



## EFFECTIVENESS OF AN INTERVENTION PACKAGE ON REDUCTION OF ORAL COMPLICATIONS AMONG PATIENTS UNDERGOING RADIATION THERAPY FOR HEAD AND NECK MALIGNANCIES

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### ABSTRACT

The present study investigated the effectiveness of an intervention package on reduction of oral complications among patients undergoing radiation therapy for head and neck malignancies. A true experimental pre test post test control group design with quantitative research approach was used for this study. The objectives of the study were to assess the levels of oral complications, determine the effectiveness of an intervention package on reduction of oral complications. A total of 60 patients undergoing radiation therapy for head and neck malignancies at Govt. Medical College Hospital, Kottayam, were assigned to control (n=30) and experimental (n=30) group using simple random sampling technique. Socio personal data sheet, clinical data sheet and oral assessment tool were used for collecting data. The data was analyzed using descriptive and inferential statistics. The result of analysis revealed that the intervention package was effective in reducing oral complications ( $p < 0.001$ ) among patients undergoing radiation therapy for head and neck malignancies.

**KEYWORDS :** Head and neck malignancies; Radiation therapy; Oral complications; Intervention package; Information booklet.

### INTRODUCTION

The total burden of cancer across the globe is estimated to be around 22 million.<sup>1</sup> Cancer has become one of the ten leading causes of death in India. Cancers especially those of oral cavity and lungs among men and cervix and breast among women account for over 50% of all cancer deaths in India.<sup>2</sup>

Radiotherapy either by itself or in combination with surgery or chemotherapy plays an essential role in the treatment of head and neck cancer.<sup>3</sup> The common side effects of head and neck radiation therapy include skin reactions, fatigue, nutritional effects and alterations in mouth and pharynx.<sup>4</sup> It is estimated that oral mucositis affects 40% of the patients undergoing chemotherapy, 75% of the patients undergoing high dose chemotherapy and bone marrow transplantation and more than 90% of the patients undergoing radiotherapy for head and neck cancer.<sup>5</sup>

Honey is a source of carbohydrates, containing 80% natural sugar mostly fructose and glucose, 18% water, 2% minerals, vitamins, and protein. Laboratory studies and clinical trials have shown that honey is an effective broad spectrum antibacterial agent. The data shows that the wound healing properties of honey include stimulation of tissue growth, enhanced epithelialisation, and minimized scar formation. These effects are ascribed to honey's acidity, hydrogen peroxide content, osmotic effect, nutritional and antioxidant contents, stimulation of immunity, and to unidentified compounds. Prostaglandins and nitric oxide play a major role in inflammation, microbial killing, and the healing process. Honey was found to lower prostaglandin levels and elevate nitric oxide end products. These properties help to explain some biological and therapeutic properties of honey, particularly as an antibacterial agent or wound healer.<sup>6</sup>

The investigator after reviewing related literatures came to know that the interventions like regular oral cavity assessment, proper oral care and application of honey have good effect in reducing oral complications among head and neck cancer patients undergoing radiation

### METHODOLOGY

A true experimental pre test post test control group design with quantitative research approach was used for this study. The study was conducted in radiotherapy department at Govt. Medical College Hospital, Kottayam. Population of the study consisted of patients with head and neck malignancies, undergoing radiation therapy. Sample include sixty patients

undergoing radiation therapy for head and neck malignancies at Govt. Medical College Hospital, Kottayam; thirty in experimental group and thirty in control group. The tools used to collect the data were socio personal data sheet, clinical data sheet and oral assessment tool.

The data collection process extended over a period of 8 weeks. Samples were selected from their first day of radiation therapy using simple random sampling technique. After obtaining informed consent from the patients, socio personal data and clinical data were collected. Assessment of oral cavity is done by using oral assessment tool. Subjects in the experimental group received one to one teaching program of 15 minutes duration and are provided the information booklet describing self care practices to be followed by the patients including daily oral examination, dental care, mouth washing, lip care, hydration and diet. Patients in the experimental group received oral application of 10 ml of Ag mark honey before and after 15 minutes of radiation therapy and 6 hours thereafter in every days of radiation therapy, and instructed them to rinse the honey in the mouth, swish it around for one minute duration, and slowly swallow. Post test was performed at the end of first, second and third week of radiation therapy (day 5, day 10 and day 15 respectively).

### RESULTS

#### Socio personal and clinical data of patients undergoing radiation therapy for head and neck malignancies

- Among the 60 samples 46.7% of patients in the control group and 50% of patients in the experimental group were belonged to the age group of 61-75 years.
- Majority of the patients in the control (73.3%) and experimental group (83.3%) were males.
- While considering the education 46.7% of patients in the control group and 70% of patients in the experimental group had secondary education.
- With regards to occupation 53.3% of the patients in the control group and 46.7% of patients in the experimental group were daily wages.
- Among the 60 samples 36.7% of the patients in the control group and 53.3% of patients in the experimental group had history of both smoking and alcoholism.
- Majority of the patients in the control group (96.7%) and the experimental group (96.7%) were taking non vegetarian diet.
- Majority of the patients in the control group (53.3%) and the experimental group (70%) had no family history of cancer.

