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Assessing the Impact of Chlorhexidine Mouthwash on Radiation-Induced Oral Mucositis in Head and Neck Cancer Patients: A Pre-Experimental Study

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Abstract

Introduction: *Cancer poses a major global health threat and is the second leading cause of death worldwide, following cardiovascular diseases, particularly in developed countries. Among cancers, head and neck cancer ranks as the 6th most common, representing about 6% of all cancer diagnoses. One of the frequent side effects of radiotherapy (RT) is mucositis, an inflammation of the mucous membranes. Chlorhexidine, a commonly used antiseptic and disinfectant found in mouthwashes, is known for its ability to reduce oral bacteria and dental plaque. The purpose of this study was to assess the effectiveness of chlorhexidine mouthwash in both preventing and treating oral mucositis in patients receiving radiotherapy for head and neck cancer.* ***Objectives of the study:*** *The objectives of the study were to assess the pre-test and post-test scores of radiation therapy-induced oral mucositis in head and neck cancer patients, to evaluate the effectiveness of chlorhexidine mouthwash in managing radiation therapy-induced oral mucositis in these patients, and to determine the association between pre-test scores and selected socio-demographic and clinical profiles of patients with radiation therapy-induced oral mucositis at the Regional Cancer Centre in PGIMS, Rohtak.* ***Material and Method:*** *A study was conducted using quantitative research approach pre-experimental, one group pre-post-test design. The sample size consisted of 60 participants, selected using a non-randomized convenience sampling technique under non-probability sampling. OMAS (Oral Mucositis Assessment Scale) was used for pre and post-test which is in public domain and free to use. Statistical analysis of data was done by using descriptive and inferential statistic.* ***Result:*** *The mean value of overall pretest score was 24.48, SD value of score was 2.501 whereas mean value of post-test score was 21.25 and SD value of score was 2.289 and. The average difference between the pre-test and post-test scores was 3.233. The results suggest that chlorhexidine had a notable effect in reducing the severity of oral mucositis. The paired 't' test revealed statistically significant results, with a P-value less than 0.05.* ***Conclusion:*** *The results indicated that patients with oral mucositis who used chlorhexidine mouthwash experienced effective healing of the condition.*

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INTRODUCTION

Cancer is a significant global public health concern and the second leading cause of death worldwide, after cardiovascular diseases, in developed nations. Head and neck cancer is the 6th most prevalent cancer globally, making up about 6% of all cancer cases. In India, oral cancer is the most common cancer among men, and the overall number of cancer diagnoses is on the rise. According to GLOBOCAN 2020, India is expected

to experience 2.1 million new cancer cases by 2040, marking a 57.5% increase from 2020. Nearly 90% of patients with head and neck cancer undergoing conventional radiotherapy or chemoradiotherapy will develop oropharyngeal mucositis, with its occurrence varying based on the specific oncology treatment regimen. Radiation therapy, a cornerstone in the management of head and neck cancers, is one of the primary etiological factors in the development of oral mucositis. The high-energy radiation used to target malignant cells also damages the rapidly dividing epithelial cells of the oral mucosa, leading to a cascade of inflammatory responses. The pathogenesis of radiation-induced oral mucositis involves a complex interplay of biological processes, including DNA damage, cytokine release, and activation of apoptotic pathways [1].

Mucositis continues throughout radiation therapy and tends to worsen as treatment progresses. It leads to poor nutrition and a reduced quality of life. While radiation therapy is effective as a treatment, it also brings complications that pose challenges, particularly in developing countries [2].

MATERIALS AND METHOD

A pre-experimental study was carried out with 60 head and neck cancer patients at the Regional Cancer Centre, a tertiary care hospital in North India. Participants who were able to understand and communicate in Hindi or English without any impairment were included. Only individuals diagnosed with head and neck cancer were part of the study. Those who did not provide consent or were unwilling to participate or follow instructions were excluded from the study. Based on the conceptual framework and objectives of the study, the following data collection instruments and techniques were used to elicit data in three sections: (a) socio demographic profile, (b) clinical profile of patient, and (c) oral mucositis assessment scale.

Section A: Socio demographic profile is designed to collect the background information of the participants under the study. There are 06 items. Here are the key components: Age, Gender, Education, Occupation, Monthly Family Income, Residence.

Section B: Clinical profile of patient is designed to collect the comprehensive summary of the patient's medical information. Here are the key components often included in a clinical profile: Cycles of radiation therapy, Duration of oral mucositis, Region of tumor, Clinical stage, Co-morbid condition, and Type of Co-morbid condition.

