

A Randomized Clinical Trial to Assess the Effectiveness of Turmeric Mouth Wash on Radiation Induced Oral Mucositis among Patient with Head and Neck Cancer Admitted at Oncology Units of Selected Hospitals of Bagalkot

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Abstract: ***Introduction:** Head and neck cancer, and specifically oral cancer, was always described as a disease of old age with most epidemiological studies describing higher incidence in the age group of fifty to seventy years old. Mucositis persist throughout radiation therapy. As radiation therapy continues mucositis worsen, contributes to poor nutrition, low quality of life. Even though on one side radiation helps as a treatment, on the other side it has its complications that are making an issue in the developing countries. **Objective:** The objective of the study was to assess the effectiveness of turmeric mouthwash as compared to routine oral care on radiation induced oral mucositis among patients with head and neck cancer. **Methods:** A randomized control design and Dorothy Orem Self Care theory Conceptual framework used for the study. The study conducted from 01 February 2021 to 30 April 2021, in the Radiation, Department of Halamma Kerudi Cancer Hospital, Bagalkot. Fifty patients were randomized into two groups and WHO Oral Mucositis Grading Scale used. The experimental groups (n25) were advised to rinse their mouth with 50 ml of turmeric mouthwash where as control group (n25) was advised to rinse their mouth with routine oral care for 30 seconds, 15 minutes before radiation therapy and 15 minutes, 4 hours and 12 hours after radiation therapy. Post intervention assessments were made on day 1, 5, 10, and 15 after intervention with turmeric mouthwash and routine oral care in the experimental and control group respectively. **Results:** The result showed that, in the experimental group the mean oral Mucositis grades obtained during Ist, IInd and IIIrd and IVth interventional assessment (Ist, 5th, 10th and 15th day) were 0, 0.48, 1.16 and 1.64 whereas in the control group were 0, 0.24, 0.72 and 1.2 respectively. This proved that, there is a significant reduction in the oral mucositis in the control group (0.24-1.2) when compared to experimental group (0.48-1.64). There was statistically significant found in the grades of oral mucositis among head and neck cancer patients in control group ($p < 0.005$) as compared to experimental group. **Conclusion:** The findings of the study revealed that turmeric mouthwash is effective for radiation induced oral mucositis. Though in experimental and control groups are having mucositis, but there was a difference in the severity of oral mucositis.*

Keywords: Radiation induced oral mucositis, turmeric mouthwash, routine oral care, Radiation therapy, Head and neck cancer.

1. Introduction

Cancer is a disease of the cells in the body. Human body consists of different types of cells, and many different types cancer arises from different type of cells. Cancer is a condition of group of diseases involving abnormal cell with the potential to invade or spread other parts of the body, it's also known as malignant tumor or neoplasm.¹

Cancer treatments depend on the type, stages and spread. The common treatments are surgery, chemotherapy, radiation therapy. Recently advanced treatments are also introduced such as stem cells transplants .Hormone therapy, immune therapy, gene therapy.⁵If cancers are diagnosed and treated in early stage will get better outlook. Some agents may cause cancer. Several chemicals and environmental toxins are responsible for changing in normal cellular DNA mutation are called mutagens and these causes' cancers which are known as carcinogens.³

Head and neck cancer is the most common type of cancer in the world. Head and neck cancer is a group of cancers that starts in the mouth, nose, throat, larynx, sinuses, or salivary glands.⁶

Head and neck cancer is common in several regions of the world. The primary risk factors associated with head and neck cancer include tobacco use, alcohol consumption, human papillomavirus (HPV) infection (for oropharyngeal cancer), and Epstein-Barr virus (EBV) infection (for nasopharyngeal cancer). The chronic exposure of the upper aero-digestive tract to these carcinogenic factors can result in dysplastic or premalignant lesions in the oropharyngeal mucosa and ultimately result in head and neck cancer. The relative prevalence of these risk factors contributes to the variations in the observed distribution of head and neck cancer in different areas of the world.⁶

