EFFECTIVENESS OF TOPICAL APPLICATION OF MIXTURE OF HONEY AND COFFEE IN RADIATION INDUCED ORAL MUCOSITIS AMONG PATIENTS WITH HEAD & NECK CANCER UNDERGOING RADIOTHERAPY AT RADIOTHERAPY DEPARTMENT OF KGMU, LUCKNOW, U.P

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Abstract

Background: Cancers commonly known as head and neck cancers typically begin in the squamous cells that line the moist, mucosal surfaces within the head and neck. Oral mucositis is erythematous and ulcerative lesion of the oral mucosa in patients with cancer being treated with chemotherapy/radiation therapy in the areas of oral cavity.

Objectives: To assess the grade of the oral mucositis among head & neck cancer patients receiving radiotherapy. 2. To evaluate the effectiveness of mixture of honey and coffee application on radiation induced oral mucositis among the study group. 3. To find the association between the radiation induced oral mucositis with selected demographic variables.

Method: quasi experimental non randomized control group design was applied and 60 samples (30 in each group) were selected by convenience sampling technique. The mixture of honey and coffee was applied to the study group before and after 15 minutes of radiotherapy till the continuation of radiotherapy and no intervention was given in the control group.

Result: The result revealed that the application of honey and coffee mixture was significantly effective on oral mucositis (p<0.001) in the study group.

Conclusion: The study concluded that, application of mixture of honey and coffee is an effective method of reducing the onset and severity of oral mucositis in comparison with no intervention.

Introduction:-
According to the W.H.O cancer is the second leading cause of death globally & is estimated to account for 9.6 million deaths in 2018.²

In the world about 57 million deaths occur every year among which cancer accounts for 27% of them. Environmental alterations, lifestyle changes, longer life span and smoking are a few causes for increase in the rate of cancer. The head & neck cancers form the seventh most common cancer in the world. They are the most common in

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developing countries, mainly in Southeast Asia. Head & neck cancers are more common in males as compared to
the females. This is mainly attributed to the use of tobacco, areca nut & alcohol etc. Head & neck cancers are more
common in several regions of the world where the prevalence of tobacco & alcohol consumption is very high.

The standard of care for head & neck cancers especially oropharyngeal cancer & inoperable oral cavity cancer, is
concurrent chemo radiation.

Oral mucositis is the most common & irritating side effect of chemo radiation. Around 80% of the patients treated
with radiotherapy suffer from Radiation Induced Oral Mucositis and may reach upto 100% in patients with altered
fraction in head and neck cancer.

In recent years, more head & neck cancer patients have been treated with radiotherapy (RT).

Nowadays a number of commercial agents have been marketed to treat or prevent oral mucositis that are expensive
& doubtful efficacy. Finance is the major issue, some home-made remedy can help the poor patients to deal with
chemoradiation induced side effects & continue their treatment without breaks in the developing countries.

Mohammad A R, Neda R (2014) conducted a RCT on coffee plus honey versus topical steroid in the treatment of
chemotherapy induced oral mucositis. The result showed that all the three treatment regimens (honey plus coffee,
honey, and steroids) reduce the severity of lesions. The best reduction in severity was achieved in HC group. H
group and S group took the second and third places. In other words, honey plus coffee regimen was the most
effective modality for the treatment of oral mucositis. The conclusion of the study was that oral mucositis can be
successfully treated by a combination of honey and coffee as an alternative medicine in a short time.

Topical application of honey to the oral cavity and pharynx results in reduction of pain to significantly low levels
resulting in lesser use of analgesics, treatment gaps and weight loss hence overall which improves their compliance
and tolerability towards radiation schedule, which helps in completing the radiation treatment protocol within given
time period, leading to the maximum possible effect achieved by RT on tumor.

Statement of the Problem:
Effectiveness of topical application of mixture of Honey and Coffee in Radiation induced Oral Mucositis among
patients with Head & Neck Cancer undergoing radiotherapy at Radiotherapy Department of K.G.M.U., Lucknow.

Objective of the Study:-
1. To assess the grade of the oral mucositis among head & neck cancer patients receiving radiotherapy.
2. To evaluate the effectiveness of mixture of honey and coffee application on radiation induced oral mucositis
   among the study group.
3. To find the association between the radiation induced oral mucositis with selected demographic variables.

Hypotheses:
H1: There will be significant difference in oral mucositis between experimental group & control group.
H2: There will be significant association between oral mucositis and selected demographic variables.

Methodology:-
Research approach:
Quantitative research approach was selected for the study.

Research Design:
Non-randomized control group design was selected for the study.

Setting of the study:
The study was conducted at the department of radiotherapy at King George’s Medical University.

Research variables:
1. Independent variables: Application of mixture of Honey & Coffee.
2. Dependent variable: Radiation Induced Oral Mucositis.

