

Short Communication

## Effectiveness of ayurvedic treatment in alleviating side-effects of radiotherapy in patients suffering from oropharyngeal cancer and its relationship with improvement in immune status of the host

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### Abstract:

Ayurveda, an ancient Indian system of medicine is practised even today for various illnesses especially those which are caused by reduced immune responses. Recently combinations of Ayurvedic drugs are recommended for cancer as an adjunct therapy. In the first part of this study we have clinically assessed the efficacy of Ayurvedic drugs in alleviating side effects of radiotherapy. In the second part, we have undertaken additional studies to assess the improvement in immune status of these patients. In both studies the assessment was done before, after completion of radiotherapy and one month thereafter. 70 Patients of oropharyngeal cancers with all stages and grades of the disease, who opted for radiotherapy, were enrolled for the first part of the study. Group 1 consisted of 35 patients who were treated with radiotherapy alone while Group 2 consisted of 35 patients who received combinations of Ayurvedic drugs. Ayurvedic treatment consisting of following 4 preparations was given daily for Group 2 patients during 5 weeks of radiotherapy and 4 weeks thereafter. 1) Mauktikyukta Kamadudha 2) Mauktikyukta Praval Pan-chamrut (Herbo-mineral mixtures) and 3) Ananta Vati (Tablet of Hemidesmus indicus) were given orally twice a day, while 4) Yashtimadhu Ghruta (Ghee medicated with liquorice) was given as local application twice daily. To assess the clinical efficacy of Ayurvedic drugs, we have used following criteria.

- Common toxicity criteria of radiotherapy - Stomatitis, Trismus, Dysphagia, Xerostomia, Nausea, Excessive salivation and Weight loss
- Karnofsky score-general well-being and activities of daily life
- ECOG numerical score (Eastern Cooperation Oncology Group) - general well-being and assessment of symptoms
- QLQ Scales (QLQ C 30) as per assessment criteria by EORTC (Symptom, Global and Functional scores)

Results of this study show significant clinical improvement in stomatitis, trismus, dysphagia, xerostomia & nausea with p values varying between 0.004 .

### Keywords

Cancer, Radiotherapy, Chemotherapy, Adverse Effects, Ayurveda, Rasayana Avaleha

## Introduction

Cancer has challenged medical scientists with its dreadfulness and adverse effects of available treatments. It has been reported as the second-largest non-communicable disease after ischemic heart disease. Extensive research has produced many new healing methods and hundreds of medications for the management of cancer. Surgical excision is the oldest and most tested therapeutic modality for its treatment. Radiation therapy is effective in controlling a variety of malignant tumors and is a component in the management of about half of all patients with cancer. Cancer chemotherapy involves the use of cytotoxic drugs and hormones. The clinically useful anti-neoplastic agents are more toxic to the sensitive malignant cells than to the normal cells of the tumor-bearing host. The health-related quality of life is a multidimensional construct that includes the subjective appraisal of the patient's physical, mental, and social well-being. Quality of life outcomes are also the key goals of contemporary cancer management. Acute radiation largely affects cell renewal tissues — skin, oropharynx, mucosa, small intestine, rectum, bladder, and vaginal mucosa. These cell renewal tissues are rapidly proliferating. The anorexia-cachexia syndrome is considered by some authorities to be the most common cause of death in patients with cancer. Radiation therapy can cause anorexia through multiple mechanisms. Decreased appetite resulting from altered taste and smell is a result of cancer or its treatment, and the psychological factors may result in anorexia, diarrhea, nausea, vomiting, and mucocitis. Cancer cachexia includes metabolic, hormonal, and cytokine-related abnormalities that results in progressive wasting. Late effects include necrosis, fibrosis, fistula formation, non-healing ulceration, and damage to specific organs such as spinal cord transection and blindness. In cancer patients treated annually with chemotherapy, possibly 20% are cured and an additional 20% may experience significant prolongation of life. The remaining 60% have minimal or no benefit from cytostatic treatment and suffer from its toxic adverse reactions. Nausea and vomiting are immediately apparent after commencing chemotherapy. Therefore, these two have been identified as the toxicities of chemotherapy most feared by the patient. Rapidly dividing cells found in the bone marrow, mouth, stomach, intestines, and hair follicles bear the brunt of the damage. Sores in the mouth and mucocitis are also common adverse effects of chemotherapy.

