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A STUDY TO ASSESS THE EFFECTIVENESS OF TOPICAL APPLICATION OF PURE HONEY ON RADIATION INDUCED MUCOSITIS IN PATIENTS UNDERGOING RADIOTHERAPY AT SELECTED HOSPITAL VADODARA, GUJARAT

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ABSTRACT

Background: Radiation-induced mucositis is a common side effect experienced by patients undergoing radiotherapy for the treatment of head and neck cancers. It is characterized by inflammation, soreness, and ulceration in the mucous membranes lining the mouth and throat. The severity of mucositis can range from mild discomfort to severe pain, which can lead to difficulty swallowing, impaired nutrition, and reduced quality of life for patients.

Aim: The main aim of the study was to assess the effectiveness of topical application of honey on reducing radiation-induced oral mucositis among cancer patients in experimental group.

Materials and Methods: A quasi experimental with pretest posttest design and non probability purposive sampling technique was used for study. The sample consists of 52 Head and neck cancer patients with radiation induced oral mucositis (for 26 experimental group and 26 for control group) at Dhiraj General hospital, Vadodara Waghodia. A pre assessment was done on the 1st day for both group and honey application was given for 2 times a day 15 minutes before and after radiation therapy continuously till 10 days in the experimental group and on the 11 day post assessment was done in both groups. The assessment tool was WHO oral mucositis grading scale. The statistical analysis was done by 't' test

Results: The finding shows that in experimental group (35%) had grade 2 and grade 3 oral mucositis before intervention. After intervention, majority of sample (77%) had grade 1 and (23%) had grade 2 oral mucositis, which was lower as compared to control group. There was significant difference between mean post test scores of cancer patient with oral mucositis in experimental group (1.2) and in control group (1.8) and obtained unpaired't' value (2.98) was higher than the tabulated value (2.05) for df (28) at 0.05 level of significance.

Conclusion: The study revealed that honey application was effective for reducing radiation induced oral mucositis among head and neck cancer patients.

Keywords: effectiveness, honey application, radiation induced oral mucositis

INTRODUCTION

Cancer, a global health issue causing one in six deaths, accounted for 19.3 million new cases and 10 million deaths in 2020 due to a complex progression of disease conditions.[1]Radation therapy is on of the treatment modalities used for treatment of cancer [2].

Radiation therapy is a crucial and commonly employed modality in the treatment of various malignancies, playing a pivotal role in the management of cancer. However, its therapeutic benefits often come at the cost of undesirable side effects, with radiation-induced mucositis being a prominent and distressing complication [3]. Mucositis, characterized by painful inflammation and ulceration of the mucous membranes within the oral cavity, can significantly impair a patient's quality of life, leading to difficulties in eating, swallowing, and speaking [4].

Various interventions have been explored to mitigate the severity of mucositis, yet a promising, natural remedy has emerged in the form of pure honey. Honey, recognized for its wound-healing and anti-inflammatory properties, presents a potentially novel approach to alleviating the discomfort and accelerating the healing process associated with radiation-induced mucositis [5].

This study aims to evaluate the effectiveness of topical application of pure honey as an adjunct therapy for patients undergoing radiotherapy, shedding light on its potential as a safe and accessible treatment option. Through rigorous investigation and scientific inquiry, we seek to contribute to the understanding of this innovative approach, ultimately improving the well-being of individuals enduring the challenges of radiotherapy.

