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Research article

True experimental study to assess the effectiveness of oral ice cubes for the prevention of oral mucositis among patients receiving chemotherapy in the selected hospital, Maldives

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Abstract:
The present study was undertaken to assess the effectiveness of oral ice cubes for the prevention of oral mucositis among patients receiving chemotherapy in selected hospital at the Maldives.
Aim: 1. To assess the presence of oral mucositis among patients receiving chemotherapy after treating with oral ice cubes. 2. Associate the presence of oral mucositis among patients, receiving chemotherapy after administration of ice cubes with their selected demographic variables.
Materials and methods: Quantitative research approach was used. Research design-The research design selected for the study is true experimental design (posttest only control group design). Research tool and research technique-The tool to collect data from the selected samples consists of two sections. Section-A: Demographic Variables. Section-B: WHO Mucositis Assessment Scale.
Result: The study reveals that the patients who received chemotherapy, 16.67 % had no oral mucositis, 23.33% had mild oral mucositis, 30 % had moderate oral mucositis, whereas 30% had severe oral mucositis, while no one developed severe oral mucositis after using the ice cube. However, in control group 0% had none mucositis, 3.3% had mild mucositis, 46.7% had moderate mucositis, and another 50% had severe mucositis, and none of them had very severe mucositis. From the percentage of frequency studied, findings are that the oral ice cubes control the level of oral mucositis in patients receiving chemotherapy.
Conclusion: The study concluded that oral ice cubes therapy helped to decrease the severity of mucositis. Further, there was no association found between the occurrence of oral mucositis, the post being treated with ice cube therapy & the demographic variables.

Key words: Ice Cubes, Chemotherapy, Mucositis

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1. Introduction

Cancer is a broad term used to encompass severe malignant diseases. There are more than 100 different kinds of cancer affecting various parts of the body. Each type of cancer is unique with its own causes, symptoms, and methods of treatment. The most common types of cancer-based on the frequency of diagnosis are bladder cancer, breast cancer, colon cancer, endometrial cancer, kidney cancer, leukemia, lung cancer, melanoma, lymphoma, pancreatic cancer, prostate cancer, and thyroid cancer [1]. Cancer is usually treated with chemotherapy, radiation therapy, and surgery. The suitable treatment required is the suggestion by the oncologist depending on the type of cancer. An oncologist is a medical doctor who has specialized in the diagnosis and treatment of cancer. There are three major categories of oncologists [2]. Medical oncologists specialize in the use of medications such as chemotherapy, hormones, and analgesics for the management of cancer. They monitor the patient through the course of treatment and help to improve the quality of life. This treatment procedure targets the entire body and not just a specific part. The drugs are given in the form of pills or intravenously which may be prescribed for a specific length of time. The drugs used targets the rapid multiplying cancerous cells [2]. A surgical oncologist is a physician who deals with the surgical

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treatment of malignant abnormalities. Radiation oncologists treat patients using high energy radiations to shrink and eradicate the tumors. Chemotherapy is one of the widely used treatments in cancer patients and is usually prescribed for patients with non-localized cancer cells also has increased possibility to be metastasized or spread, to various parts in the body.

Chemotherapy can be used to reduce the symptoms and pain associated with cancer as well as to slow the growth of cancerous tumors. Chemotherapy utilizes a powerful combination of drugs which is taken per oral or injected directly into the bloodstream. The doses are commonly administered over a course in a set duration. The treatment frequency generally depends on the type of cancer cells and the manner in which the patient may tolerate and respond[3].

Chemotherapy-induced oral mucositis is a therapeutic challenge frequently encountered in cancer patients. This side effect causes significant morbidity and may delay the treatment regimen as well as increase the therapeutic expenses.

Oral mucositis represents a major non-hematologic complication of cytotoxic chemotherapy causing significant morbidity, pain, dysphagia, dyspepsia, and subsequent dehydration and malnutrition reducing the quality of life of affected patients. In addition, oral mucositis is a significant risk factor for systemic infections, particularly in neutropenic patients. [4]

Various chemotherapy agents increase the risk of oral mucositis. Chemotherapy is used for the treatment of solid tumors such as breast and colorectal leads to the development of mucositis in about 5%-40% of patients. Of these 5% to 15% have grades 3-4 as per WHO oral mucositis assessment scale. Some chemotherapy drug regimens such as 5-fluorouracil (5-FU) tend to have a higher rate of mucositis about 20%-50% whereas drugs such as domethotrexate (MTX) and other antimetabolites have 20%-60% of alimentary tract mucositis.[5]