**Demographic variables:**
Age, sex, cigarette smoking/ tobacco chewing, duration of smoking/ tobacco chewing.

**Target population:**
People clinically diagnosed with head and neck cancer i.e. newly diagnosed patients who met inclusion criteria in the radiotherapy department.

**Accessible population:**
Patients with head and neck cancer undergoing radiation therapy at radiotherapy department, who met the inclusion criteria and agree to participate in the study, were recruited as subjects.

**Sample size:**
It consisted of total 60 patients (30 in each group).

**Sampling technique:**
In this study convenience sampling technique of non probability sampling method was used.

**Criteria for sample selection:**

**Inclusion criteria:**
1. Previously untreated, histologically proven squamous cells carcinoma of head & neck.
2. Age 18-65 years.
3. Patient with grade 0 oral mucositis
4. Normal Renal, Cardiac, Liver, Lung function.
5. Patient willing to participate.
6. Patients should receive concurrent Chemo-radiotherapy as primary treatment.

**Exclusion criteria:**
1. Metastatic cancer including both head and neck cancer together.
2. Co-morbidities like diabetes mellitus, hypertension, colorectal cancer, depression etc.
3. Patients who had oral mucositis.

**Description of the data collection tool and technique:**

**Section 1: Demographic variables and clinical profile:**
Demographic variables include age, gender and smoking habits. Clinical profile includes weight loss during treatment, number of radiation fractions, duration of oral mucositis and oral hygiene followed.

**Section 2: RTOG grading system for oral mucositis:**
This section includes standard RTOG grading system for oral mucositis. The RTOG grading is reliant on a clinician’s ability to judge the anatomical changes associated with oral mucositis (size & characteristics of ulceration) and available in public domain which includes 5 grades that starts from grade 0 to grade 4.

**Steps of application of mixture of honey and coffee:**
1. In the study group, the subjects received the topical application of mixture of honey & coffee in the 3:1 ratio respectively, i.e. mixture of 100 gm will contain 75gm of honey & 25 gm of instant coffee. The subjects were explained to keep the mixture for 30 seconds in the mouth and then swallow it.
2. 10 ml of the mixture of honey and coffee was applied on the oral mucosa of the subjects for 2 times in a day i.e., 15 minutes before & 15 minutes after the radiotherapy.
3. In the control group the subjects did not receive any intervention.
4. The treatment will be continued till the radiotherapy goes.
5. At every 7th day the post test was conducted to assess the grade of oral mucositis in both groups.

**Results:-**

**Section 1:** Distribution of the demographic and clinical characteristics among study and control group.
Table 1: Frequency and percentage distribution of demographic variables of patients undergoing radiotherapy \( n=60 \).  

| Variable                                           | Study group (n=30) | Control group (n=30) |   |
|----------------------------------------------------|--------------------|----------------------|---|
|                                                    | \( f \)  | \( % \)  | \( f \)  | \( % \)  |   |
| **Age in years**                                   |     |     |     |     |   |
| 18-30                                              | 1    | 3.3  | 1    | 3.3  |   |
| 31-42                                              | 3    | 10   | 3    | 10   |   |
| 43-54                                              | 12   | 40   | 11   | 36.6 |   |
| 55-65                                              | 14   | 46.6 | 15   | 50   |   |
| **Gender**                                         |     |     |     |     |   |
| Male                                                | 25   | 83.3 | 26   | 86.6 |   |
| Female                                              | 5    | 16.6 | 4    | 13.3 |   |
| **Type of substance abuse (Cigarette smoking / tobacco chewing)** |     |     |     |     |   |
| Smoking                                             | 1    | 3.3  | 3    | 10   |   |
| Tobacco chewing                                    | 18   | 60   | 19   | 63.3 |   |
| Both                                                | 8    | 26.6 | 5    | 16.6 |   |
| None                                                | 3    | 10   | 3    | 10   |   |
| **Duration of smoking/ tobacco chewing in years**    |     |     |     |     |   |
| 1-3 years                                           | 3    | 10   | 9    | 30   |   |
| 4-6 years                                           | 0    | 0    | 1    | 3.3  |   |
| 7-9 years                                           | 6    | 20   | 4    | 13.3 |   |
| 10 or above                                         | 18   | 60   | 13   | 45.3 |   |
| **Weight loss during treatment in kg**              |     |     |     |     |   |
| None                                                | 17   | 56.6 | 1    | 3.3  |   |
| 1-2kg                                               | 7    | 23.3 | 5    | 16.6 |   |
| 3-4kg                                               | 6    | 20   | 15   | 50   |   |
| 5-6kg                                               | 0    | 0    | 9    | 30   |   |
| Above 6 kg                                          | 0    | 0    | 0    | 0    |   |
| **No. of radiotherapy fractions**                   |     |     |     |     |   |
| 1-5 fractions                                       | 0    | 0    | 0    | 0    |   |
| 6-10 fractions                                      | 0    | 0    | 0    | 0    |   |
| 11-15 fractions                                     | 0    | 0    | 0    | 0    |   |
| 16-20 fractions                                     | 0    | 0    | 0    | 0    |   |
| 21-25 fractions                                     | 3    | 10   | 2    | 6.6  |   |
| 26-30 fractions                                     | 15   | 50   | 11   | 36.6 |   |
| 31-35 fractions                                     | 12   | 40   | 17   | 56.6 |   |
| **Duration of development of OM in weeks**          |     |     |     |     |   |
| 1 week                                             | 4    | 13.3 | 17   | 56.6 |   |
| II week                                            | 4    | 13.3 | 13   | 43.3 |   |
| III week                                           | 22   | 73.3 | 0    | 0    |   |
| IV week                                            | 0    | 0    | 0    | 0    |   |
| V week                                             | 0    | 0    | 0    | 0    |   |
| None                                                | 0    | 0    | 0    | 0    |   |
| **Oral hygiene followed**                          |     |     |     |     |   |
| Once in a day                                       | 8    | 26.6 | 16   | 53.3 |   |
| Twice a day                                         | 8    | 26.6 | 0    | 0    |   |
| Neem sticks                                         | 9    | 30   | 7    | 23.3 |   |
| Gargle                                              | 5    | 16.6 | 7    | 23.3 |   |