Oral mucositis has become the most common, unavoidable, and upsetting side effect experienced by HNC patients receiving RT [6]. Studies that were published showed that oral mucositis will occur in nearly all HNC patients receiving

RT [7]. Additionally, data revealed that almost 50% of HNC patients develop grade 3 or higher oral mucositis after being exposed to 66–70 Gy of radiation over the course of 6-7 weeks, with 1.8–2 Gy of radiation per fraction [8, 9]. Pain, trouble swallowing, poor nutrition, an increased risk of infection, and treatment stoppage are all consequences of oral mucositis. It has a major effect on the quality of life (QoL) of patients [10]. Severe mucositis also raises medical costs and lengthens hospital stays [11]. Therefore, it's imperative to create efficient techniques for treating and preventing oral

Oral zinc sulphate [12] and laser therapy [13] are two of the many pharmaceutical and non-pharmacological treatments that have been developed to treat radiation-induced oral mucositis [14]. But as of yet, no firm intervention framework has been developed [15, 16]. Thus, investigating other agents is crucial. The by product of floral nectar and the honeybee's upper aero-digestive tract, honey is concentrated due to the process of dehydration within the beehive [17]. Honey is a traditional medicine that has been shown to be beneficial in treating burn injuries, mouth infections, and surgical wounds [18, 19]. Many clinical trials have been conducted to far to investigate the potential benefits of honey in treating and preventing radiation-induced oral mucositis in patients with head and neck cancers.

The National Institutes of Health's Consensus Development Panel states that no drugs can prevent mucositis, and prevention relies on oral care programs, pain relief, and eliminating microorganisms. Honey, a by-product of honeybees, has been used in modern medicine to inhibit bacterial growth and enhance healing. Biswall successfully used topical honey to manage radiation mucositis [20, 21].

MATERIAL AND METHODS

An experimental and evaluative approach is adopted to assess the effectiveness of topical application of pure honey on radiation induced mucositis in patients receiving radiation therapy at selected hospital of Vadodara as it helps to find out association of oral mucositis with selected demographic variables in experimental group. A purposive sampling procedure was used to select sample for the study. The research included all patients, both males and females between the age of 18-80years, who receiving radiation therapy at selected hospital of Vadodara. The total number of sample in the study was 52. After describing the goal of the study, data was obtained through pre-test. Before conducting the study letter of approval was obtained from institutional ethical committee. The data collection done by the

self-structural demographic variable questions and WHO recommended Oral toxicity assessment scale.

DATA ANALYSIS

All data collected was coded and put into Microsoft Excel. To summarize the questionnaire results, descriptive statistics were employed. The result in terms of percentages were then derived using the statistical analysis of the completed questionnaire.

Table 1: Demographic characteristics in Experimental Group and Control Group

Demographics	Experiment group (Frequency)	%	Control group (Frequency)	%	Total
Age groups					
18-35	7	26.92	6	23.08	13
36-50	15	57.69	16	61.54	31
51-65	4	15.38	4	15.38	8
Gender					
Male	16	61.54	14	53.85	30
Female	10	38.46	12	46.15	22
Food habits					
Vegetarian	13	50.00	11	42.31	24
Non-vegetarian	13	50.00	15	57.69	28
Smoking					
No	13	50.00	14	53.85	27
Yes	13	50.00	12	46.15	25
Alcoholic					
No	9	34.62	13	50.00	22
Yes	17	65.38	13	50.00	30
Chewing tobacco					
No	15	57.69	13	50.00	28
Yes	11	42.31	13	50.00	24
Chewing the battle leaves					
No	19	73.08	20	76.92	39
Yes	7	26.92	6	23.08	13
Education					
Illiterate	16	61.54	16	61.54	32
Primary Education	10	38.46	10	38.46	20
Profession					
Working	16	61.54	13	50.00	29
Unemployed	10	38.46	13	50.00	23
Total	26	100.00	26	100.00	52

Table 2: Comparison of experiment group and control group with pre-test grades of Oral mucositis

Pretest grades	Experiment group	%	Control group	%	Total	%	Chi-square	p-value
Grade 1	8	30.77	11	42.31	19	36.54	1.0740	0.5850
Grade 2	9	34.62	9	34.62	18	34.62		
Grade 3	9	34.62	6	23.08	15	28.85		
Total	26	100.00	26	100.00	52	100.00		