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Radiation therapy uses high energy particles or waves such as x-rays gamma rays, electron beams, or protons to destroy or damage cancer cells.⁶ Even radiation therapy damages normal cells and usually it repairs themselves. Radiotherapy acts as a curative, control and palliative treatment.⁸

Radiotherapy to the head and neck or to the pelvis or abdomen is associated with the occurrence of oral mucositis, often exceeding 50% of patients. Among patients undergoing head and neck radiotherapy, pain and decreased oral function may persist long after the conclusion of therapy. Fractionated radiation dosage increases the risk of mucositis to > 70% of patients in most trials.⁸

Oral mucositis, an inflammatory response of oral-pharyngeal mucosa in response to systemic chemotherapy or from radiotherapy for the head and neck carcinoma is extremely painful and increases morbidity of the patients.¹⁰ Depending on the severity, oral mucositis is grouped as tolerable mucositis [grade 1 and 2 mucositis] and intolerable mucositis [grade 3 or higher].⁹

Turmeric is one of nature's most powerful healers. Turmeric has been used for over 2500 years in India. Long known for its anti-inflammatory properties, recent research has revealed that turmeric is a natural wonder, proving beneficial in the treatment of many different health conditions from cancer to Alzheimer's disease. To heal many health disorders like liver problems, digestive disorders, treatment for skin diseases and wound healing turmeric has long been used in Medicine as an anti-inflammatory. Curcumin is the active ingredient in turmeric which has been shown to have a wide range of therapeutic effects.¹⁹

2. Materials and Methods

Study design: It is a true experimental randomized control design conducted at in selected cancer hospitals of Bagalkot Karnataka.

Setting of the study: The study was conducted at selected cancer hospitals of Bagalkot Karnataka. The recruitment and data collection of participants was carried out in outpatient and inpatient department.

Participants: Sample consists of a subset of units that compose the population. In the present study, the samples consists of 60 Head and Neck cancer patients who undergoing radiation therapy and developing oral mucositis. Admitted at selected cancer hospitals of bagalkot.

Criteria for sample selection:

Inclusion criteria: This study will include,

- Patients above 18 years of age
- Patients with head and neck cancer of stage I to stage IV, according to TNM classification
- Only turmeric mouthwash will be
- Who all are willing to participate

Exclusion criteria: This Study will exclude the,

- Patients with HIV infections, diabetes mellitus, Hypertension Hyperthyroidism.

- Patients having allergy for turmeric mouthwash.
- Patients using any other prophylactic mouthwashes.

Sample Size estimation: In this present study the Sample size was calculated by using "power analysis" the sample size was estimated by using the results (mean and standard deviation). The level of confidence was 95 % ($\alpha=5\%$) and $z_{\alpha}=0.95$ The power of test was considered 80% The sample size was estimated by statistician was 45. Considering the attritions of data, the researcher enrolled 50 subjects. Sample consists of a subset of a population selected to participate in research Study. In the present study Head and Neck Cancer patients, who met the inclusion criteria were selected as samples. The sample size for the present study is 50. The present study sample size consists of 50 Head and Neck Cancer patients, attending Halamma Kerudi Cancer Hospital, Bagalkot, Karnataka.

Description of data collection tools

The data collection instruments were divided into 2 sections-

Section 1- Baseline proforma

It is interview proforma consisting 8 items regarding baseline data of the subjects.

Section 2: It is based on clinical appearance and status. The WHO Oral Mucositis Grading Scale is dependent on both subjective and objective variables, and measures anatomical, symptomatic, functional components of oral mucositis.

Grading:

The Grade 0: Indicates normal. Grade I: Indicates soreness and erythema present. Grade II: Indicates oral erythema and ulcers present moderate degree but patient can be tolerated solid diet. Grade III: Indicates oral ulcers present, severe degree, patient can be tolerate only liquid diet. Grade IV: Indicates orally cannot tolerate anything, very severe degree.

Data Collection: Data collection was done from 1-02-2021 to 30-04-2021 at Halamma Kerudi Cancer Hospital Bagalkot.