Section C: Oral mucositis assessment scale is a widely used tool for assessing the severity of oral mucositis, a common side effect of cancer treatment. The scale was developed by the National Cancer Institute (NCI) and is available in the public domain, which means that it can be used freely by healthcare professionals and researchers without the need for permission or licensing (Table 1).

CRITERIA FOR MEASURING LEVEL OF ORAL MUCOSITIS

The study setting was selected for convenience, and the principal investigator oversaw the data collection process. Participants were notified that their participation was voluntary and were provided with an information sheet about the study prior to filling out the questionnaire and checklist. Following ethical approval and authorization from the appropriate authorities, individuals who were able to read and write in Hindi or English were invited to take part in the study. Participant information, including study details, informed consent forms, and structured knowledge questionnaires, were provided to all subjects. Participants were encouraged to complete the forms independently, and any difficulties in understanding or filling out the forms were addressed by the principal investigator.

Table 1. Level of oral mucositis.

Assessment score	Intervention level
13–20	Level-I
21–26	Level-II
27–39	Level-III

STATISTICAL ANALYSIS

The data were analyzed using IBM's Statistical Package for the Social Sciences (SPSS version 20.0 for Windows). A significance threshold of 0.05 ($p<0.05$) was maintained throughout the analysis. Continuous variables were summarized using mean and standard deviations, while categorical variables were expressed as frequencies and percentages. Pearson's correlation coefficient was computed to evaluate the relationship between the variables.

RESULT

Among 60 subjects, majority of the sample were in the age group of 38–47 years (43%), the majority of the subject were males (88%). The majority of the subjects were 10th pass (43%), the majority of the subjects in occupation were labors (47%), the majority subjects have the family income less than Rs. 10,000 (60%). The majority of the subject residence were from the rural area (65%). The majority of the samples were receiving between 12 and 21 cycles of radiation therapy (55%), the majority of the subjects were laying between 9 and 12 days of oral mucositis (40%). The majority of the subjects had the primary tumor of Oropharynx (48%), the majority of the subjects had the stage II of the cancer (48%), the majority subjects did not have the co-morbid condition (88%).

The majority of the subjects had the other co-morbid condition (88%). In the Post-test, 73% had the level 2 oral mucositis, 47% had the level 1 oral mucositis, and 24% had the level 3 of oral mucositis. After providing the chlorhexidine mouthwash in post-test, 53% had the level 2 oral mucositis, and 47% had the level 1 oral mucositis. The mean value of overall pretest score was 24.48, SD value of score was 2.501, whereas mean value of post-test score was 21.25 and SD value of score was 2.289. The mean difference between the pre-test and post-test scores was 3.233. The data suggests that chlorhexidine was strongly linked to a decrease in the severity of oral mucositis. The paired 't' test results revealed a statistically significant difference with a P-value of less than 0.05 (Tables 2–7 and Figures 1 and 2).

There is a significant correlation between the pre-test score and the duration of oral mucositis, while none of the other variables show any association with the pre-test score of oral mucositis.

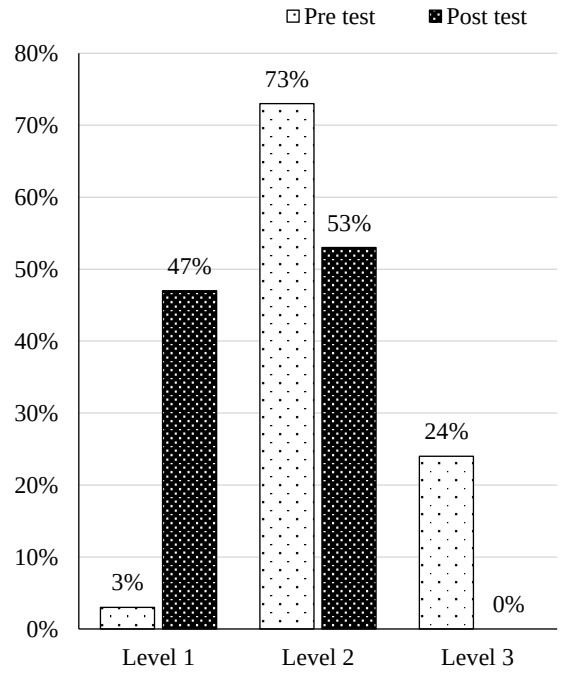

Figure 1. Bar chart showing Distribution of frequency and percentage of pre and post-test.