Section II: Findings related to the grade of the oral mucositis among head & neck cancer patients receiving radiotherapy.

Table 2: Distribution of Subjects According to Development of Oral Mucositis \( n=60 \).  

| Development  | Control | Study Group | Total | Significance |
|--------------|---------|-------------|-------|--------------|

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Table 2 shows that in control group most of the subjects developed Oral Mucositis in I week while in Study group the Oral Mucositis was developed mostly in III week. The significant difference was found in period of Oral Mucositis development between control & Study group (p<0.001).

**Section III: Comparison of RTOG Score between Study and control group.**

Table 3: Comparison of RTOG Score between Study and control group.

| RTOG Score   | Control Group | Study Group | Mann Whitney Test |
|--------------|---------------|-------------|-------------------|
|              | Mean          | SD          | Mean              | SD       | z-value       | p-value   |
| Pre Test     | 0.00          | 0.00        | 0.00              | 0.00     | -             | -         |
| Post Test I  | 0.57          | 0.50        | 0.13              | 0.35     | -3.49         | <0.001    |
| Post Test II | 1.27          | 0.45        | 0.27              | 0.45     | -5.90         | <0.001    |
| Post Test III| 1.80          | 0.41        | 1.13              | 0.35     | -5.13         | <0.001    |
| Post test IV | 2.53          | 0.51        | 1.37              | 0.49     | 5.89          | <0.001    |

Table no. 3 shows that in all the posttests the RTOG score of control groups was significantly more than the study group (p<0.001)

**Section IV: Association between the effectiveness of mixture of honey and coffee on radiation induced oral mucositis with selected demographic variables.**

Table 4: Association between the effectiveness of mixture of honey and coffee on radiation induced oral mucositis with selected demographic variables.

| S. no. | Variables                  | Categories                        | Grading for oral mucositis RTOG Score | No. | %   | chi sq | p-value |
|--------|----------------------------|-----------------------------------|--------------------------------------|-----|-----|--------|--------|
| 1      | Age in years               | 18-30                             | G1 1 G2 0 G3 2                        | 3%  | 6.89| 0.331  |
|        | 31-42                      | 3 3 0                             |                                       | 10% |     |        |
|        | 43-54                      | 7 13 4                            |                                       | 40% |     |        |
|        | 55-65                      | 8 10 10                           |                                       | 47% |     |        |
| 2      | Gender                     | Male                              | 14 23 14                             | 85% | 2.97| 0.227  |
|        | Female                     | 5 3 1                             |                                       | 15% |     |        |
| 3      | Type of substance abuse    | Smoking                           | 0 3 1 4                             | 7%  | 6.17| 0.405  |
|        | (Cigarette smoking / tobacco chewing) | Tobacco chewing | 11 17 10                   | 63% |     |        |
|        |                             | Both                              | 5 3 4 12                           | 20% |     |        |
|        |                             | None                              | 3 3 0 6                            | 10% |     |        |
| 4      | Duration of smoking/ tobacco chewing in years | 1-3 years | 2 8 2 12 | 20% | 5.49| 0.482  |
|        |                             | 4-6 years                         | 0 1 1 2                           | 3%  |     |        |
|        |                             | 7-9 years                         | 3 3 4 10                          | 17% |     |        |
|        |                             | 10 or above                       | 11 11 8                           | 50% |     |        |
| 5      | Weight loss during treatment in kg | None | 17 1 0 18 | 30% | 74.2| <0.001 |
|        |                             | 1-2kg                              | 1 11 0 12                          | 20% |     |        |
|        |                             | 3-4kg                              | 2 14 6 22                          | 37% |     |        |
|        |                             | 5-6kg                              | 0 0 8 8                            | 13% |     |        |
Table no. 10 shows that weight loss during treatment was more in the control group than in the study group and the difference was found to be significant (p<0.001). Number of radiotherapy fractions were associated with RTOG score as increased fractions of radiotherapy increases the grading of oral mucositis significant (p<0.001). Duration of oral mucositis was found to be more in the control group than in the study group and found significant (p<0.001). Oral hygiene followed was significantly (p<0.013) high in the study group than in the control group.

