CLINICAL STUDY

Evaluation of Clinical Response of Carcinolyt (Herbal Nutrients) To Control Adverse Effects of Radiotherapy in Cancer Patients

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ABSTRACT

The Best in the cancer treatment will come through a combination of conventional and alternative medicine. Ayurveda can play a vital role in palliative, promotive and preventive strategy against cancer. The importance and utility of Ayurveda in cancer management is because there are limitations to the present treatment modalities of this fatal disease, which are well known for their toxic effects and complications. In the present study, an indigenous formulation— Carsinolyt (awaleha & Ghan Satva) was evaluated to prevent side effects of Radiotherapy Trial was done on forty patients, Group A Patients were given carsinolyt and radiotherapy simultaneously whereas Group B patients were given radiotherapy only.

The results achieved were encouraging with improvement of 56.62% in mucosal reactions, 37.5% in Haematological status, 18.18% in Pain, 8.33% in Salivary reactions, and 21.42% in Skin reactions. Carsinolyt incorporates Agnideepak, Amadoshahar, Vrana shodhak, Vrana ropak, Vedna sthapak, Vishaghan, Gandmala Nashak, Mukh shodhak, Raktashodhak & Balya drugs and the reduction of cytotoxic effects of radiotherapy also owe to the same actions.

Carsinolyt proved to be non-toxic, immunomodulator, adaptogenic and radioprotective preparation. **Key words:** Herbal, Radioprotective, Cancer, Radiotherapy, *Vrana shodhak, Rakta Shodhak, Agnideepak, Balya,* Cytotoxic.

INTRODUCTION

The poignancy of the disease cancer is that the patients get aware of this intricate problem only after the complete invasion of the body. The prevailing treatment modalities-Surgery, Chemotherapy and Radiotherapy do not fulfill the requirements and objectives of treatment. Moreover during the treatment various other diseases or symptoms prop up as the side effects which may occur as early or late effects (J Clin Oncol, 1997; 15: 103-109). Ayurveda believes in the vishudda treatment (Ch.Ni.8/27) i.e. the treatment which gives rise to other problems is not a treatment in real sense. So it was opined that the best of cancer treatment would come through a combination of conventional and alternative medicine (Indian J Exp Biol, 1999 Jan; 37(1): 23-6 & 27-31). It was hypothesized to practically implement the integrated approach i.e. Western Medicine and Ayurveda hand ip. han,d; Western Medicine whose approach is to regard cance,r as a foreign body which needs to be annihilated and Ayurveda to safeguard the patient to alleviate the toxic effects of the treatment modalities (J Exp Clin Cancer Res 1999 Sep; 18(3): 325-9).

This study was under taken to evaluate the

efficacy of an Ayurvedic Compound preparation with the aim :-

- * to alleviate the side effects of radiotherapy.
- * to improve the quality of life of patients.

MATERIAL AND METHODS

The study drug-CARSINOLYT was formulated with anticancerous as well as rejuvenator herbs according to the principles of Ayurveda. The compound was prepared in the N.I.A. Pharmacy in the form of awaleha and ghansatva.

Forty patients of head & neck cancer were selected from Cancer unit, Department of Shalyatantra N.I.A. Jaipur and Radiotherapy unit. of S.M.S. Hospital, Jaipur. The patients were divided into two groups with twenty patients in each-

Group A Carsinolyt & radiotherapy.

Group B Radiotherapy.

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Table -I Ingredients of Carcinolyt vati -

Kanchnar	Kutaki
Khadir	Manjishtha
Chiraita	Rohitaka
Kuth (Bhallataka
Varuna	Daruharidra
Ashwagandha	Sadabahar
Kumari	Guduchi
Neem	Gomutra
Atisha	

Dose - 500 mg. bid with milk

Table -II Ingredients of carsinolyt awaleha

Salparni	Haridra
Bilwa	Pippali
Gambhari	Dalchini
Gokshura	Chitraka
Satavari	Shankhpushpi
Punarnava	Madhuyasthi
Mudgaparni	Chhoti Ele
Mashparni	Nagkeshar
Bala	Yavakshara
Errand	Madhu
Jivanti	Goghrita
Amla	Gudah
Haritaki	

Dose - Half TSF bid with milk

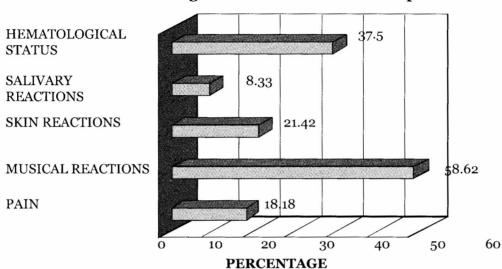
Table -III Grading Pattern

		GRADING					
Criteria	0	1	2	3	4		
PAIN	No Pain	Local tolerable pain sometimes	Pain on chewing and swallowing	Severe pain radiating to head/neek/ears	Pain at rest with disturbance of sleep		
MUCOSITIS	No mucosal reactions	Slight oropharyngeal Mucositis	Patchy oropharyngeal Mucositis	Confluent oropharyngeal Mucositis	Oropharyngel ulcerations		
SALIVARY	No reactions	pH diminished	pH low and dryness of mouth	pH low, dryness of mouth & one -two taste loss	Total dysfunction of salivary glands		
SKIN REACTIONS	No reactions	Slight erythema	Dry desqua- mation of skin	Confluent moist reactions	Ulcerations		
HEMATOLOGICAL STATUS	Normal Hb%, TLC, Platelets count	Insignificantly Low Hb%, TLC, Platelets count	Significantly Low Hb%, TLC, Platelets count	Moderate pancytopenia	Serve pancytopenia		