- Among the group majority of the patients in the control group (53.3%) and 43.3% of patients in the experimental group had malignancy in the oral cavity.
- Majority of patients in the control group (56.8%) and the experimental group (46.7%) received a dose per fraction of 176-200 cGy.
- Majority of patients in the control group (70%) and experimental group (73.3%) had normal weight (BMI 18.5-24.9).

Chi square value shows that there was no statistically significant difference between control and experimental group in terms of age, gender, education, occupation, adverse health habits, diet and family history of cancer, site of malignancy, dose per fraction of radiation and BMI and hence groups were homogenous in nature.

**Oral complication of patients undergoing radiation therapy for head and neck malignancies**

**Table 1: Frequency distribution and percentage of levels of oral complications in patients undergoing radiation therapy for head and neck malignancies based on first, second and third post test score**

(n = 60)

Levels of oral complications	Post test 1 (day-5)		Post test (day-10)				Post test 3 (day-15)					
	Control n=30		Experimental n=30		Control n=30		Experimental n=30		Control n=30		Experimental n=30	
	f	%	f	%	f	%	f	%	f	%	f	%
Normal (1-7)	0	0	10	33.3	0	0	0	0	0	0	0	0
Mild (8-14)	30	100	20	66.7	20	66.7	30	100	0	0	21	70
Moderate (15-21)	0	0	0	0	10	33.3	0	0	30	100	09	30

From the table, it is evident that after completion of one week radiation therapy (on D5), 100% of patients in control group and 66.7% of patients in the experimental group developed mild oral complication. Remaining 33.3% of patients in experimental group had no oral complications. After completion of second week radiation therapy (on D10), 66.7% of patients in the control group had mild oral complications and 33.3% of patients developed moderate oral complication but in experimental group 100% of patients developed only mild oral complications. After completion of third week radiation therapy (on D15), 100% of patients in control group and 30% of patients in the experimental group developed moderate oral complications and remaining 70% of patients in experimental group had only mild oral complications.

**Effectiveness of intervention package on oral complications among patients undergoing radiation therapy for head and neck malignancies**

**Table 2: Mean and standard deviation of pre test and post test oral complications scores of patients undergoing radiation therapy for head and neck malignancy**

(n = 60)

Oral complications	Control group (n=30)		Experimental group (n=30)	
	Mean	SD	Mean	SD
Pre test	7.2	0.41	7.13	0.35
Post test 1	9.1	1.52	7.9	0.92
Post test 2	13.63	2.09	10.3	1.45
Post test 3	17.53	2.01	13.9	1.27

Table 2 shows that mean pre intervention oral complications

assessment score of patients undergoing radiation therapy for head and neck malignancies were 7.2 for control group and 7.13 for experimental group. The mean first post test oral complication assessment score in the control group was 9.1 and in the experimental group were 7.9. The mean second post test oral complication assessment score in the control group were 13.63 and in the experimental group were 10.3. The mean third post test oral complication assessment score in the control group were 17.53 and in the experimental group were 13.9.

**Table 3: Summary of ANCOVA of oral complications in patients undergoing radiation therapy for head and neck malignancies in the control and experimental group**

(n=60)

Group	Sum of squares	df	Mean square	F
Post test 1	22.36	1	22.36	14.14***
Post test 2	170.98	1	170.98	56.45***
Post test 3	205.07	1	205.07	76.63***

\*\*\*significant at 0.001 level.

Table 3 shows that F value of ANCOVA is significant at 0.001 levels in post test 1, post test 2 and post test 3. Hence the null hypothesis is rejected and it is inferred that there is a significant difference in the post assessment scores of oral complications among patients undergoing radiation therapy for head and neck malignancies in control and experimental group in post test 1, post test 2 and post test 3.

**DISCUSSION**

The study finding revealed that there was a significant difference in the post assessment scores of oral complications among patients undergoing radiation therapy for head and neck malignancies in the control and experimental group in post test 1, post test 2 and post test 3. It can be concluded that the intervention package was effective in reducing severity of radiation induced oral complications in patients undergoing radiation therapy for head and neck malignancies.

The result of the present study also comparable to a study done on topical application of honey in the management of radiation mucositis in Malaysia. Forty patients diagnosed with head and neck cancer undergoing radiation therapy were selected. Honey application was given to the experimental group and no interventions were given to the control group. The study result showed that topical application of honey was effective in reducing severity of radiation induced oral mucositis (p<0.001).<sup>7</sup>

**CONCLUSION**

Adequate knowledge regarding self care practices to be followed by the patients including daily oral examination, dental care, mouth washing, lip care, hydration, diet and application of honey helps to reduce the oral complications. Thus the morbidity and mortality due to oral complications can be reduced in patients receiving radiation therapy for head and neck malignancies.

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