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RESEARCH ARTICLE

EFFECT OF APPLICATION OF HONEY ON RADIATION-INDUCED MUCOSITIS IN PATIENTS UNDERGOING RADIOTHERAPY AT SELECTED GOVERNMENT HOSPITALS, KOLKATA, WEST BENGAL

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ABSTRACT

A pre-experimental study was undertaken to assess effect of application of honey on radiation induced mucositis in patients undergoing radiotherapy at selected Govt. Hospitals, Kolkata, West Bengal. The conceptual framework was adopted for the study was based on Imogene King's systems Theory of Goal Attainment model. One group pre-test post-test design was adopted. Thirty head and neck cancer patients were selected from radiotherapy department of N.R.S Medical College & Hospital by non-probability convenience sampling technique. Data collected by semi-structured questionnaire and WHO Oral Mucositis Assessment Scale. In pre-test majority (70%) of patient's falls under grade 3 and 6.7% falls under grade 1 mucositis. In the other hand in post-test there were 43.3% under grade 3 and no mucositis 3.3%. The mean score of oral mucositis after intervention was lower than mean score of before intervention which is statistically significant as evident from the calculated 't' value of 3.88 which is higher than the tabulated 't' value (2.05) for df (29) at 0.05 level of significance. The findings of the study can be implicated in nursing practice, nursing education, nursing administration and nursing research. It was recommended that a quasi-experimental study is required to find out the effectiveness of application of honey.

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INTRODUCTION

This year World Cancer Day celebrated under the theme "I am and I will". On this day, 4th Feb, 2019 each and everybody can write worldwide for a single purpose of cancer in an inspiring and positive way.

"I am and I will" –The theme suggest it is all about ourselves; our story and commitment.

- We can empower
- We show support
- We can take personal action to do more against cancer. [1]

Mucositis is a most common and serious complication of radiation therapy. There are supplementary treatments of mucositis with some medications but those are not provided as standard treatment for mucositis. In this relation, honey has a satisfactory effect. [2] Patients mostly suffer from mucositis after their radiation. Evidences show that the trial of honey treatment on radiation induced mucositis have got positive results. Hence the severity of mucositis can be limited and onset of further mucositis will be delayed. [3] The main goals of cancer diagnosis and treatment program are to cure or considerably prolong the life of patients and to ensure the best possible qualities of life for cancer survivors. Anciently cancer was 6th cause of the death. But in present scenario cancer has become 2nd cause of death. There are many complimentary treatments against the complication of radiotherapy and chemotherapy. The application of honey is showing good result in mucositis among patients undergoing radiotherapy. [4] The global target is to achieve 25% reduction of premature deaths due to cancer and non-communicable diseases. We can achieve this target if we raise our hand personally against cancer. [1] It is seen that all cancer patients will develop oral mucositis to some degree. Studies are showing that there is an incidence of 29-66% of all radiotherapy patients of head and neck cancer developing severe oral mucositis. [5] Among all complications of radiotherapy oral mucositis is the most common and debilitating for patients. It affects the quality of life by limiting their ability to tolerate the radiation therapy as well as compromising their nutritional status.

Need for the study: Radiation induced oral mucositis occurs 80% of head and neck cancer patients. It is a normal tissue damage due to radiotherapy. That leads to the decrease in the quality of life of the patient and continuity of the therapy of cancer is affected.
This interruption of therapy becomes a challenge for radiation oncologists. They need to change in dose fractionation. In altered fractional radiotherapy patients are getting mucositis in 100% cases. In 56% cases of mucositis due to radiotherapy are grade 3 & grade 4. [6]

There are sudden negative effects on patient's quality of life due to radiation- induced mucositis.

Major clinical consequences are

- Hospital admission (62%)
- Long Hospital stay for vital parenteral nutrition 70% was with grade 3 & 4
- Intravenous analgesia
- Intravenous antibiotics.

Cancer treatment discontinuity happens in 35% cases due to dose limiting toxicity. [6] These are many treatments approved for radiation- induced mucositis. Nutritional support as well as various complimentary methods are significantly effective for reduction of severity of mucositis and onset of mucositis. Various agents are used for complimentary treatment of radiation- induced mucositis. Honey is one of them. The effect of honey is investigated in many preclinical studies. Honey has mucosal protective effect and it has been seen that honey reduces severity of radiation- induced mucositis.[4] However, one specific honey was used in preclinical trials. More studies are needed to confirm the therapeutic potential of honey application in radiation- induced mucositis and to strengthen existing studies. During clinical field at oncology department in N.R.S Medical College and Hospital, Kolkata, researcher has seen patients undergoing radiotherapy suffering from oral mucositis. They are grading from mild to life threatening mucositis affecting quality of life. Treatment is running with various medicines. They are maintaining their regular oral hygiene. In one of the worst cases researchers have seen that the patient could not take food orally. It gradually limits their intake. This grave situation is a constant reminder of the disease and death, as patients verbalized their feelings. Researcher has selected this problem statement for her research study and she hopes that it will be beneficial to individual, family and society at large.