Informed consent was taken from all the patients in the study after explaining the benefits and risks associated with the treatment. Detailed history sheets along with present status of patient as well as disease was documented. Patients of Group A were given *Awaleha* and *ghansatwa* in the dose of 10 gm twice daily and 500 mg thrice daily respectively with milk. Radiotherapy was given under the supervision of experts in radiotherapy

unit of SMS medical college, Jaipur. The patients were followed with a definite time schedule and assessed for pain, mucositis, salvari reactions, skin reactions, hematological status & clinically for symptoms. The weekly and monthly assessment charts were worked out. The statistical analysis was done by student's t-test. The results are represented here in graphical from (Graph-I).

Percentage Relief in Patients of Group A



Results

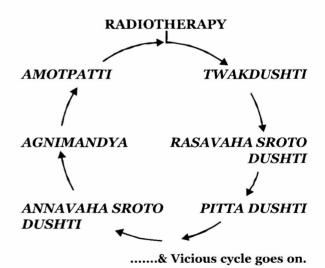
It is clear from the Graph that the percentage relief in mucosal reactions is 58.62% and in haematological status-37.5% are significant whereas in pain-18.18%, salivary reactions -8.33%, skin reactions-21.42%; the results are worth noting and indicate some effectiveness to protect the tissues against radiotherapy.

DISCUSSION

If at all we want Ayurveda to be employed in anticancerous strategy from implementation point of view; it has got good chance to improve the quality of life and to provide protection from adverse effects of radiotherapy. Before describing mechanism of action of carsinolyt, the pathogenesis of adverse effects should be kept in mind-

The side reactions of chemotherapy and radiotherapy have been categorized according to *srotas* (systems) of the body.

- * Pranavaha srotas Hoarseness of voice.
- * Udakavaha Srotas Dryness of mouth, excessive thirst.
- * Annavaha Srotas Loss of appetite, vomiting, nausea, loss of taste, acidity, pain in abdomen.



- * Rasavaha Srotas Fever, weakness, loss of taste, loss of appetite, nausea, body ache.
- * Raktavaha srotas Skin pigmentation, stomatitis, epistaxis, bleeding through openings of the body, burning all over the body.
- * Mansavaha Srotas Leg cramps, frozen shoulder.
- * Asthivaha Srotas Alopecia
- * Majjavaha Srotas Vertigo, headache, joint Pain.
- * Purishvaha Srotas Diarrhea, constipation, symptoms similar to sprue, piles, swelling and burning of anal region.

The result depicts the maximum efficacy on mucositis and hematological status of the patients: this may be due to effect of component drugs which have *Vrana shodhak, Vrana ropak, Vishaghan, Mukh shodhak, Rakta-shodhak* effect. The reason for low effectiveness in skin & salivary reactions was probably due to less duration of treatment. Moreover, the rate of destruction of tissues (skin & salivary glands) due to radiotherapy is much more than regeneration of tissues. Still the results are more conspicuous in Group A than Group B.

Carsinolyt is not cytotoxic because it is purely indigenous in nature and moreover no other side effect was noticed during the course of treatment and thereafter. The reduction of cytotoxic effects of radiotherapy is suggestive of many underlying mechanisms like adaptogenic role, antioxidant defense mechanism, protection of mucosa against radiation injury, protective role in haematopoeisis, immunomodulation and stimulation.

Mode of action of different ingredients of CARSINOLYT in the symptoms produced as side reactions Radiotherapy:

WITH RESPECT TO RASA AND VIPAKA,

Madhur Rasa & Madhur Vipaka Stomatitis, acidity, Burning sensation, Dryness of mouth & Epistaxis, Weakness & Cramps in legs, Vertigo & Sprue like symptoms

Tikta Rasa

: Loss of taste.

Katu Rasa and

Loss of appetite, Pain.

Katu vipaka

Kashaya Rasa

Vomiting, Epistaxis &

Diarrohea, Excessive Sweating.

CONCLUSION:

In the present study Carsinolyt *Ghanvati* and *leham* in the dose of 500 mg and 10 gms respectively

thrice daily with milk has shown its efficiency in reducing the side effects of Radiotherapy. It was a preliminary study and further requires extensive research work induding enzyme and immunoglobin assay with prolonged study duration. Incorporating the shodhan therapy may be of added advantage.

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