Table 3: Comparison of experiment group and control group with post-test grades of Oral mucositis

Post-test grades	Experiment group F	%	Control group	%	Total	%	Chi-square	p-value
Grade 1	20	76.92	12	46.15	32	61.54	8.2860	0.0160*
Grade 2	6	23.08	8	30.77	14	26.92		
Grade 3	0	0.00	6	23.08	6	11.54		
Total	26	100.00	26	100.00	52	100.00		

*$p<0.05$

Table 4: Comparison of pre-test and post-test grades of Oral mucositis in experiment group by pairs test' t' test

Grades	Pre-test	%	Post-test	%	t-value	p-value
Grade 1	8	30.77	20	76.92	3.7236	0.002*
Grade 2	9	34.62	6	23.08		
Grade 3	9	34.62	0	0.00		
Total	26	100.00	26	100.00		

Table 5: Comparison of pretest and post-test grades of Oral mucositis in control group by 't" test

Grades	Pretest	%	Post-test	%	t-value	p-value
Grade 1	11	42.31	12	46.15	3.5236	0.006
Grade 2	9	34.62	8	30.77		
Grade 3	6	23.08	6	23.08		
Total	26	100.00	26	100.00		

*p<0.05

Table 6: Comparison of experiment group and control group with pretest and post-test grades of Oral mucositis by independent t test

Treatment	Groups	Mean	SD	SE	t-value	P-value	Significant.
Pretest	Experiment group	2.0	0.8	0.2	1.0242	0.3107	NS
	Control group	1.8	0.8	0.2			
Post-test	Experiment group	1.2	0.4	0.1	-2.9794	0.0044*	S
	Control group	1.8	0.8	0.2			

*p<0.05

Table 7: Association between pretest grades of oral mucositis and demographic characteristics in experimental group

Demographics	Pretest grades of oral mucositis							Chi-square	p-value
	Grade 1	%	Grade 2	%	Grade 3	%	Total		
Age groups									
18-35	4	57.14	1	14.29	2	28.57	7	4.1180	0.3900
36-50	3	20.00	7	46.67	5	33.33	15		
51-65	1	25.00	1	25.00	2	50.00	4		
Gender									
Male	5	31.25	6	37.50	5	31.25	16	0.2390	0.8870
Female	3	30.00	3	30.00	4	40.00	10		
Food habits									
Vegetarian	4	30.77	6	46.15	3	23.08	13	2.0000	0.3680
Non-vegetarian	4	30.77	3	23.08	6	46.15	13		
Smoking									
No	3	23.08	5	38.46	5	38.46	13	0.7220	0.6970
Yes	5	38.46	4	30.77	4	30.77	13		
Alcoholic									
No	3	33.33	2	22.22	4	44.44	9	1.0240	0.5990
Yes	5	29.41	7	41.18	5	29.41	17		
Chewing tobacco									
No	6	40.00	3	20.00	6	40.00	15	3.4670	0.1770
Yes	2	18.18	6	54.55	3	27.27	11		
Chewing the battle leaves									
No	7	36.84	7	36.84	5	26.32	19	2.3510	0.3090
Yes	1	14.29	2	28.57	4	57.14	7		
Education									
Illiterate	7	43.75	4	25.00	5	31.25	16	3.5250	0.1720
Primary Education	1	10.00	5	50.00	4	40.00	10		
Profession									
Working	4	25.00	6	37.50	6	37.50	16	0.6500	0.7230
Unemployed	4	40.00	3	30.00	3	30.00	10		
Total	8	30.77	9	34.62	9	34.62	26		

*p<0.005*indicates significant   S-Significant   NS-non significant

Table 8: Association between post-test grades of oral mucositis and demographic characteristics in experimental group