Problem statement: Effect of application of honey on radiation- induced mucositis in patients undergoing radiotherapy at selected Govt. Hospitals, Kolkata, West Bengal.

Purpose: The purpose of the study is to find out the effectiveness of application of honey on radiation-induced mucositis in patients who are undergoing radiotherapy.

Objectives

- To assess the oral mucositis among patients undergoing radiotherapy.
- To assess the effectiveness of application of honey on radiation induced mucositis in patients undergoing radiotherapy at selected Govt. Hospital, Kolkata, W.B.
- To find out the association between pre-test mucositis in patients undergoing radiotherapy with the selected demographic variables.

Operational definitions

- **Effect:** In this study effect defined as the positive outcome of honey application in oral cavity to heal the oral mucositis in cancer patients undergoing radiotherapy.
- **Mucositis:** Mucositis refers to the inflammation of oral cavity and tongue which is the side effect of major ionizing radiation toxicities and normal tissue injuries that result from radiotherapy, characterized by whitish or reddish patches and sores causing pain, difficulty in speech & swallowing and loss of appetite.
- **Application of honey:** In this study application of honey refers to introducing 10 ml of Food Safety and Standard Authority of India (FSSAI) approved honey into the oral cavity and asking the client to hold it for 5 minutes until it spreads over and then to swallow it and it is to be done 3 times a day for 7 days as they were non- diabetic.
- **Cancer patients:** In this study cancer patients refer to the persons diagnosed to have disease with abnormal proliferation of cells in head and neck.
- **Radiation therapy:** In this study it refers to a kind of therapeutic measure for 2^{nd}, 3^{rd}, 4^{th} stage of cancer, in which certain cancer cell killing drugs are given and ionizing rays are passed to the affected areas of such patients.

Assumptions

- All the cancer patients receiving radiotherapy may develop oral mucositis as side effect.
- Honey application may have positive effects on healing of oral mucositis induced by radiotherapy.
- Oral honey application may differ in healing effects depending on different patient's condition of mucositis.
- All the selected patients undergoing radiotherapy may follow the instructions regarding oral honey application at home and their statements will be true.

Hypothesis

H1: There is statistically significant difference between mean pre and post-test observation of oral mucositis at 0.05 level of significance.

H2: There is statistically significant association between pre-test mucositis with the selected demographic variables at 0.05 level of significance.

REVIEW OF LITERATURE

Charalambous M *et al*. (2018) conducted a randomized controlled trial on the effect of the use of thyme honey in minimizing radiation induced oral mucositis in head and neck cancer patients at Bank of Cyprus Oncology Center, Cyprus. Generalized estimating equations revealed that patients in the intervention group were graded lower in the objective assessment of oral mucositis ($p < 0.001$). Quality of life of the patients in the same group was also statistically significantly higher than that of the patients of the control group ($p <$

0.001). [7] Co JL *et al*. (2016) conducted a meta-analysis and systematic review of literature on effectiveness of honey on radiation induced oral mucositis, time to mucositis, weight loss, and treatment interruptions among patients with head and neck cancer at Department of Radiotherapy of Benavides Cancer Institute, University of Santo Tomas Hospital, Manila, Philippines. This evidenced that honey gave benefit to patients with head and neck malignancy by delaying the onset of oral mucositis, weight loss and decreasing treatment interruption. The results showed honey is a reasonable treatment for radiation-induced mucositis, but more randomized clinical trials (RCTs) should be done. [8] Riley P *et al*. (2015) conducted a study on interventions for preventing oral mucositis in patients with cancer receiving treatment: oral cryotherapy at Chochrane Oral Health Group, School of Dentistry, The University of Mancester. Evidence suggests that it does reduce oral mucositis in the adults, but researchers were less certain about the size of the reduction, which could be large or small. However, researchers were confident that there was an acceptable decrease in severe oral mucositis in those adults. This Cochrane review includes some very recent and currently unpublished data, and strengthens international guideline statements for adults receiving the above cancer treatments. [9]