Mucositis is caused by acute changes in the epithelium of the oral cavity resulting in the death of rapidly dividing epithelial cells. Chemotherapeutic agents inhibit the growth and malnutrition of oral mucosal cells disrupting the primary mucosal barrier in the mouth and throat. The direct effects on the oral mucosa from chemotherapy can begin as early as 2 to3 days after the administration of chemotherapy and generally peak in severity 7 to 10 days later with resolution occurring within 2 weeks. [6]

Virus, bacteria or fungus can infect the sores or ulcerations in the mouth caused by mucositis. The resulting pain can make it difficult for a patient to eat, which can lead to weight loss and an overall disparagement of health. The pain is often described as a burning sensation, much like the sunburn on the inside of the mouth. The symptoms are characterized by redness, swelling, dry mouth, and open sores or ulcerations. Such manifestations on the mucosa can cause patients to experience great difficulty when eating, drinking, swallowing, speaking and even sleeping [6].

Need for the study

In the light of above fact and personal experience of the investigator, as a staff in the clinical area, while caring for cancer patients receiving chemotherapy, it was observed that most of the patients have mucositis related to side effects of chemotherapy. Hence the Researcher, interested in the above area who wanted to prevent side effects of chemotherapy, felt to conduct this research study for the benefit of patients to improve their quality of life.

Statement of the problem

A study to assess the effectiveness of oral ice cubes on the prevention of oral mucositis among patients receiving chemotherapy in a selected hospital, Maldives.

Objectives

1. To assess the presence of oral mucositis among patients receiving chemotherapy after treating with oral ice cubes.
2. Associate the presence of oral mucositis among patients, receiving chemotherapy after administration of ice cubes with their selected demographic variables

Hypothesis

The following hypothesis is formulated for the study and will be tested at 0.05 level of significance.

H_1-There will be a significant reduction in the occurrence of mucositis in patients receiving chemotherapy after administration of ice cubes.

H_2- There will be a significant difference in the occurrence of oral mucositis between the patients receiving chemotherapy who were treated with ice cubes.

H_3– There will be a significant association between the occurrence of oral mucositis among patients receiving chemotherapy before administration of ice cubes & their selected personal variables viz age, gender, education, occupation, income, religion, diet, and family history of illness.

2. Materials and methods:

Research approach

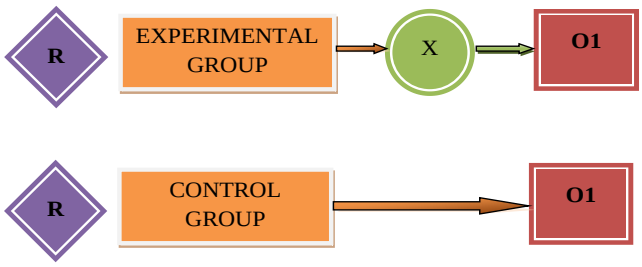
Experimental approach

The quantitative research approach was used. In which post test only control design was adopted for this study to determine the effectiveness of ice cubes in preventing oral mucositis.

The investigator assigned the participants to two group's namely experimental group and control group and the effectiveness was measured through WHO mucositis assessment scale in each group.

Research design

The research design selected for the study was true experimental design (posttest only control group design).The true experimental design is in which test units are randomly allocated to an experimental group and a control group. The experimental group is exposed to a treatment and both groups are measured afterward.



Key: R= Randomization, X= oral ice cubes, O1 = Posttest

Figure 1: Schematic representation of research design

The setting of the study

The study was conducted in Indira Gandhi Memorial Hospital, Maldives.

Study population

The total population of the present study is 60 patients who received chemotherapy in Indira Gandhi Memorial Hospital, Maldives.

Sample size

60 samples received chemotherapy, 30 samples in the experimental group who received oral ice cubes post chemotherapy and 30 samples in the control group.

Sampling technique

Non-probability convenience sampling is used in which a convenient sampling technique was adopted for this study. The researcher selected the most readily available persons meeting the inclusion criteria as participants in the study.

Research tool and research technique

The tool to collect data from the selected samples consists of two sections.

Section-A: Demographic Variables

1**.** It consists of age, gender, education, occupation, income, religion, dietary pattern, family history of illness.

Section-B: WHO mucositis assessment scales

WHO mucositis assessment scales is to assess the severity of oral mucositis in patients receiving chemotherapy. Each item is rated on 5 point scale, scoring from 0 to 4.

The scoring system is divided into the following categories **0**=none, **1**= mild, **2**= moderate, **3**= severe, **4**= very severe

Plan for data analysis

Data were analyzed on the basis of objectives and hypothesis.

Descriptive statistics.

- Frequency distribution and the percentage will be used to assess the demographic variables.

Inferential statistics

Inferential statistics are used to determine the comparison and association

Analyzed data will be presented in the form of tables, diagrams, graphs based on the findings.

