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An Experimental Study to Evaluate the Effectiveness of Cryotherapy on Occurrence of Oral Mucositis among Patients Receiving Cancer Chemotherapy in Selected Hospitals of New Delhi

Abstract

An experimental study was conducted to evaluate the effectiveness of cryotherapy on occurrence of oral mucositis among patients receiving cancer chemotherapy in selected hospitals of New Delhi. The objectives of the study were to assess and compare the effectiveness of cryotherapy on occurrence of oral mucositis among patients receiving cancer chemotherapy in experimental and control groups to establish relationship between occurrence of oral mucositis among patients receiving cancer chemotherapy in experimental group and control group with selected variables. The conceptual framework adopted for the study was based on system model. Quantitative research approach was used in the study to accomplish the objectives of the study. The research design for the study was pre-test and post-test control group design. The sample comprised 60 patients in oncology units of Safdarjung Hospital, selected by random sampling by lottery method. The collected data was analyzed by using both descriptive and inferential statistics. The results showed that there was significant difference between occurrence of oral mucositis among patients receiving cancer chemotherapy in experimental and control groups. In experimental group, there was no significant association between occurrence of oral mucositis among patients receiving cancer chemotherapy with selected variables, viz., gender, nutritional status, duration of illness, concurrent illness, and time period of chemotherapy treatment started, course/cycle, frequency, and other treatment modalities at 0.05 level of significance. In the control group, there was no significant relationship between occurrences of oral mucositis among patients receiving cancer chemotherapy with selected variables, viz., nutritional status, duration of illness, time period of chemotherapy treatment started, course/cycle, frequency, and other treatment modalities at 0.05 level of significance. In the control group, there was significant relationship between occurrence of oral mucositis among patients receiving cancer chemotherapy with selected variables, viz., gender and concurrent illness at 0.05 level of significance. The finding of the present study showed that the majority of the patients with chemotherapy treatment, who were exposed to cryotherapy, experienced reduced occurrence of oral mucositis as compared to patients who were not exposed to cryotherapy.

Keywords: Cancer chemotherapy, Cryotherapy, Oral mucositis.

Introduction

The global cancer burden is growing at an alarming pace. It is estimated that one million people will die every year from cancer. The estimated number of new cancer patients in India per year is about 7 lac and over 3.5 lac people die of cancer each year.¹ Kotnis et al.² stated that cancer is an enormous global health burden, touching every region and socio-economic level.

Today, cancer accounts for one in every eight deaths worldwide, more than HIV/ AIDS, tuberculosis, and malaria combined. In spite of good advancements for diagnosis and treatment, cancer is still a big threat to our society. Soon after diagnosis, patients face various interventions, including 4 to 6 months of chemotherapy, and may experience many physiological and psychological discomforts that interfere with living and can result in depression and a poor quality of life as stated by Prue et al.³ An increased rate of oral mucositis is seen in patients with hematologic malignancies, those receiving stomatotoxic agents which include the antimetabolites 5-Fluorouracil, methotrexate and cytarabine; concomitant radiation therapy increases the risk of oral mucositis because of synergistic effects with the chemotherapeutic agents.⁴ Symptoms of mucositis vary from pain and discomfort to an inability to tolerate food and fluids. Mucositis may also limit the patient's ability to tolerate either chemotherapy or radiation. Moreover, speech and self-esteem are reduced. It is, therefore, extremely important that mucositis be prevented whenever possible or at least treated to reduce its severity and possible complications.

Many agents of differing mechanisms of action have been used in the prevention and treatment of oral mucositis induced by anticancer therapies. Currently, no intervention is completely successful at preventing or treating oral mucositis. In 2012, the mucositis study groups of Multinational Association of Supportive Care in Cancer (MASCC) and the International Society for Oncology (ISOO) guidelines recommended the use of cryotherapy to reduce oral mucositis in patients receiving chemotherapy. Therefore, it was essential to comprehend the efficacy of cryotherapy-induced oral mucositis and adopt its uses accordingly in consultation with medical oncologists to decrease oral complications due to chemotherapy and enhance the patient's comfort, early recovery, and quality of life. Hence, an experimental study was conducted to evaluate the effectiveness of cryotherapy on occurrence of oral mucositis among patients receiving cancer chemotherapy in selected hospitals of New Delhi. The objectives were to assess and compare the effectiveness of cryotherapy on occurrence of oral

mucositis among patients receiving cancer chemotherapy and to establish relationship between occurrence of oral mucositis among patients receiving cancer chemotherapy in experimental and control groups with selected variables.

Materials and Methods

The conceptual framework for the present study was based on the open-system model, which consisted of three phases: input, process, and output in a specific content, including evaluation of all phases. A quantitative research approach with pre-test post-test control group design was used in the study. Formal administrative approval was taken from competent authority and the final study was conducted in the oncology unit of Safdarjung Hospital, New Delhi. Samples comprising 60 patients receiving chemotherapy treatment and meeting the sampling criteria were selected by random sampling. Two blocks from oncology ward were randomly selected by lottery method and assigned as control and experimental group. Informed consent was obtained from each participant in the experimental and control groups. A formal ethical approval was sought from the Institutional Review Board of Jamia Hamdard and written informed consent was taken from each study subject. For collection of relevant data, a structured record analysis from patient records and a standardized observational tool (WHO oral toxicity scale) were used. The tool was validated and used for data collection. The reliability of assessment was established by inter-observer reliability, which was 0.99. Data related to the demographic information, disease profile and information regarding chemotherapy administration was collected through record analysis. Pre-test data on oral mucositis was collected through observation using standardized tool and recorded in the data collection sheet.