Francis M & William S (2014) conducted a study on effectiveness of Indian turmeric powder with honey as complementary therapy on oral mucositis: a nursing perspective among cancer patients in Mysore. In the study, quasi experimental non-equivalent control group pretest post-test design was used and non-probability purposive sampling technique was adopted to select 60 cancer patients with treatment induced oral mucositis, 30 patients in experimental and 30 patients in control group. The independent 't' value for post-test 2 and 3 were significant between experimental and control group. It concluded that the application of Indian turmeric and honey on treatment-induced oral mucositis is effective. [2]

Amna Amanat *et al*. (2014) conducted a randomized controlled study at clinical oncology department of Mayo Hospital, Lahore, Pakistan. The results of this study showed that Ziziphus honey significantly reduced the severity of mucositis in treatment arm. It is really encouraging to note that patients of head and neck cancer suffering from severe mucositis due to radiotherapy can be lessened to a great extent simply by such a feasible and affordable option. [3]

RESEARCH METHODOLOGY

Research approach: The research approach adopted in this study is pre-experimental research approach. It aimed at evaluating the effectiveness of application of honey on radiation induced oral mucositis.

Research design: The research design is the overall plan or blueprint of the study under investigation and it is the structure and strategies of investigation for answering the questions that the researcher selects to carry out in the study. Research design adopted for the present study is One group pre-test post-test design. In this study researcher plan to assess the oral mucositis twice i.e

- Prior application of honey, on day one.
- After Seven days continuous application of honey, on day eight.

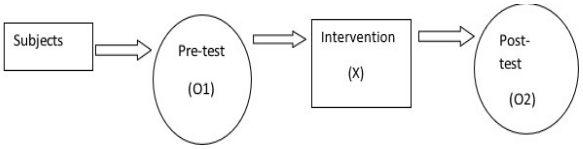

Fig1. Schematic presentation of one group pretest-posttest design

Pre-test: Assessment of oral mucositis before intervention i.e application of honey.

Intervention: Application of honey 10 ml into the oral cavity, three times a day for consecutive seven days.

Post-test: Assessment of oral mucositis after intervention i.e on day eight.

Variables under study

- Demographic variables: Age, Gender, day of radiation.
- Independent variable – Application of honey.
- Dependent variable – Status of mucositis.

Population: A population is any group of individuals that has one or more common characteristics that are of interest of the researcher. The population of the study consists of head and neck cancer patients attending radiotherapy department undergoing radiotherapy.

Sample: Patients of radiation induced oral mucositis attending radiotherapy department undergoing radiotherapy.

Sampling technique: The method of sampling is the non-probability – convenience sampling.

Sample size: The sample size refers to the subset of the population that are selected for a study. In this study the sample size was 30.

Sample criteria

Inclusion criteria:

- Patients with histological confirmed head and neck cancer planned for external beam radiotherapy.
- Patients of radiotherapy induced oral mucositis of grade 1, 2, and 3.

Exclusion criteria

- Patients having xerostomia,
- Patients who were suffering from systemic disease
- Patients having oral sores due to ill-fitting dentures.
- Patients of hyperglycemia were excluded from the study.

Data Collection tool and techniques

Based on objectives of the study the following data collection tools were developed in order to obtain necessary information.

Table 1. Data collection tool and techniques

Variables	Tool	Technique
Demographic variable & research variable	Semi-structured Interview Schedule.	Interviewing.
Oral mucositis assessment	WHO Oral Mucositis Assessment Scale.	Observation

The data presented in the table 1, shows that semi-structured interview schedule was prepared to demographic information

of sample and a structured tool i.e WHO Oral Mucositis Assessment Scale was used to assess the grade of mucositis.

Analysis and interpretation of data

SECTION I: Description of socio-demographic characteristics of sample

Table 2 frequency and percentage distribution of age, gender, numbers of radiotherapy, number of mouth was hes and history of addiction

n =30

	Demographic variables	Frequency (F)	Percentage (%)
1.	**Age in years**		
	40 – 49	4	13.3
	50 – 59	6	20.0
	60 – 69	14	46.7
	70 – 79	6	20.0
2.	**Gender**		
	Male	29	96.7
	Female	1	3.3
3.	**Numbers of radiotherapy**		
	11^{th} – 20^{th}	7	23.3
	21^{st} – 30^{th}	18	60.0
	31^{st} – 40^{th}	5	16.7
4.	**Numbers of mouth wash**		
	6 – 10 times	13	43.3
	11 – 15 times	17	56.7
5.	**History of addiction**		
	Yes	27	90
	No	3	10

The data presented in table 2 shows that majority of patients falls under age group of 60-69 years (46.7%) and only 13.3% patients are under age group of 40-49 years. Maximum is male patients (96.7%). Out of 30 head and neck cancer patient's maximum (60 %) were getting 21^{st} -30^{th} number of radiotherapy and minimum were getting 31^{st} -40^{th} numbers of radiotherapy at the time of data collection. Among them 56.7 % were washing their mouth 11-15 times daily and 43.3% washes 6-10 times. Majority of patient's having history of addiction (90%) and 10% of patient's had no history of addiction.

