹⁷ Latex contains anthraquinone, glycosides that are potent stimulant laxatives. Aloe gel is rich in vitamins [A (β -carotene), C and E],¹⁸ glutathione peroxidase, several isoenzymes of superoxide dismutase and minerals like zinc and selenium.^{14,18,19}

OCIMUM SANCTUM

It is a medicinal herb widely used in the ayurveda system of medicine in india. It is used for treating various infections, many skin diseases, common cold and cough, malarial fever and hepatic disorders. It also possesses anti-bacterial¹⁹, anti-inflammatory²⁰, antiviral²¹, anti-carcinogenic²², antioxidant and immunostimulatory activities.²³ Uma Devi et al²⁴ reported its radioprotective property for the first time. Aqueous and alcoholic extract of leaves have radioprotective properties, but its aqueous extract was more effective in increasing survival.²⁴ Its extract was compared with WR-2721, a standard radioprotector.²⁵ Its intraperitoneal injection in mice before delivering 2 Gy total body Gamma-radiation produced a significantly higher bone marrow stem cell survival. Ocimum sanctum contain two active components namely, orientin and vicenin. These components protected human lymphocyte chromosomes against radiation.^{26,27}

AZADIRACHTA INDICA

Neem (Azadirachta indica), a member of the Meliaceae family, is a fast growing tropical evergreen tree with a highly branched and stout, solid stem. There is interesting and compelling evidence to suggest that neem may be used as a tumor suppressor. Neem extracts and its purified products have been examined for induction of apoptosis among the cancer cells. Treatment with neem extract²⁸ suppressed the level of expression of bcl-2 protein, which is a strong pro-survival factor in cancer cells and at the same time enhanced the level of expression of pro-apoptotic Bax protein.²⁹ There are many evidences to suggest that neem products e.g., Azadirachtin A, nimbolide and nimbidin possess convincing anticancer properties.^{30,31}

CURCUMA LONGA (HALDI)

Curcumin (diferuloylmethane), the yellow pigment in Indian saffron (*C. longa*; also called turmeric, *haldi*, or *hardara* in the East and curry powder in the West), has been consumed by people for centuries as a dietary component and for a variety of proinflammatory ailments.³² with wound healing properties in rodents.^{33,34} Widespread research within the last decade in cell culture and in rodents has shown that curcumin can sensitize tumours to different chemotherapeutic agents. Likewise evidence too demonstrates that this agent can sensitize a variety of tumours to Gamma-radiation including glioma, neuroblastoma, cervical carcinoma, epidermal carcinoma, prostate cancer, and colon cancer. The mechanism behind its chemosensitiser and

radiosensitiser activity demonstrates that it down regulates several growth regulatory pathways and precise genetic targets including genes for nuclear factor kappa-light-chain enhancer of activated B cells, Signal transducer and activator of transcription 3, Cyclooxygenase - 2, Akt (Protein Kinase B), antiapoptotic proteins, growth factor receptors, and multidrug - resistance proteins. While it acts as a chemosensitiser and radiosensitiser for tumours in some cases, curcumin has also been revealed to

safeguard normal organs from chemotherapy and radiotherapy-induced toxicity. The protective effects of curcumin seem to be facilitated by its ability to induce the activation of nuclear factor (erythroid - derived 2) and expression of antioxidant enzymes, directly neutralize free radicals, and inhibit p300 histone acetyl transferase (HAT) activity. These preclinical studies are expected to lead to clinical trials to prove the potential of this age - old golden spice for treating cancer patients.^{35,36}

Evaluation of skin toxicity and mucosal reaction was done as per RTOG-criteria.