Demographics	post-test grades of oral mucositis							Chi-square	p-value
	Grade 1	%	Grade 2	%	Grade 3	%	Total		
Age groups									
18-35	6	85.71	1	14.29	0	0.00	7	0.4220	0.8100
36-50	11	73.33	4	26.67	0	0.00	15		
51-65	3	75.00	1	25.00	0	0.00	4		
Gender									
Male	13	81.25	3	18.75	0	0.00	16	0.4390	0.5080
Female	7	70.00	3	30.00	0	0.00	10		
Food habits									
Vegetarian	12	92.31	1	7.69	0	0.00	13	3.4670	0.0630
Non-vegetarian	8	61.54	5	38.46	0	0.00	13		
Smoking									
No	10	76.92	3	23.08	0	0.00	13	0.0000	1.0000
Yes	10	76.92	3	23.08	0	0.00	13		
Alcoholic									
No	7	77.78	2	22.22	0	0.00	9	0.0060	0.9400
Yes	13	76.47	4	23.53	0	0.00	17		
Chewing tobacco									
No	11	73.33	4	26.67	0	0.00	15	0.2570	0.6120
Yes	9	81.82	2	18.18	0	0.00	11		
Chewing the battle leaves									
No	15	78.95	4	21.05	0	0.00	19	0.1630	0.6860
Yes	5	71.43	2	28.57	0	0.00	7		
Education									
Illiterate	12	75.00	4	25.00	0	0.00	16	0.0870	0.004*
Primary Education	8	80.00	2	20.00	0	0.00	10		
Profession									
Working	13	81.25	3	18.75	0	0.00	16	0.4390	0.5080
Unemployed	7	70.00	3	30.00	0	0.00	10		
Total	20	76.92	6	23.08	0	0.00	26		

RESULTS

The distribution of patients with oral mucositis, according to age in Experimental group 15 (57.69%) were in the age group between 36-50 years, 7 (26.92%) were in the age group between 18-35 years, 4 (15.38%) were in the age group between 51-65 years, 6(20%) were in the age group of above 61 years. In control group 16(61.54%) were in the group between 36-50 years, 6 (23.08%) were in the age group between 18-35years, and 4(15.38%) were in the age group 51-65 years. With regards to gender of patients in Experimental group 16 (61.54%) were male and 10(38.46%) were female. In control group 14(53.85%) were male and 12(46.15%) were in the female. With regards to food habits of patients in Experimental group 13 (50%) were vegetarians and 13(50%) were non-vegetarians. In control group 15(57.69%) were non-vegetarians and 11(42.31%) were vegetarians. With regards to smoking habits of patients in Experimental group 13 (50%) were smoking and 13(50%) were no smoking. In control group 14(53.85%) were no smoking and 12(46.15%) were smoking. With regards to consumption of

alcohol of patients in Experimental group 17 (65.38%) were yes consuming alcohol and 9(34.62%) were no alcohol. In control group 13(50%) were yes consuming alcohol and 13(50%) were no consuming alcohol. With regards to chewing of tobacco of patients in Experimental group 19(73.08%) were not chewing tobacco and 7(26.92%) were yes chewing tobacco. In control group 20(76.92%) were not chewing tobacco and 6(23.08%) were yes chewing tobacco. With regards to chewing of battle leaves of patients in Experimental group 19(73.08%) were not chewing battle leaves and 7(26.92%) were yes chewing battle leaves. In control group 20(76.92%) were chewing battle leaves and 6(23.08%) were not chewing battle leaves. With regards to educational status of patients in Experimental group 16(61.54%) were no formal education and 10(38.46%) were primary education. In control group 16(61.54%) were no formal education and 10(38.46%) were primary education. With regards to profession of patients in Experimental group 16(61.54%) were working and10 (38.46%) were unemployed. In control group 13(50%) were working and13 (50%) were unemployed. **(Table 1).**

The table 2 shows the results of both groups Experimental Group: In the pre-test Oral mucositis,9(34.62%) of the patients had grade 3 and grade 2 and in Control Group: In the pretest,11(42.31%) were patients had grade 1,9(34.62%) were had grade 2 and 6(23.08%) were had grade 3. **(Table 2).**