**Discussion:-**

**Major findings and discussions of the study:**

There was significant effect in RTOG Score after the intervention in study and control group on posttest III and IV p<0.001.

Oral hygiene showed highly significant effect on RTOG score (p<0.001) among demographic variables.

The significant difference was found in period of Oral Mucositis development between control & Study group (p<0.001). In control group most of the subjects developed Oral Mucositis in I week while in study group the Oral Mucositis was developed mostly in III week.

The findings of the study showed that there is highly significant difference in the study group due to the effect of application of mixture of honey and coffee on oral mucositis in posttest I, II, III and IV with p value p<0.001. Whereas, the findings of the study were supported by the following literature: Khanal, B. et al., (2010) literature indicates that honey appears to promote wound healing, so the authors investigated whether its anti-inflammatory properties might limit the severity of radiation induced oral mucositis. A single blinded, randomized, controlled clinical trial was carried out to compare the mucositis-limiting qualities of honey with lignocaine. A visual assessment scale permitted scoring of degrees of mucositis and statistical evaluation of the result was performed using the X² test. Only 1 of 20 patients in the honey group developed intolerable oral mucositis as compared to lignocaine group, indicating that honey is strongly protective (RR=0.067) against the development of mucositis. The proportion of patients with intolerable oral mucositis was lower in the honey group and this was statistically significant (p=.000). Honey applied topically to the oral mucosa of the patients.

From the above study the investigator draws the conclusion that findings of the study in the reviews are supporting the findings of the current study as the results are similar in some aspects. There are some of the factors that might have influenced the results may be use of some other drug or ointments for the oral mucositis. The current study can be accepted and practiced in the real scenario to overcome the burden of cancer patients dealing with the complications of cancer treatment.
Conclusion:-
From the findings of the study, it has been observed that application of mixture of honey and coffee is beneficial reducing the onset and severity of radiation induced oral mucositis among head and neck cancer patients. Relevant literature, journal were reviewed to enrich the knowledge on the selected study and it facilitates in selection of appropriate conceptual frame work, developing a model and research plan.

Nursing Implications:
The findings of the study have depicted that mixture of honey and coffee application is effective in reducing the severity of oral mucositis in patients receiving radiotherapy. Honey is a simple, easily available, cost effective method for oral mucositis which in turn improves the dietary intake of the patient.

Nursing education:
Nursing students and beginners should develop knowledge and skill in the management of oral mucositis in cancer patients and should gain more knowledge about the benefits of honey application in oral mucositis.

Nursing practice:
This study has important implication in nursing care of cancer patients with oral mucositis. Honey application is a cost effective method to bring down the severity of oral mucositis. This helps to reduce the anxiety of the patients related to radiation induced oral mucositis.
1. This also helps to improve the dietary intake of the patients.
2. This also reduce the risk to discontinue the radiotherapy treatment.

Nursing administration:
1. Developing policies and protocols jointly fosters and stress collaboration and it discuss on the expectations of staff working in the radiotherapy unit.
2. Provision for the successive implementation of honey application.
3. Develop a separate written protocol on honey and coffee mixture application.
4. Conduct in service education to the staff nurses on these therapies.

Nursing research:
The main goal of nursing research is to provide better care to the patients. The present study implies base to conduct the qualitative and quantitative studies on the effectiveness of honey application in treatment of the radiation induced oral mucositis. Nurses should be provided opportunity to conduct small research projects on this topic. Emphasis should be given to the utilization of research findings. Utilization of the research findings helps in evidence based practice.

Limitations:
1. Interventions were administered only to selected patients.
2. Study is limited only to 60 patients.

Future Recommendations:-
1. Honey application can be compared with candid gel.
2. The study can be conducted in a larger population.
3. A new protocol can be prepared regarding the honey application.
4. In service education can be conducted regarding benefits of honey application for treatment related to oral mucositis to the health care professionals.

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