Grade	Description
0	No change over baseline
1	Follicular, faint or Dull erythema/ epilation/ dry squamation/ decreased sweating
2	Tender or bright edema, patchy moist desquamation/ moderate edema
3	Confluent, moist desquamation, pitting edema
4	Ulceration, Haemorrhage, necrosis

MATERIALS AND METHODS

The study was approved by the institutional ethic committee. Written informed consent was obtained from all the participants. Inclusion criteria included 60 patients of Head and neck carcinoma more than 18 years of age of either sex were included in the study. In Group-1, 30 patients received the Beclomethasone cream that was topically applied from the day-1 of radiotherapy till 4-weeks after completion of radiotherapy.while In Group-2, 30 patients received the local application of the herbal paste over skin that began from the day-1 of radiotherapy till 4-weeks after completion of radiotherapy. Exclusion criteria included patients known to be allergic to ingredients of Herbal paste or with H/o allergy to steroids.

Preparation of Herbal Paste: A viscous gel-like material was collected from the incised leaf of Aloe vera plant. Fresh Ocimum sanctum leaves, Azadirachta indica leaves (50 grams each) and Curcuma longa roots (5 gram). This was further grounded into a paste with the help of mixer/grinder. This paste was properly mixed with 100 gram of Aloe vera juice.

STUDY PROTOCOL

60 patients of Head and neck cancer were divided into two groups of 30 patients each:

Group I: 30 patients received application of Beclomethasone cream.

Group 2: 30 patients received application of polyherbal paste containing *Aloe vera gel*, *Ocimum sanctum*, *Azadirachta indica* and *Curcuma longa* extracts.

Efficacy was judged by comparing Group I versus Group II patients as per RTOG-grading criteria.

RESULTS

For measuring radiation-induced reactions, Non-parametric test like chi-square test was applied and number of patients in different grades was calculated as per RTOG-criteria.

For measuring radiation-induced mucosal reactions, Non-parametric test i.e chi-square test was applied and number of patients in different grades was calculated as per RTOG-criteria.

1] At 4th week, comparing two groups as a whole, treatment with herbal paste prevented radiation induced mucosal ulceration in group II-patients and was considered to be statistically significant[P<0.01].

2] At 6th and 7th week, comparing two groups as a whole, in Group-II patients, herbal treatment was again statistically significant in healing mucosal ulcers and prevented patients going to Grade-III.

3] Even at 6th-month, difference between two groups was statistically significant.[P<0.01]

Table 1: Mucosal Reactions [as per RTOG criteria]

		No of patients				
		GRADE 0	GRADE 1	GRADE 2	GRADE 3	p Value
4 TH WEEK	Steroid Group	02	19	09	0	< 0.01
	Herbal Group	02	22	06	0	
5 TH WEEK	Steroid Group	0	12	18	0	P = 0.72
	Herbal Group	0	16	14	0	
6 TH WEEK	Steroid Group	0	3	21	6	P < 0.01
	Herbal Group	0	8	22	0	
7 TH WEEK	Steroid Group	0	0	25	5	P < 0.01
	Herbal Group	0	6	24	0	
6 TH MONTH	Steroid Group	4	22	04	0	P < 0.01
	Herbal Group	8	21	01	0	

Table 2: Skin Reactions [as per RTOG criteria]

		No of patients				
		GRADE 0	GRADE 1	GRADE 2	GRADE 3	p Value
4 TH WEEK	Steroid Group	0	24	06	0	P < 0.01
	Herbal Group	02	28	02	0	
5 TH WEEK	Steroid Group	0	18	12	0	P< 0.052 [borderline significant]
	Herbal Group	0	22	08	0	
6 TH WEEK	Steroid Group	0	08	12	10	P< 0.057
	Herbal Group	0	09	21	0	
7 TH WEEK	Steroid Group	0	01 [3.3%]	21	08	P < 0.01
	Herbal Group	0	10 [33.3%]	20	0	
6 TH MONTH	Steroid Group	03	16	10	01	P < 0.01
	Herbal Group	10	18	02	0	

For measuring radiation induced skin-injury, again chi-square test was applied, since data was qualitative and number of patients entering into different grades was assessed by RTOG-criteria.