Variables of the study:

Statistical Analysis: The tabulation of data in terms of mean, median and standard deviation to analyze the pre-test and post test oral mucositis score. Independent 't' test will be used to assess the effectiveness between two groups. Chi square test will be used to compare the grades of oral Mucositis in experimental and control group on 5th day. Chi square test will be used to compare the grades of oral Mucositis in experimental and control group on 10th day. Chi square test will be used to compare the grades of oral Mucositis in experimental and control group on 15th day.

Ethical Consideration: Ethical clearance certificate was obtained from B.V.V.S Sajjalashree Institute of Nursing Sciences, institutional ethical committee. Written consent was obtained from each participant.

3. Results

Table 1: Frequency and Percentage Wise Distribution of Samples according to their Socio Demographic Variables in Experimental Group and Control Group

S. No	Demographic Variables	Experimental Group		Control Group	
		N=25	P=100%	N=25	P=100%
		F	P	F	P
1)	Age				
	1) < 30 years	2	8%	1	4%
	2) 31-40 years	5	20%	8	32%
	3) 41-50 years	8	32%	7	28%
	4) 51-60 years	7	28%	6	24%
	5) >60 years	3	12%	3	12%
2)	Gender				
	1) Male	21	84%	21	84%
	2) Female	4	16%	4	16%
3)	Occupation				
	1)Farmer	7	28%	9	36%
	2)Housewife	2	8%	2	8%
	3)Business	5	20%	3	12%
	4)Government employee	4	16%	4	16%
	5)Private employee	5	20%	4	16%
	6) Coolie	2	8%	3	12%
4)	Site of Head & neck cancer				
	1) Oral cavity	9	36%	6	24%
	2) Oropharynx	4	16%	3	12%
	3) Hypopharynx/Larynx	7	28%	9	36%
	4) Others	5	20%	7	28%
5)	Cancer stage				
	1) I	2	8%	3	12%
	2) II	5	20%	4	16%
	3) III	11	44%	11	44%
	4) IV	7	28%	7	28%
6)	Habit of tobacco chewing				
	1) Yes	12	48%	14	56%
	2) No	13	52%	11	44%
7)	Habit of smoking				
	1) Yes	13	52%	14	56%
	2) No	12	48%	11	44%
8)	Dose of Radiation				
	1) 60Gy	10	40%	7	28%
	2) 66 Gy	8	32%	7	28%
	3) 70 Gy	7	28%	11	44%

Table 2: Findings of oral mucositis score in both groups by treatment days, N=50

Interventions days	Group	Sample Size (n)	Mean	Standard deviation (SD)	Standard error(S.E)
Day 1	Experimental	25	0	0	0
	Control	25	0	0	0
Day 5	Experimental	25	0.24	0.435	0.087
	Control	25	0.48	0.509	0.101
Day 10	Experimental	25	0.72	0.458	0.091
	Control	25	1.16	0.374	0.074
Day15	Experimental	25	1.2	0.5	0.1
	Control	25	1.64	0.489	0.097

Revealed that the mean oral mucositis grades of Experimental and Control group in pre assessment (Ist day) are 0. In the experimental group the mean oral mucositis

grades obtained during IInd, IIIrd, IVth post treatment assessment (5th, 10th and 15th day) score was 0.24,0.72,1.2 whereas in the control group were 0.48,1.16,1.64 respectively. This shows that there is a significant reduction in the mucositis in the control group (0.48-1.64) when compared to study group (0.24-1.64).

Table 3: Comparison between the grades of mucositis in control and study group on Ist post treatment (day 5) by using Karl Pearson Chi-square test, N=50, Df = 1

Day 5	Experimental	Control
Grade 0	19(76%)	13(52%)
Grade I	06(24%)	12(48%)
Total	25	25

Reveals that X² calculated value (3.12) is more than X² tabulated value (3.84). Hence H₁ is not accepted. There is no significant association between the mean post interventional oral mucositis grading scale score of turmeric mouthwash and mean post interventional oral mucositis grading scale score of routine oral care on radiation induced oral mucositis among patients with head and neck cancer at 0.05 level of significance.