The **Table 3** shows the results of both groups Experimental Group: In the post-test grade of Oral mucositis, 20(76.92%) of the patients had grade 1,6(23.08%) patients had grade 2 and In Control Group: In the post-test grade of Oral mucositis,12(46.15%) were patients had grade 1,8(30.77%) were had grade 2 and 6(23.08%) were had grade 3. Hence in experimental group after topical application of pure honey reduced Oral mucositis. Hence p<0.05 **(Table 3)**.

The **Table 4** shows the results of pretest and post-test grades of Oral mucositis in Experimental, during pre-test In study group 9(34.62%) had grade 2 and grade 3 oral mucositis and 8(30.77%) had grade 1 oral mucositis. In posttest in experimental group,20(76.92%) had grade 1oral mucositis,6(23.08%) had grade 2 oral mucositis. Honey application was effective to reducing the oral mucositis among patients undergoing radiation therapy Hence p-value less than 0.002 **(Table 4)**.

The table 5 shows the results of pretest and post-test grades of Oral mucositis in control group during pre-test In control group 11(42.31%) had grade 1,9(34.62%) were grade 2 and 6(23.08%) were grade 3 oral mucositis. In posttest in control

group,12(46.15%) had grade 1oral mucositis,8(30.77%) were grade 2 oral mucositis and 6(23.08%) had grade 3 oral mucositis. There is no reducing the oral mucositis among patients undergoing radiation therapy in control group Hence p-value less than 0.006 **(Table 5)**.

The **Table 6** shows the results represents, the mean score on level of oral mucositis among patients undergoing radiation therapy with or without chemotherapy in experimental group the mean pretest assessment value was 2.0 and the standard deviation was 0.8 and in the control group the mean pretest assessment was 1.8 and the standard deviation was0.8. The p-value 0.3107 no significant. In experimental group the mean pretest assessment value was 1.2 and the standard deviation was 0.4 and in the control group the mean pretest assessment was 1.8 and the standard deviation was0.8. The p-value (0.0044) *p<0.05 significant. That is honey application was effective to reducing the oral mucositis among patients undergoing radiation therapy in post-test **(Table 6)**.

The **Table 7** showed that demographic variables Age, Gender, food habits, smoking, alcohol, tobacco chewing, chewing battle leaves, education level and profession had shown no statistically significant association with the pretest grades of oral mucositis. P<0.005 **(Table 7)**.

The **Table 8** showed that demographic variables Age, Gender, food habits, smoking, alcohol, tobacco chewing, chewing battle leaves, and profession had shown no statistically significant association with the posttest grades of oral mucositis. P<0.005. Hence education status of patients statistically significant association with the post-test grades of oral mucositis among patients. P<0.005. Hence topical application of pure honey is effective in reducing oral mucositis in experimental group **(Total 8)**.

DISCUSSION

The research try to find out the effectiveness of topical application of pure honey on the radiation induced mucositis patients of head and neck cancer receiving radiation therapy. Data was collected by using self-structured demographic questtionarie and WHO recommended Oral toxisity assessment scale. The study comprised a total sample of 52 samples from selected hospital of Vadodara. The sampling technique used was purposive sampling technique. Data analysis was done using SPSS software.

CONCLUSION

The study concluded that the **effectiveness** of topical application of pure honey on the radiation induced mucositis patients of head and neck cancer receiving radiation therapy was effective. In study group 34.62% had grade 2 and grade 3 oral

mucositis and 30.77% had grade 1 oral mucositis. In posttest in experimental group,76.92% had grade 1oral mucositis,23.08% had grade 2 oral mucositis. The p-value (0.0044) *p<0.05 significant. That is honey application was effective to reducing the oral mucositis among patients undergoing radiation therapy in post-test.

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