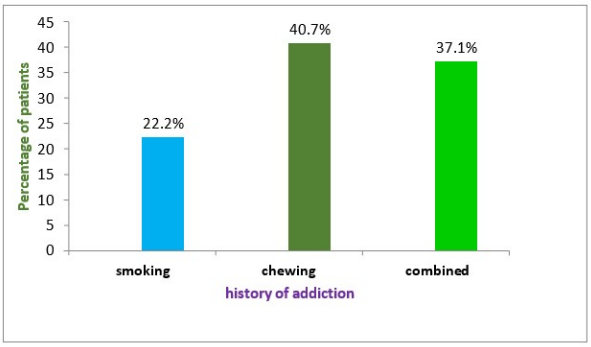

Figure 2 Bar diagram shows percentage distribution of history of addiction.

Data depicted in Figure 2 indicates that maximum patients (40.7%) having addiction on chewing and 22.2% having addiction on smoking.

SECTION II: Analysis of pre-test and post-test grade of oral mucositis. In order to find out the grade of radio therapy-induced mucositis of patients after discussion with experts it was decided to use WHO oral mucositis assessment scale.

The sample who score 4, was reflected to having life threatening mucositis, those who scored 3 was said to have severe mucositis, those who have scored 2 was said to have moderate mucositis and those who have scored 1 was said to have mild mucositis.

Table 3 Frequency and percentage of oral mucositis according to grade

n = 30

Grade of mucositis	scores	Pre-test		Post-test	
		Frequency	Percentage	Frequency	Percentage
Grade 0	0	--	--	1	3.3
Grade 1	1	2	6.7	5	16.7
Grade 2	2	7	23.3	11	36.7
Grade 3	3	21	70.0	13	43.3
Grade 4	4	--	--	--	--

Table 3 showed that in pre-test no patients under grade 0 and grade4. Majority (70%) of patient's falls under grade 3 and 6.7% falls under grade 1 mucositis. In the other hand in post-test there were 43.3% under grade 3 and no mucositis 3.3%.

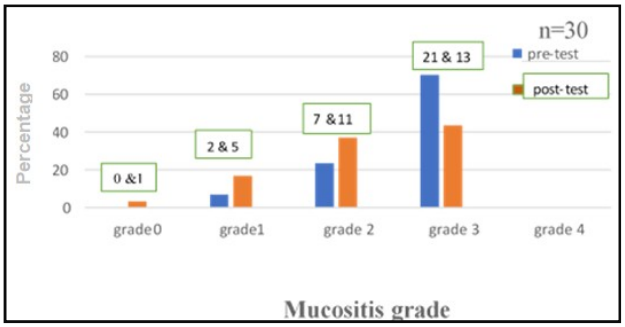

Figure 3. Bar diagram shows comparison of mucositis grades between pre-test and post-test.

Figure 3 showed that in pre-test no patients under grade 0 and grade4. Majority (70%) of patient's falls under grade 3 and 6.7% falls under grade 1 mucositis. In the other hand in post-test there were 43.3% under grade 3 and no mucositis 3.3%.

SECTION III: Effectiveness of application of honey on radiation induced mucositis.

H01: There is no statistically significant difference between mean pre and post-test observation of oral mucositis at 0.05 level of significance.

H1: There is statistically significant difference between mean pre and post-test observation of oral mucositis at 0.05 level of significance.

Table 4. Mean, Median, Standard deviation and paired 't' test of pre-test and post-test grade of mucositis.

n=30

Grade of oral mucositis	Mean	Mean difference	SD	Median	't' value
Before intervention	2.63		0.61	3	
		0.40			3.88*
After intervention	2.23		0.87	3	

t (29) = 2.05, P<0.05*

The data presented in table 4 indicates that the mean score of oral mucositis after intervention was lower than mean score of oral mucositis before intervention with the mean difference of 0.40 which is statistically significant as evident from the

calculated 't' value of 3.88 which is higher than the tabulated 't' value (2.05) for df(29) at 0.05 level of significance. Hence null hypothesis (H0) was rejected and research hypothesis (H1) was accepted. So, the above analysis and interpretation of data presented in the tables indicated that application of honey on radiation induced mucositis was effective as it significantly improved the status of mucositis.