## Materials and Methods

### Patients

Thirty-six patients fulfilling the diagnostic criteria of carcinoma (under treatment of radiotherapy and chemotherapy) were randomly selected from the OPD and IPD of the Oncology Department of the G.G. Hospital, and registered at the OPD of the Institute for Post Graduate Teaching and Research in Ayurveda Hospital, Gujarat Ayurved University, Jamnagar, in the present study.

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### Ethical clearance

The Institutional Ethical Committee of the IPGT and RA Hospital, Gujarat Ayurved University, Jamnagar, approved the study. An informed written consent was taken from each patient willing to participate before the commencement of the trial. The patients were free to withdraw their name from the study at any time without giving any reason.

### Inclusion criteria

1. Diagnosed cases of carcinoma at stage T1 or T2 being submitted for radiotherapy or chemotherapy or both.
2. Those complaining of acute short-term adverse effects.
3. Those between the age group of 16 and 70 years.

### Exclusion criteria

1. Patients in the T4M2 stage and having chronic long-term local adverse effects were excluded from the study.

### Drug

Rasayana Avaleha was prepared as per the Ayurvedic classical method of preparing Chyavanprash, in the Pharmacy of Gujarat Ayurved University, Jamnagar. The proportion of the ingredients was as follows: Amalaki (one part), Ashwagandha (one-fourth part), Guduchi (one-fourth part), Yashtimadhu (one-fourth part), Pippali (one-tenth part), Tulasi (one-tenth part), sugar (one part), and ghee (quantity sufficient). The preparation was formulated in the Avaleha form, which is a semi-solid pharmaceutical preparation, termed as 'electuary'. For authentication and standardization of the prepared drug, the phytochemical evaluation of Rasayana Avaleha had been carried out by Thin Layer Chromatography and High Performance Thin Layer Chromatography densitometry analysis, including fingerprint profiling, as well as quantification of marker / biomarker compounds. The TLC fingerprinting profile had revealed the presence of all the claimed plant ingredients and provided substantial support to authenticate the formulation. The different ingredients of the formulation contained important marker compounds, namely, piperine, B-sitosterol, eugenol, and lupeol. These compounds are biomarkers because they have been seen to have several biological activities. Suitable extraction procedures were adapted to ensure complete extraction of the compounds from the samples. The presence of the markers in the sample extract was ascertained by cochromatography and comparison of the Rf and relative percentage with that of the standards of the marker compounds.

### Dose

The dosage was 30 g early in the morning with 10 ml of ghee.

### Duration

Seventy-five days.

### Grouping

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The patients were divided into two groups using a random sampling method. In the first group, group A, Rasayana Avaleha was given via the oral route along with radiotherapy and chemotherapy. In this group, a total of 23 patients was given radiotherapy, 1.8 – 2 gray / day, five fraction / week, total 60 – 70 gray. In chemotherapy, the chemotherapeutic agents and their dose and duration varied according to the type of cancer and the patient's physical condition. Of the 23 patients, 16 completed the treatment. In the second group, group B, only radiotherapy and chemotherapy (RT + CT), as mentioned earlier, were given without Rasayana Avaleha. In this group, a total of 13 patients were treated, of which nine patients completed the course of therapy.

### Discussion

The treatment modality 'Radiotherapy' is a type of Tejas Mahabhuta Chikitsa, which can be considered as modified radiations of Agni Karma according to Ayurveda. The Ushna, Tikshna, and Ruksha Guna of Agni Mahabhuta perform the functions listed against radiotherapy. These properties cause the vitiation of Pitta, Vata, and Rakta, which may be local and generalized. Because of the increase in the Ruksha, Ushna, and Tikshna properties, the Kapha decreases leading to Oja Kshaya. This also leads to Dhatupaka (vitiation of tissue elements). Thus, the patient taking this treatment loses his own Bala to protect himself against the adverse effects of radiotherapy.

