

A STUDY TO ASSESS THE EFFECTIVENESS OF ICE CUBE APPLICATION ON ORAL MUCOSITIS AMONG PATIENTS WITH HEAD AND NECK CANCER RECEIVING TREATMENT INJECTION 5-FLUOROURACIL IN DEEPAK HOSPITAL, JALNA, MAHARASHTRA.

Dr. VIDHYA LAKSHMI P. ASSOCIATE PROFESSOR, V.N.I.O.N, JALNA.

Ms. Priyanka Mukade, Basic B.Sc. Nursing, Ms. Sapna Gaikwad, Basic B.Sc. Nursing,

Ms. Prerna Salve, Basic B.Sc. Nursing, Ms. Rohinee Alhat, Basic B.Sc. Nursing,

Ms. Dipali Joshi, Basic B.Sc. Nursing, Ms. Aishwarya Kardile, Basic B.Sc. Nursing,

Ms. Pradnya Padhibhar, Basic B.Sc. Nursing.

ABSTRACT: A Quasi experimental study was conducted to assess the effectiveness of ice cube application on oral mucositis among patients with head and neck cancer receiving treatment injection 5- fluorouracil in Deepak Hospital Jalna, Maharashtra. Data was collected from the patients of head and neck cancer with oral mucositis in Deepak Hospital Jalna, Maharashtra. The research design used for the study was two group pre-test and post-test design. 40 patients selected by convenient sampling technique. The pre-test was done by using oral mucositis index score (OMI) developed by WHO. After the pre-test, intervention was given as ice cube application for 30 minute up to 7 days. Then finally the post-test assessment was done to assess the effectiveness of ice cube application on reduction of oral mucositis among patients with head and neck cancer by using the oral mucositis index score (OMI). Paired 't' test was used for data analysis. The study was concluded that the ice cube application is effective to prevent oral mucositis among patients with head and neck cancer.

INTRODUCTION:

Cancer is a potentially fatal disease caused by environmental factors that mutate genes encoding critical cell regulatory proteins. One defining feature of cancer is the rapid creation of abnormal cells that grow beyond the usual boundaries that destroy surrounding normal tissue and can spread to vital organs through the lymphatic system or blood stream. This process is referred to as metastasis. There are over 200 different known cancers that affect human being.

One of the common acute adverse effect of cancer treatment is mucositis, which is manifested in 80% of patients undergoing chemotherapy and radiotherapy. Oral complications that arise with chemotherapy include mucositis, xerostomia (drymouth), bacterial, fungal or viral infections, dental caries and loss of taste. Oral mucositis also represents a non haematologic complication of cytotoxic chemotherapy associated with 4 significant morbidity, pain, odynodysphagia (Painfull Swallowing), dysgeusia (Distortion of the sense of taste) and subsequent dehydration and malnutrition.

Oral mucositis can be severely painful. Cryotherapy, is a treatment modality based on the application of low temperatures on a body part. The purpose of this treatment is to reduce inflammation, cellular metabolism, pain and spasm and increase vasoconstriction and cellular survival.

NEED FOR STUDY:

Among the side effect of chemotherapy, oral mucositis is an important, very common and a big burden to the patient, who are receiving a high dose myeloablative chemotherapy used in hematopoietic stem cell, transplant complaints of mouth pain and difficulties in swallowing, eating, drinking and talking which are the most prevalent and debilitating symptoms which may affect many patient throughout the course of oral mucositis and might cause profound psychological distress and impairment of patient quality of life and functional status. In incidence of oral mucositis varies widely based on the specific type of cancer and the modalities used for the treatment but about 40,000 people develop oral complication from cancer each year. It will directly affect the oral intake and leads to the weight reduction in cancer patient and may ends in malnourishment in some cases. There are various treatment modalities are available to reduce oral mucositis such as honey application, calcium phosphate,

vitamin E application but among these oral cryotherapy is to be cheap, easily available and effectiveness in cases with oral mucositis, sucking ice cubes was often recommended as a way of providing relief from the symptoms of oral mucositis.

STATEMENT OF PROBLEM:

“A study to assess the effectiveness of ice cube application on oral mucositis among patients with head and neck cancer receiving treatment injection 5 –flurouracil in Deepak Hospital, Jalna, Maharashtra.”