Oral ice cubes were applied to experimental group for 5 days, 5 minutes prior, 2 times during and 5 minutes after chemotherapy administration. Post-test observation was done using WHO oral toxicity scale.

The data thus obtained was analyzed using descriptive and inferential statistics.

Results

Table 1. Frequency and Percentage Distribution of Demographic Variables of Subjects in Both the Groups

S. No.	Demographic Variables	Experimental Group (n ₁ =30)		Control Group (n ₂ =30)		Chi Square Test (Degree of Freedom)	p-Value
		F	%	F	%		
1	Gender						
	Male	14	46.7	16	53.3	0.267 (1)	0.606
	Female	16	53.3	14	46.7		
2	Age						
	14–34 years	11	36.6	8	26.6	1.07 (2)	0.585
	35–54 years	13	43.4	13	43.4		
55–74 years	6	20.0	9	30.0			
3	Nutritional status (BMI)						
	Under-weight	27	90.0	28	93.4	0.3 (Fisher's exact test)	1.000
	Normal	3	10.0	2	6.6		

*p<0.05 level of significance

Table 2. Frequency and percentage distribution of disease profile of the subjects in both the groups

S. No.	Disease Profile	Experimental Group (n ₁ =30)		Control Group (n ₂ =30)		Chi Square Test (Degree of Freedom)	p-Value
		F	%	F	%		
1.	Duration of illness						
	≤ 6 months	13	43.4	10	33.4	0.0005 (Fisher's Exact test)	0.446
	7 months–1 year	7	23.3	13	43.4		
	1–2 years	6	20.0	5	16.6		
	2–4 years	4	13.3	2	6.6		
2.	Concurrent illness						
	Yes	7	23.3	10	33.3	0.739 (1)	0.390
	No	23	76.6	20	66.6		

*p<0.05 level of significance

Table 3. Frequency and Percentage Distribution of Chemotherapy Administration of the Subjects in Both the Groups

S. No.	Chemotherapy Administration	Experimental Group (n ₁ =30)		Control Group (n ₂ =30)		Fischer's Exact Test	p-Value
		F	%	F	%		
1	Duration of chemotherapy treatment						
	≤6 month	16	53.3	17	56.7	0.06 (Chi Square) 1(df)	0.795
	≥7 month	14	46.7	13	44.3		
2	No. of cycles of chemotherapy						
	≤2	14	46.6	12	40.0	0.0002	0.033*
	3-4	9	30.0	17	56.6		
≥5	7	23.4	1	3.4			
3	Frequency of chemotherapy						
	Every week	12	40	4	13.3	0.00022	0.043*
	Every 2 weeks	14	46.7	16	53.3		
Every 3 weeks	4	13.3	10	33.4			
4	Other treatment modalities						
	Radiotherapy	3	10.0	4	13.4	0.007	0.853
	Surgery	5	16.6	6	20.0		
None	22	73.4	20	66.6			

*p<0.05 level of significance

The data presented in Tables 1, 2 and 3 shows that both the groups were homogenous with respect to the demographic variables, disease profile, and

chemotherapy administration except in the variables in terms of number of cycles and frequency of chemotherapy

Table 4. Frequency and Percentage Distribution of Subjects according to the Occurrence of Oral Mucositis in Experimental and Control Groups

Variables	Experimental Group (n ₁ =30)		Control Group (n ₂ =30)		Chi Square Test (Degree of Freedom)	p-Value
	F	%	F	%		
1 st day No mucositis a. Grade 0	30	100.0	30	100.0	-	-
5 th day a. Grade 0 b. Grade 1/Grade 2	25 5	83.3 16.7	14 16	46.6 53.4	8.86 1	0.003*

n=n₁+n₂=60

*P<0.05 level of significance

The data in Table 4 shows that there was a significant difference in occurrence of oral mucositis among patients receiving cancer chemotherapy in experimental and control groups. However, in the experimental group, there was no significant association between occurrence of oral mucositis among patients receiving cancer chemotherapy with selected variables, viz., gender (p=0.642), nutritional status (p=0.433), duration of illness (p=0.308), concurrent illness (p=1.000), time period of chemotherapy started (p=1.000), course/cycle (p=0.396), frequency (p=1.000) and other treatment modalities (p=0.396) at 0.05 level of significance. Similarly, in the control group, there was no significant relationship between occurrence of oral mucositis among patients receiving cancer chemotherapy with selected variables, viz., nutritional status (p=1.000), duration of illness (p=0.487), time period of chemotherapy treatment started (p=0.491), course/cycle (p=0.567), frequency (p=0.413) and other treatment modalities (p=0.567) at 0.05 level of significance.

Conclusion

The findings of the present study showed that the majority of the patients with chemotherapy treatment, who were exposed to cryotherapy, experienced reduced occurrence of oral mucositis as compared to patients who were not exposed to cryotherapy. A similar study conducted by Cascinu⁵ to evaluate the effectiveness of cryotherapy in prevention of oral mucositis found that in experimental group receiving ice cubes, oral mucositis was not observed. They recommended that if cryotherapy were used during the time of chemotherapy, then oral mucous membranes would

have less severe exposure to 5-fluorouracil and thus develop less mucositis. These findings are in line with the findings of the current study. In consideration of the valid body of knowledge about oral cryotherapy, it is time for applying them to the practice and nurses are crucial to application of the evidence in those areas.

Nurse administrators can formulate the protocol for the administration of cryotherapy and make the proper provision of logistics (refrigerator, ice cubes, ice trays, and recording sheet) supplied at least to oncology department. The results of the present study show that oral cryotherapy has significant contribution in the protection of oral health by reducing mucositis score according to the WHO oral toxicity scale.

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Conflict of Interest: None

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