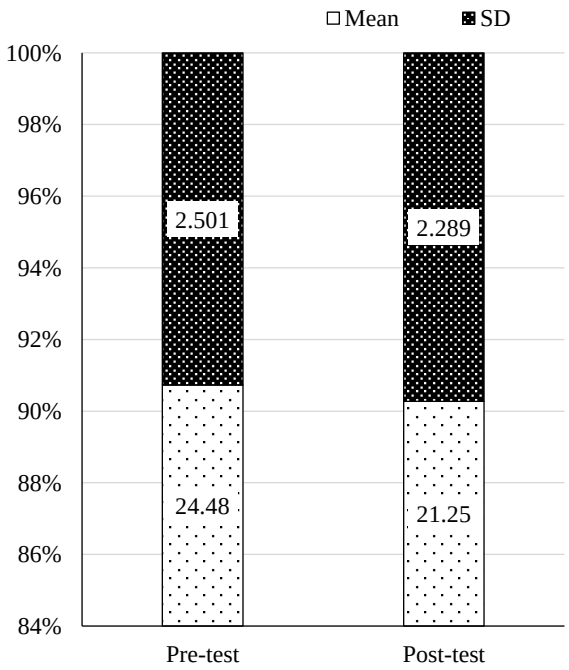

Figure 2. Bar chart showing mean and SD according to pre and post-test.

Table 2. Describing the frequency and percentage distribution of socio demo-graphical characteristics of the study subjects (N=60).

S.N.	Socio demographic characteristics	Frequency	Percentage
1.	*Age (years)*		
	18–27 years	02	3%
	28–37 year	12	20%
	38–47 years	26	43%
	Above 48 years	20	34%
2.	*Gender*		
	Male	53	88%
	Female	7	12%
	Others	00	0%
3.	*Education*		
	Illiterate	15	25%
	10th	26	43%
	12th	19	23%
	Graduation	00	0%
	Post-graduation	00	0%
4.	*Occupation*		
	Farmer	23	38%
	Labor	28	47%
	Government employee	09	15%
	Non-employee	00	0%
	Self-business	00	0%
5.	*Monthly family income*		
	Less than 10,000	36	60%
	10,001–30,000	34	40%
	30,001–50,000	00	0%
	50,001 and above	00	0%
6.	*Residence*		
	Rural	39	65%
	Urban	21	35%

Table 3. Describing the frequency and percentage distribution of clinical profile of the study subjects.

S.N.	Clinical profile of patient	Frequency	Percentage
1.	*Cycles of radiation therapy*		
	1–11 cycles	07	12%
	12–21 cycles	33	55%
	22–32 cycles	20	33%
2.	*Duration of oral mucositis*		
	1–4 days	03	5%
	5–8 days	14	23%
	9–12 days	24	40%
	13–15 days	19	32%
3.	*Region of primary tumor*		
	Oral cavity	25	42%

	Oropharynx	29	48%
	Salivary gland	06	10%
	Nasopharynx	00	0%
	Larynx	00	0%
4.	*Clinical stage of cancer*		
	I	13	22%
	II	29	48%
	III	18	30%
5.	*Co-morbid condition*		
	Yes	07	12%
	No	53	88%
6.	*Type of co-morbid condition*		
	HTN	04	7%
	DM	01	2%
	HTN and DM	02	3%
	Liver disease	00	0%
	Others	53	88%

Table 4. Showing the frequency and percentage of pre and post-test.

S.N.	Level of assessment	Pre test			Post test		
		Frequency	***Percentage***	***Mean ± SD***	***Frequency***	***Percentage***	***Mean± SD***
1.	Level 1	2	3%	24.48±2.501	28	47%	21.25±2.289
2.	Level 2	44	73%		32	53%	
3.	Level 3	14	24%		0	0%	

Table 5. Assessing the effectiveness of chlorhexidine mouthwash.

S.N.	Assessment score	Mean	SD	MD	T value
1.	Pre-test score	24.48	2.501	3.233	20.899 (S*)
2.	Post-test score	21.25	2.289		

Table 6. Level of association between pre-test with socio demographic variables.