OBJECTIVES:

- To assess the pre-test grading of oral mucositis among patients with head and neck cancer receiving treatment injection 5- flurouracil in experimental group and control group.
- To assess the post-test grading of oral mucositis among patients with head and neck cancer receiving treatment injection 5- flurouracil in experimental group and control group.
- To compare the pre-test and post-test grading of oral mucositis among patients with head and neck cancer receiving treatment injection 5- flurouracil in experimental group and control group.
- To associate the pre-test grading of oral mucositis among patients with head and neck cancer receiving treatment injection 5- flurouracil with their selected demographic variables and clinical variables in experimental group and control group.

HYPOTHESIS:

H1: There will be a significant difference between the pre- test and post-test grading of oral Mucositis in experimental group and control group.

H2: There will be a significant association between the pre-test on grading of oral mucositis among the patient with head and neck cancer in experimental group and control group with their selected demographic variables.

METHODOLOGY:

The methodology is the blueprint of the study. In other words, it outlines how the study will be conducted. (Polit 2011).

Research Approach: Quantitative approach was used for this study. Quantitative approach is the numeric information that is obtained from a formal measurement and is analysed statistically.

Research Design: Research design is the plan and strategy of investigation for answering the research questions. It is an overall blue print, with the researcher selected to carry out this study. Quasi Experimental design is used in this study.

GROUP	PRE-TEST	INTERVENTION	POST-TEST
E	O1	X (ICE WATER SOLUTION)	O2
C	O1		O2

Population:

The Target population of the study constitutes all the head and neck cancer patients receiving treatment injection 5 –flurouracil in Deepak Hospital Jalna, Maharashtra..

Description of the Study:

The study was conducted in all the head and neck cancer patients receiving treatment injection 5-flurouracil in Deepak Hospital , Jalna.

SAMPLING:

- **Sample:** Patients with cancer receiving treatment injection 5- fluorouracil and who fulfills the inclusion criteria were the samples.
- **Sampling technique and sample size:** Total sample size was 40, among whom, 20 in experimental group receive application of ice cubes, and 20 in control group receive no intervention.
- **Criteria for Sample Selection:** The sample selection was based on the following inclusion and exclusion criteria.

Inclusion Criteria:

- Cancer patients who are receiving treatment injection 5- fluorouracil.
- Who are having oral mucositis.
- Who are willing to participate in this study.

Exclusion Criteria:

- Who are having oral mucositis but not receiving injection 5-Fluorouracil.
- Those who are in critical condition.
- Those who are not admitted in Deepak Hospital, Jalna.

VARIABLES:

Independent variable: Rinsing the mouth with ice cube water solution on oral mucositis associated with injection 5-fluorouracil.

Dependent variables: Reducing severity at oral mucositis in head and neck cancer patients.

Description of the Tool: The tool consists of 2 sections.

Section- A: Demographic Variables

- It consists of demographic data with questions regarding age , sex , weight , education , any prior problems in oral cavity , occupation , habits like smoking , tobacco chewing , pan masala chewing and using dentures by the patients.

Section-B:

- It consists of two scales to assess the severity of oral mucositis . It includes oral mucositis index.

The World Health Organization (WHO) has developed a grading system for oral mucositis based on clinical appearances and functional status. The WHO scale is dependent on both objectives and subjective variables, and measures the anatomical, symptomatic as well as functional components of oral mucositis.

GRADING OF ORAL MUCOSITIS INDEX

Grade	Description
0 (None)	None
I (Mild)	Oral Soreness, Erythema
II (Moderate)	Oral Erythema, Ulcers, Solid Diet Tolerated
III (Severe)	Oral Ulcers, Liquid Diet Only
IV (Life- Threatening)	Oral Alimentation Impossible

TECHNIQUES OF DATA COLLECTION: Sampling technique are the strategies applied by the researcher during statistical sampling process in order to improve the accuracy and efficiency of estimation. Convenience sampling technique is used in this study.