- Chi-square test is used to find out variations between post-test in the experimental group
- Chi-square test will be used to determine the association between the severity of oral mucositis among experimental and control group after the intervention and their selected demographic variables.

Section-I

Table 1: This provides frequency and percentage distribution of sample according to demographic variables

Distribution of samples according to selected demographic data. (N-30)

Demographic Characteristics	Experimental group (n= 30)		Control group (n= 30)	
	F	%	F	%
Age in years				
a.30-39 years	3	10	8	26.67
b.40-49 years	7	23.33	9	30
c.50-59 years	11	36.67	7	23.33
d.60-69 years	9	30	6	20
Gender				
a.Male	11	36.67	9	30
b.Female	19	63.33	21	70
Education status				
a. Literate	25	83.33	28	93.33
b. Illiterate	5	16.67	2	6.67
If literate……				
a. Primary	3	10	6	20
b. High school	6	20	9	30
c. Higher secondary	9	30	6	20
d. Graduate	7	23.33		
Monthly income				
a. Upto Rs5000	10	33.33	7	23.33
b. Rs5001-10000	10	33.33	10	33.33
c.Rs10001-15000	6	20	11	36.37
d.>15001	4	13.33	2	6.67
Religion				
a. Christian	17	56.66	14	46.67
b. Hindu	10	33.33	13	43.33
c. Muslim	3	10	3	10
Occupation				
a. Sedentary work	7	23.33	10	33.33
b. Moderate work	14	46.67	11	36.67
c. Heavy work	9	30	9	30
Dietary pattern				
a. Vegetarian	3	13	3	10
b. Non-vegetarian	27	90	27	90
Family History of Cancer				
a. Father	0	0	0	0
b. Mother	0	0	0	0
c. Both parents	0	0	0	0

Table 1 portrays the demographic variables like age, gender, education, income, religion, occupation, dietary pattern, and family history that were used in both the experimental and control group in order to determine their relationship in affecting the severity of oral mucositis.

Table 2

Assess the level of oral mucositis after administration of oral ice cubes by W H O oral mucositis Assessment Scale

Level	Frequency	Percentage
None (0)	5	16.67
Mild (1)	7	23.33
Moderate (2)	9	30
Severe (3)	9	30
Very severe (4)	0	0
Total	30	100

Table no 2 shows that 16.67 % developed no oral mucositis, 23.33% had mild oral mucositis, 30% had moderate oral mucositis, 30% suffered severe oral mucositis, no one developed very severe oral mucositis after using oral ice cubes post-chemotherapy

Table 3

Effect of oral ice cubes

Level	Experimental group		Control group	
	F	%	F	%
None (0)	5	16.67	0	0
Mild (1)	7	23.33	1	3.3
Moderate (2)	9	30	14	46.7
Severe (3)	9	30	15	50
Very severe (4)	0	0	0	0

Table no 3 illustrates from the percentage of frequency studied that findings were suggestive of oral ice cubes helped to control the level of oral mucositis in cancer patients who received chemotherapy by reducing the severity.

4. Discussion

A study to assess the effectiveness of oral ice cubes on the prevention of oral mucositis among patients receiving chemotherapy in a selected hospital, Maldives. The study findings are discussed in this chapter with reference to the objectives.

Demographic variables:

Majority of the sample, 11 out of 30 (36.67%) in the experimental group were between the age group of 50-59 years and 9 out of 30 (30%) in the control group were between the age group of 40-49 years. In context with gender, the experimental group was 19 out of 30(63.33), were females 21 samples out of 30 (70) were in the control group. Referring the educational status, the majority of samples 25 out of 30 (83.33%) were literate in the experimental group while 28 out of 30 (93.33%) were literates in the control group. In terms of monthly income, 10 out of 30 (33.33 %) in the experimental group were earning between Rs5001- 10000 whereas 11 out of 30 (36.67%) in the control group earned income between Rs10001-15000. Regarding religion, the majority of samples 17 out of 30 (56.66%) were Christian in the experimental group, and 14 out of 30 (46.67%) were Christian in the control group. With the occupation, the majority of samples 14 out of 30 (46.67%) were moderately active workers in the experimental group also 11 out of 30 (36.67%) were moderately active workers in control group. Regarding diet, the majority of samples, 27 out of 30 (90%) in the experimental group and 27 out of 30 (90%) in the control group were nonvegetarian.

Assess the level of oral mucositis after administration of oral ice cubes by W H O oral mucositis Assessment scale

The study reveals that 16.67 % developed no oral mucositis, 23.33% had mild oral mucositis, 30% had moderate oral mucositis, 30% suffered severe oral mucositis, and however, no one developed very severe oral mucositis after using oral ice cubes post-chemotherapy.