Various types of chemotherapeutic drugs are used for the management of cancer. According to a study, in cancer patients treated with chemotherapy, 20% may be cured, and 20% may experience significant prolongation of life, while the remaining 60% may have minimal or no benefit from cytostatic treatment and suffer from its toxic and adverse reactions. Chemotherapeutic agents can be considered as Visha Dravya (toxins) as per Ayurveda. These agents are Ushna Veerya (hot potency), Tikshna Dravyas working as a two-edged sword, and while destroying cancerous cell also destroy healthy normal fast-growing cells of the gastrointestinal tract, mucous membrane, skin, hair root, and so on. Hence, the medicotherapeutics of chemotherapy can be explained on the basis of Visha. The chemotherapeutic agents seem to possess properties like Ruksha, Ushna, Tikshna, Sukshma, Ashukari, Vyavayi, Vikasi, Vishada, Laghu, and the like. Most of these properties are opposite to the Rasa, Kapha, and Ojas and similar to the Rakta, Pitta, and Vata; hence, chemotherapeutic agents may also cause Vata, Pitta, Vriddhi (vitiation of Vata and Pitta) and Kapha Kshaya (depletion of Kapha) along with Rasa Rakta Kshaya (depletion), leading to Oja kshaya.

In Ayurveda, the management of Agnidagdha (burn), Dhatupaka (vitiation), and Visha Chikitsa (toxin treatment) is described with scattered references. The patients can be protected from the adverse effects of radiotherapy and chemotherapy by using Vata Pitta Shamaka, Kapha Ojas Vardhaka, and Rasa Rakta Prasadaka herbs. Most of the Rasayana drugs, especially those that are Balya, Brimhana, Shramahara and Jeevaniya, will be useful in the management

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of these conditions. Most of the drugs selected as ingredients of Rasayana Avaleha are proved under the Rasayana, and ghee is also an important drug used as Agada (anti-toxic) and in Dagdha Chikitsa (anti-burn).

On the basis of the above Doshika configuration, the Samprapti (pathophysiology) of the Lakshanas (symptoms) appearing as adverse effects of radiotherapy and chemotherapy can be explained properly by the explanation of the Samprapti of these Lakshanas. The classical Samprapti of Chhardi, Arochaka, Kushtha, Trishna, and Shosha can be used, and these become very useful while framing the treatment modalities of these conditions. All over the world, experimental studies are being carried out regarding the adjuvant / protective effect of various Ayurvedic herbs in cases of radiotherapy and chemotherapy. On the basis of the classical probing of the adverse effects of RT + CT and the research reports available, herbs like Amalaki (*Emblica officinalis*), Ashwagandha (*Withania somnifera*), Guduchi (*Tinospora cordifolia*), Yashtimadhu (*Glycyrrhiza glabra*), Jivanti (*Leptadenia reticulata*), Tulasi (*Ocimum sanctum*), and Pippali (*Piper longum*) have been selected for the present study.

The fruits of *Emblica officinalis* have antioxidant and antiemetic properties. The efficacy of *Emblica officinalis* in relieving the dyspeptic symptoms as well as in promoting the healing of ulcers is well known.[15] The anabolic activity reported in Amalaki (*Emblica officinalis*) increases the positive nitrogen balance, and the total protein level leads to an increase in body weight.[16] Ashwagandha (*Withania somnifera*) exhibits adaptogenic, immune stimulation activity and an anti-mutagenic effect, suggesting a high potential of this plant in cancer management.

### Conclusion

From the present study, it can be concluded that Rasayana Avaleha gives better results in controlling the adverse effect of chemotherapy and radiotherapy in comparison with the control group. Therefore, administration of Rasayana Avaleha along with chemotherapy and radiotherapy can improve the quality of life of cancer patients. Although the sample size studied is small, the research emerges as a ray of hope toward the successful integrated treatment of an allopathic modality along with Ayurvedic medicine as an adjuvant. This therapy certainly improves the quality of life of the patient and may enhance the life expectancy. In a nutshell, Rasayana Avaleha is an effective adjuvant therapy in protecting the patient from the adverse effect of chemotherapy and radiotherapy.

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