INTERVENTION:

- Greeting the study subjects, “Good morning”.
- We are from IVth year Basic B Sc Nursing V.N.I.O.N Jalna
- Make the patient to sit comfortable
- Explain the steps of procedure to the patient
- Assessment of oral mucositis
- Rinsing the mouth with ice cube water solution for 30 minutes
- Providing the consent to participant in the study
- In a clean bowl add ice cube (3) and pour 50 ml of water to get ice water solution
- Ask the patient to rinse the mouth with ice water for 5 minutes before chemotherapy cycle, 5 minutes during the chemotherapy cycle and 20 minutes after chemotherapy infusion with total duration of 30 minute
- After pretest on the same day ice cube water provided and also post test conducted to the participants in the experimental group

- Post-test is conducted to assess the grading of oral mucositis after the intervention of rinsing the mouth with ice cube water solution by using the oral mucositis index
- The procedure will be continued for 7 days.

METHOD OF DATA ANALYSIS:

- **Paired 't' test :** Analysis of 'T' test is applied to test the effectiveness of rinsing the mouth with ice cube water solution on oral mucositis among the patient with head and neck cancer receiving treatment 5-fluorouracil in Deepak Hospital, Jalna.
- **Chi-Square test:** Chi-square test was used to measure and association between the pretest grading of oral mucositis index and selected clinical variable in experimental group where calculated.

RELIABILITY AND VALIDITY OF TOOL

It is the degree of consistency and accuracy with which an instrument measures the attribute for which it is designed to measure this study, the tool was validated by various guides and experts in Vasantrao Naik Institute of Nursing, Jalna.

- **Reliability:** Reliability is defined as the extent to which an instrument yields the same results on repeated measures. The test-retest reliability of this tool has been shown to be good. The researcher selected the tool based on the character of the study, variables of the study and based on the projected outcome.
- **Validity:** It refers to the adequacy of the sampling of the domain being studied. Content validity has been obtained from seven experts, two doctors and five nursing personnel in the department of medical and surgical nursing. The researcher made necessary changes in the study based on the expert opinion, in order to maintain the validity of the tool.

PILOT STUDY: The pilot study was conducted in Deepak Hospital, Jalna. Ethical clearance was obtained through the ethical committee. A written permission was obtained from the concerned authority prior to the study.

The convenience sampling technique was used to select 20 samples. The purpose of the study was explained to each subject and written consent was obtained from them. The collected data were analyzed using descriptive and inferential statistics. The study was found feasible, practicable and acceptable. No modification was made in the tool or in the study design.

METHOD OF DATA COLLECTION: Structured Interview Schedule was used to collect the data based on the study objectives.

DATA COLLECTION PROCEDURE: The data collection period was 7 days. After obtaining permission from the concerned authority, a survey is conducted by the researcher to find out the grading of oral mucositis in cancer patients receiving treatment with 5-fluorouracil. Informed consent is taken from the concerned authority.

The sample is obtained on the basis of inclusion criteria. Initially the researcher developed a rapport with the patients. Then the researcher conducted a pretest by assessing the grading of oral mucositis receiving treatment injection 5-fluorouracil among cancer patients along with the collection of basic demographic data. On the same day ice cubes (Rinse the mouth with ice water for 5 minutes before chemotherapy cycle 5 minutes during the chemotherapy cycle and 20 minutes after chemotherapy infusion) are given to the participants in the experimental group and the researcher instructed them to sip the ice cubes 5 minutes prior to and 5 minutes during and 20 minutes after chemotherapy. Post test is conducted by the researcher to assess the grading of oral mucositis after the ice cube application using the Oral Mucositis Assessment Scale (OMI) on 1st day and 7th day of chemotherapy. The data thus collected were compiled for data analysis.

PLAN FOR DATA ANALYSIS: Data were collected, arranged and tabulated. Descriptive statistics like frequency, percentage and mean were used for categorical data. Inferential statistics were used to find out the effectiveness of ice cube application on oral mucositis and Chi-Square test was used to associate the oral mucositis with the demographic variables.