Comparison of the effect of oral ice cubes

The present study reveals that experimental group 16.7% of sample developed no mucositis, 23.33% had mild mucositis, 30% had normal mucositis,30% suffered severe mucositis, however, no one developed very severe mucositis post administration of oral ice cubes. Whereas in control group, 0% had no mucositis, 3.3% had mild mucositis, 46.7% developed moderate mucositis, and another 50% had severe mucositis, but none of them suffered very severe mucositis.

From the percentage of frequency studied, findings were suggestive of oral ice cubes helped to control the level of oral mucositis in cancer patients who received chemotherapy.

Association between the level of oral mucositis and demographic variables of chemotherapy patients after administration of oral ice cubes

There is no association found between the onsets of oral mucositis among patients receiving chemotherapy after administration of oral ice cubes with their selected demographic variables.

In order to find out the association between the presence of oral mucositis and age, the chi-square test was computed and the obtained χ^2 value of 3.148 at df (3) was not significant at 0.05 level.

The onset of oral mucositis and gender, calculated χ^2 value 2.766 at df(3) was not significant at 0.05 level.

Also, the onset of oral mucositis and education, calculated χ^2 value 4.423 at df(3) were not significant at 0.05 level.

Further, the occurrence of oral mucositis with literate, calculated χ^2 value 4.53 at df(3) at 0.05 level found not significant.

It was also found that there was no association between the presence of oral mucositis and monthly income. The obtained χ^2 value is 2.93 at df(3) which was not significant at 0.05 level.

Comparing the occurrence of oral mucositis with religion, the calculated χ^2 value 6.53 at df(3) was not significant at 0.05 level.

Moreover relating oral mucositis and occupation, the calculated χ^2 value of 2.31 at df(3) was not significant at 0.05 level.

Table 4: Association between the level of oral mucositis and demographic variables of chemotherapy patients after administration of oral ice cubes (N=30)

Demographic Characteristics	Level of oral mucositis				Total	$\chi^2$5%level of Significance
	None	Mild	Moderate	Severe		
Age in Years						
a.30-39 years	1	1	0	1	3	
b.40-49 years	1	2	2	3	7	3.148 3d.f 16.92 Not significant
c.50-59 years	2	2	4	3	11	
d.60-69 years	1	2	3	3	9	
Total	5	7	9	9	30	
Gender						2.766 3d.f 7.82 Not significant
a.Male	2	4	3	2	11	
b.Female	3	3	6	7	19	
Total	5	7	9	9	30	
Education status						4.423 3d.f 7.82 Not significant
a. Literate	4	6	8	7	25	
b. Illiterate	1	1	1	2	5	
Total	5	7	9	9	30	
If literate……						4.53 3d.f 16.92 Not significant
a.Primary	0	1	1	1	3	
b.High school	1	1	2	2	6	
c.Higher secondary	2	2	3	2	9	
d.Graduate	1	2	2	2	7	
Total	4	6	8	7	25	
Monthly income						2.93 3d.f 12.59 Not significant
a. Upto Rs5000	1	2	3	3	10	
b. Rs5001-10000	2	2	3	3	10	
c.Rs10001-15000	1	1	2	2	6	
d.>15001	1	1	1	1	4	
Total	5	7	9	9	30	
Religion						6.53 3d.f 12.59 Not significant
a. Christian	3	3	5	6	17	
b. Hindu	2	3	3	2	10	
c. Muslim	0	1	1	1	3	
Total	5	7	9	9	30	
Occupation						2.31 3d.f 12.59 Not significant
a. Sedentary work	1	2	2	2	7	
b. Moderate work	2	3	5	4	14	
c. Heavy work	2	2	2	3	9	
Total	5	7	9	9	30	
Dietary pattern						3.62 3d.f 7.82 Not significant
a. Vegetarian	1	1	1	0	3	
b. Non vegetarian	4	6	8	9	27	
Total	5	7	9	9	30	

Chi score test was used to find out the relation between the presence of oral mucositis among patients receiving oral ice cubes post-chemotherapy with their demographic variables and was found to have no association with any of the variables.

Nevertheless, oral mucositis with the dietary pattern, the calculated χ^2 value 3.62 at df(3) was not significant at 0.05 level.

It is found that there is no association with the onset of oral mucositis among patients receiving chemotherapy after administration of oral ice cubes with their demographic variables such as age, gender, education, occupation, income, religion, dietary pattern, family history of illness. So, the researcher accepts the null hypothesis and rejects the research hypothesis. [7]

Conclusion

The following conclusions were drawn from the study. The study proved that oral ice cubes control for level of oral mucositis for a cancer patient receiving chemotherapy. There was no association between the occurrence of oral mucositis among patients receiving chemotherapy after administration of oral ice cubes & their selected demographic variables

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