SECTION IV: Findings related to association between pretest mucositis of patients with selected demographic variables.

H02: There is no statistically significant association between pre-test mucositis with selected demographic variables at 0.05 level of significance.

H2: There is statistically significant association pre-test mucositis with selected demographic variables at 0.05 level of significance.

Table 5 Chi square value and their significance between pre-test mucositis and selected demographic variables such as age, numbers of radiotherapy, numbers of mouth wash and history of addiction

n = 30

Demographic variables	<median	>median	df	χ^2	Remarks
Age in years					
40 - 59	5	5	1	5.96	Significant*
60 – 79	2	18			
Numbers of radiotherapy					
11 – 25	4	4	1	4.33	Significant*
26 – 40	3	19			
Numbers of mouth wash					
5 – 10	1	14	1	4.65	Significant*
11 – 15	6	9			
History of addiction					
Yes	6	21	1	0.13	Not significant
No	1	2			

Table value of chi square= 3.84, df=1, p< 0.05*

The data presented in the table 5 indicates that significant association was found in respect to the pre-test mucositis grades at 0.05 level of significance. So, the research hypothesis (H2) was accepted and null hypothesis (H02) was rejected for demographic variables such as age, numbers of radiotherapy and numbers of mouth wash. Data also revealed that there was no significant association present between history of addiction and pre-test mucositis in patients. So, research hypothesis was rejected for history of addiction of patient.

DISCUSSION

Findings related to description of socio-demographic characteristics of sample

- Majority of patients falls under age group of 60-69 years (46.7%).
- Maximum is male patients (96.7%).
- Maximum (60 %) were getting 21st -30th number of radiotherapy and minimum were getting 31st -40th numbers of radiotherapy at the time of data collection.
- Maximum 56.7 % were washing their mouth 11-15 times daily and 43.3% washes 6-10 times.
- Majority of patient's having history of addiction (90%) and 10% of patient's had no history of addiction.

Findings related to analysis of pre-test and post-test grade of oral mucositis

- In pre-test no patients under grade 0 and grade 4.
- Majority (70%) of patient's falls under grade 3.
- Grade 1 mucositis was 6.7% of patients.
- In the other hand in post-test there were 43.3% under grade 3 and no mucositis 3.3%.

Findings related to effectiveness of application of honey on radiation induced mucositis: Mean score of oral mucositis after intervention was lower than mean score of oral mucositis before intervention with the mean difference of 0.40 which is statistically significant as evident from the calculated 't' value of 3.88 which is higher than the tabulated 't' value (2.05) for df (29) at 0.05 level of significance. Hence null hypothesis (H0) was rejected and research hypothesis (H1) was accepted.

Findings related to association between pretest mucositis of patients with selected demographic variables: Significant association was found in respect to the pre-test mucositis grades at 0.05 level of significance for demographic variables such as age, numbers of radiotherapy and numbers of mouth wash. Data also revealed that there was no significant association present between history of addiction and pre-test mucositis in patients at 0.05 level of significance. Nursing is a profession and with the changing trends it is important for nursing personnel to keep themselves up-to-date with the change.

IMPLICATIONS

Nursing actions become more evidence- based practice. The result obtained from the study helped the researcher to derive certain implications in the following areas:

Nursing Practice: Practice is to determine the effect of nursing intervention so as to improve the patient care quality. Health personnel have added responsibility to educate the public regarding the side effects of cancer treatment along with the relieving measure. Nursing personnel can provide information regarding positive effects of honey application as a remedy of oral mucositis.

Nursing Education: Nursing education has evolved through the year, now focusing on holistic health approach and in the development of independent nurse practitioners providing efficient nursing care on the preventive, promotive, curative and rehabilitative approach. This study can be applicable in nursing education. The study results could have greater effect on nursing education as well as different nursing departments can utilize these findings to direct their students during their clinical practices positively.

Nursing research: Nurse researcher should conduct the experimental research with the help this study which provides more scientific knowledge to nursing profession.

Nursing administration: By using the data obtained from this study administrators can establish or create a plan for inclusion of honey application in cancer treatment modalities.

RECOMMENDATIONS

- A similar study can be conducted among other cancer patients who can develop mucositis as a side effect of cancer treatment.
- A similar study can be conducted with control group.
- A similar study can be done with large sample size.

- A similar study can be done with randomized sampling.

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