RESULT:

- With regard to age, the majority of study subjects with head and neck cancer were belong to 41-60 years of age (65%).
- Regarding gender, 65% of study subjects were female.
- Based on educational status 70% of study subjects with head and neck cancer had primary education.
- With regard to religion, 55% of study subjects with head and neck cancer were Hindu.
- Majority of the study subjects with head and neck cancer 90% were Married.
- Majority of the study subjects 30% were Coolie
- Regarding personal habit, 35% of the study subjects were habituated to take Pan.
- Totally 70% of the study subjects were Non-Vegetarian.
- Majority of the study subjects totalling 55% were belong to Semi-Urban area.
- The calculated 't' value i.e. 8.90 are much higher than the tabulated value at 5% level of significance for overall OMI score of head and neck cancer patients which is statistically acceptable level of significance. Hence it is statistically interpreted that the Ice Cube Application on OMI score among head and neck cancer patient of experimental group was effective. Thus the stated **hypothesis H₁** was accepted.
- The calculated 't' i.e. 1.40 at 5% level of significance. Also the calculated 'p'=0.17 which was much higher than the acceptable level of significance i.e. 'p'=0.05. Hence it is interpreted that the ice cube application on OMI among head and neck cancer patients is statistically not associated with their pre test OMI score. Thus the stated **hypothesis H₂** was rejected.

- The paired 't' test was used to find out association between effectiveness of ice cube application on oral mucositis with selected demographic variables.
- The calculated 'p' value were greater than 0.05 which confirmed the fact that there is no significance association of pre-test grading of oral mucositis among the patients with head and neck cancer receiving treatment injection 5-flurouracil with their selected demographic variables and clinical variables in experimental group and control group. The variables such as age, gender, educational status, religion, marital status, occupation, habits, dietary pattern, geographical location, type of cancer, primary tumor site, voice, swallowing and chemotherapy cycle are not associated with pre-test grading of oral mucositis.

- **REFERENCE:**

1. <https://pubmed.ncbi.nlm.nih.gov/18383657/>
2. <https://pubmed.ncbi.nlm.nih.gov/14724910/>
3. <https://pubmed.ncbi.nlm.nih.gov/21133051/>
4. <https://pubmed.ncbi.nlm.nih.gov/18268357/>
5. <https://clinicaltrials.gov/ct2/show/NCT03605186>
6. <https://pubmed.ncbi.nlm.nih.gov/32402773/>
7. <https://pubmed.ncbi.nlm.nih.gov/15946283/>

TOOL

Section-A:

DEMOGRAPHIC VARIABLES

1 . Age of the patients (in years)

- a) 21-40 years
- b) 41-60 years
- c) >60 years

2 . Gender

- a) Male
- b) Female

3 . Educational Status

- a) Illiterate
- b) Primary Education
- c) Higher Secondary
- d) Graduation and above

4. Religion

- a) Hindu
- b) Christian
- c) Muslim
- d) Other

5. Marital status

- a) Unmarried
- b) Married
- c) Widower/widow

6.Occupation

- a) Coolie
- b) Employee
- c) Business
- d) Retired / Not Working

7. Habits

- a) Smoking
- b) Alcohol
- c) Pan
- d) Tobacco Chewing
- e) No ill Habits

8. Dietary Pattern

- a) Vegetarian
- b) Non- Vegetarian

9. Geographical Location

- a) Urban
- b) Semi- Urban
- c) Rural

CLINICAL VARIABLES**1. Type of Cancer**

- a) Oropharynx
- b) Nasopharynx
- c) Buccal Mucosa
- d) Palate

2. Primary Tumour Site

- a) Oral Cavity
- b) Pharynx
- c) Larynx
- d) Paranasal Sinuses
- e) Salivary Glands

3. Voice

- a) Clear
- b) Hoarseness of voice
- c) Difficult to talk

4. Swallowing

- a) Normal swallow
- b) Pain on swallow
- c) Unable to swallow

5. Chemotherapy Cycle

- a) 1st Cycle
- b) 2nd Cycle
- c) 3rd Cycle
- d) 4th Cycle

6. Treatment Protocol

- a) Injection 5- Flurouracil
- b) Injection Methotrexate
- c) Injection Cytarabin

SECTION B: Oral Mucositis Index (OMI)**GRADING OF ORAL MUCOSITIS INDEX (WHO)**

Grade	Description
0 (None)	None
I (Mild)	Oral Soreness, Erythema
II (Moderate)	Oral Erythema, Ulcers, Solid Diet Tolerated
III (Severe)	Oral Ulcers, Liquid Diet Only
IV (Life- Threatening)	Oral Alimentation Impossible