Table 4: Comparison between the grades of oral mucositis in experimental and control group on IInd post treatment (day 10) by using Fisher's Exact test, N=50, DF = 1

Day 10	Experimental	Control
Grade 0	7(28%)	1(4%)
Grade I	18(72%)	20(80%)
Grade II	0(0%)	4(16%)
Total	25	25

Reveals that calculated Chi- square value is (0.0488) is more than X² tabulated value (3.84). Hence H_{1,2} is accepted. There is no significant association between the mean post interventional oral mucositis grading scale score of turmeric mouthwash and mean post interventional oral mucositis grading scale score of routine oral care mouthwash on radiation induced oral mucositis among patients with head and neck cancer at 0.05 level of significance.

Table 5: Comparison between the grades of oral mucositis in Experimental and Control group on IIIst post treatment (day 15) by using Karl Pearson Chi-square test, N=50, Df =1

Day 15	Experimental	Control
Grade 0	1(4%)	0(0%)
Grade I	18(72%)	09(36%)
Grade II	06(24%)	16(64%)
Grade III	0(0%)	0(0%)
Total	25	25

Reveals that calculated value (8.1) is more than X² tabulated value (3.84). Hence H₁ is accepted. There is significant association between the mean post interventional oral mucositis grading scale score of turmeric mouthwash and mean post interventional oral mucositis grading scale score of routine oral care mouthwash on radiation induced oral mucositis among patients with head and neck cancer at 0.05s level of significance.

Table 6: Comparison of pre interventional radiation induced oral mucositis among patients in experimental and control group with their selected socio demographic variables, N=50

S. No.	Demographic Variables	DF	Chi Square	Table Value	P Value	Association
1)	Age	4	1	9.49	0.05	Not significant
2)	Gender	1	0.369	3.84	0.05	Not significant
3)	Occupation	5	0.45	11.07	0.05	Not significant
4)	Site of Head and Neck Cancer	3	1.29	7.82	0.05	Not significant
5)	Cancer stage	3	0	7.82	0.05	Not significant
6)	Habit of tobacco chewing	1	0.32	3.84	0.05	Not significant
7)	Habit of smoking	1	0.08	3.84	0.05	Not significant
8)	Dose of Radiation	2	1.48	5.99	0.05	Not significant

Signifies the comparison of pre interventional radiation induced oral mucosities among patients in experimental and control group with their selected socio demographic variables.

Chi-square was calculated to find out the comparison of pre interventional radiation induced oral mucosities in both Experimental and control group with their selected socio demographic variables by using contingency table.

Calculated Chi-square value is lesser than table value for socio demographic variables in Experimental and control group, Age ($X^2=1$, $T=9.49$), Gender, ($X^2=0.369$, $T= 3.84$), Occupation ($X^2=0.45$, $T=11.07$) , Site of head and neck cancer($X^2 =1.29$, $T=7.82$), Cancer stage($X^2 =0$, $T=7.85$), Habit of tobacco chewing($X^2=0.32$, $T= 3.84$), Habit of smoking($X^2=0.08$, $T= 3.84$) and Dose of radiation($X^2=1.48$, $T= 5.99$).

The findings propose that there was no significant comparison found between pre interventional radiation induced oral Mucositis and age, gender, occupation, Site of head and neck cancer, Cancer stage, Habit of tobacco chewing, Habit of smoking and Dose of radiation at $P<0.05$ level.

Therefore H_2 is rejected for all socio demographic variables, that is , there is no significant comparison between with pre interventional radiation induced oral mucosities their selected socio demographic variables among cancer patients after application of turmeric powder in experimental group and routine oral care for control group at $P<0.05$ level.

4. Limitations of the study

The present study was limited to 50 head and neck cancer patients with radiation induced mucositis at Radiation Department of Halamma Kerudi Cancer Hospital, Bagalkot. It was a single blind study conducted by a single investigator

Conflict of interest: None

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