1] At 4th -week, comparing two groups, difference between two groups was statistically significant in preventing skin - reactions.[P<0.01]

2] At 5th week, difference between two groups in preventing skin reactions was borderline significant.[P<0.052].

3] At 7th -week, difference between two groups was statistically significant and herbal paste treatment prevented patients going into Grade-III of skin reactions.

4] At 6th month, again difference between two groups was statistically significant.

DISCUSSION

Present study revealed a marked beneficial effects of herbal gel containing *Azadirachta indica*, *aloe vera*, *Ocimum sanctum* and *Curcuma longa* on radiation induced skin injury in patients with Head and neck carcinoma as compared to topical Beclomethasone cream. Beneficial effect of herbal preparation may be due to their antioxidant, free radical scavenging and immunostimulant properties of ingredients present in these 4 herbal extracts. It is now well established that exposure to ionizing radiation causes production of reactive oxygen species[ROS], reactive nitrogen species[RNS] and also the generation of other free radicals. Free radicals are highly reactive and are capable of altering all biological molecules including lipids, DNA and proteins. Since plants contain different phytochemicals their radioprotective activity may be mediated through several mechanisms. Scavenging of radiation -induced free radicals and elevation of cellular antioxidants might be foremost mechanism for radioprotection due to the presence of polyphenols. These polyphenols could up - regulate messenger RNA of antioxidant enzymes such as catalase, GSH transferase, GSHPx, superoxide dismutase (SOD) and hence counteract the oxidative stress - induced by ionizing radiations. Protection against radiation - induced damage is also conferred by the up-regulation of DNA repair genes, which bring about an error free repair of DNA damage. Certain extent of radioprotective activity is provided by the reduction in LPO and elevation in non - protein sulfhydryl groups. The plants and herb may also inhibit activation of protein kinase C, mitogen activated protein kinase, cytochrome P-450,

nitric oxide and several other genes that may be responsible for inducing damage after irradiation. Phytochemicals produce their radioprotective effects through various mechanisms, with their activity being measured predominately as either antioxidants, free radical scavengers, DNA repair modulators or preventers of DNA damage and lastly based on anti-inflammatory action. In the past 20 years, there has been a major shift towards evaluating phytochemicals as radioprotectors, primarily due to their potential bioequivalence, efficacy and in most cases low toxicity, relative to many of the established synthetic compounds available. Plants ability is in part due to the numerous antioxidant phytochemicals that they possess as part of normal metabolic processes. Polyphenols like flavonoids and their naturally occurring derivatives are structurally adapted in order to be activated by electron donating substituents which inhibit energy transfer mechanisms, ultimately suppressing oxidative stress and stabilising redox processing.³⁷

CONCLUSION

To conclude, radiation toxicity is a major problem for patients receiving therapy for malignancies. To date, there are only a limited number of radioprotectant agents used clinically to minimise the severity and duration of toxicities associated with radiation therapy. There are a number of promising agents emerging, however, further studies assessing their effects is required. Herbal extract paste in our study prevented post-radiation induced mucosal and skin-reactions and showed better effect than beclomethasone cream in patients of head and neck carcinoma receiving radiotherapy. The protective effects persisted for 6 month. Thus herbal paste made in our study exhibited radiation mitigator and radioprotector potential.

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Source of Support: Nil.

Conflict of Interest: None Declared.

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Cite this article as: Shalini Sharma, Vivek Sharma, MC Gupta, Yashpal Verma. Comparative Evaluation of Efficacy and Safety of Herbal Preparation vis-a-vis Beclomethasone Cream on Radiation Induced Skin Injury in Head and Neck Carcinoma Patients Receiving Radiotherapy or Chemoradiation in Oncology Department at a Tertiary Care Hospital. *Int J Med Res Prof.* 2019 Jan; 5(1):14-18. DOI:10.21276/ijmrp.2019.5.1.004