Socio demographic	Level of intervention			Total N=60	Calculated value X^2/P value	DF	Result
	Level-1	***Level-2***	***Level-3***				
Age							
18–27 years	0	2	0	2	3.885[a]/.692	6	Not significant
28–37 years	0	9	3	12			
38–47 years	1	21	4	26			
Above 48 years	1	12	7	20			
Gender							
Male	2	38	13	53	.708[a]/.702	2	Not significant
Female	0	6	1	7			
Others	0	0	0	0			
Education							
Illiterate	0	11	4	15	.848a/.932	4	Not significant
10th	1	19	6	26			
12th	1	14	4	19			
Graduation	0	0	0	0			
Post- graduation	0	0	0	0			
Occupation							
Farmer	0	17	6	23	2.448a/.654	4	

Labor	2	20	6	28			Not significant
Government employee	0	7	2	9			
Non-employee	0	0	0	0			
Self-business	0	0	0	0			
Monthly family income							
Less than 10,000	2	25	9	36	1.626a/.444	2	Not significant
10,001–30,000	0	19	5	24			
30,001–50,000	0	0	0	0			
50,001 and above	0	0	0	0			
Residence							
Rural	1	27	11	39	1.587a/.452	2	Not significant
Urban	1	17	3	21			

Table 7. Level of association between pre-test with clinical profile of patient.

Clinical profile	**Level of intervention**			**Total N=60**	**Calculated value X^2/P value**	**DF**	**Result**
	Level-1	***Level-2***	***Level-3***				
Cycles of radiation therapy							
1–11 cycles	0	5	2	7	2.535[a]/.638	4	Not significant
12–21 cycles	2	25	6	33			
22–32 cycles	0	14	6	20			
Duration of oral mucositis							
1–4 days	1	1	1	3	13.445[a]/.306	26	Significant
5–8 days	1	12	1	14			
9–12 days	0	18	6	24			
13–15 days	0	13	6	19			
Region of primary tumor							
Oral cavity	0	21	4	25	6.128a/.190	4	Not significant
Oropharynx	1	19	9	29			
Salivary glands	1	4	1	6			
Nasopharynx	0	0	0	0			
Larynx	0	0	0	0			
Clinical stage of cancer							
I	0	10	3	13	2.465a/.651	4	Not significant
II	1	23	5	29			
II	1	11	6	18			

DISCUSSION

In this hospital based pre-experimental study done among 60 patients, 73% had the level-2 oral mucositis, 47% head level-1 oral mucositis, 24% had level-3 oral mucositis in pre-test score after providing the chlorhexidine mouthwash. The 53% had the level-2 oral mucositis, 47% had the level-1 oral mucositis in the post test. The pre-test mean score was 24.48 with SD of 2.501. Further, post-test mean score is 21.25 with SD 2.289. It indicates that there is effectiveness of chlorhexidine mouthwash in level of oral mucositis mean difference score of 3.233. The present study was supported by other studies also [3, 4].

Bhargava and Shrivastava conducted a study with 60 patients, 30 in each group, who were assigned to either receive conventional fractionation or concomitant boost radiotherapy with concurrent cisplatin [5]. Toxicity was monitored weekly during treatment and at 1 and 3 months after completing the treatment. Patients were instructed to use 5 ml of Chlorhexidine mouthwash three times daily during treatment and for 3 months after finishing radiation therapy. In both groups, grade I mucosal toxicity was observed in 18 patients (60%). Grade II mucosal toxicity occurred in 12 patients (40%) in group A

and 10 patients (33.33%) in group B. Grade III mucosal toxicity was noted in 2 patients (6.66%) in group B, but none in group A.

Cardona *et al*. conducted a study to assess the effects of chlorhexidine on the occurrence and severity of oral mucositis in cancer patients through randomized placebo-controlled trials [6]. The combined results revealed that chlorhexidine did not significantly decrease the incidence of mucositis when compared to the placebo (P=0.129), nor did it significantly reduce its severity (P=0.127). However, subgroup analysis of patients receiving chemotherapy showed a potential trend toward significance (P=0.054). Thus, chlorhexidine was not found to be significantly effective in preventing mucositis or reducing its severity, with moderate quality evidence for severity reduction and low-quality evidence for incidence prevention.

Our study emphasizes the effectiveness of chlorhexidine mouthwash in preventing oral mucositis caused by radiation therapy, contributing to a reduction in distress and complications. Healthcare professionals, particularly nurses, are essential in identifying the most effective strategies to address these health challenges [7–9].

LIMITATIONS

This study had several limitations:

- The participant sample was relatively small.
- The data collection tool used was standardized, which restricted the researcher from making modifications.
- The focus of the study was limited to assessing the effectiveness of chlorhexidine mouthwash in managing radiation therapy-induced oral mucositis in patients with head and neck cancer [10].

CONCLUSION

In conclusion, based on the above findings, this study provides evidence that the level of oral mucositis is higher in the pre-test scores. After the administration of chlorhexidine mouthwash, in post-test, the patients with oral mucositis had low level score as compared to pre-test. These findings revealed that when the patients with oral mucositis used chlorhexidine mouthwash they are able to heal more effectively. There is partial significant association between pre-test score with selected clinical profile of patient.

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