Research Article

A Quasi-Experimental Study to Assess the Effectiveness of Sodium Bicarbonate Oral Irrigation on Oral Mucositis among the Cancer Patients who Admitted at Cancer Hospital and Research Institute, Gwalior City (Madhya Pradesh)

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Abstract

Background: According to epidemiological data, head-and-neck cancers constitute for 12% of all malignancies in the world. It is estimated that a total of 4,00,000 cases of the mouth and throat, 1,60,000 cases of laryngeal cancer, and 3,00,000 people die each year.

Aim: The aim of the study is to assess the effect of sodium bicarbonate (SB) oral irrigation on oral mucositis.

Methods: The evaluative research approach is applied; the research design is quasi-experimental with experimental group pre-test, treatment and post-test and control group pre-test and post-test design. The study was conducted in the cancer hospital research institute in Gwalior, Madhya Pradesh. The target population was cancer patients, receiving five-point rating scale related to oral mucositis during the period of study. The sample of study comprises 60 (30 control and 30 experimental groups) cancer patients, fulfilling the sample criteria. Non-probability convenient sampling technique was adopted.

Results: The pre- and post-test mean oral mucositis score of control group was 72 and standard deviation was 25.69. In experimental group, pre-test mean oral mucositis score was 78.69 and standard deviation score was 18.64 and post-test mean score was 53.43 and standard deviation was 16.63. The "*t*" test score of the control group was 0 and the probability was 2.05 according to the degree of freedom was 29, which indicates that it is no significant score. In the experimental group, the "*t*" test score was 30.07 and the probability was 2.05, according to the degree of freedom was 29, which indicates that it is a significant score.

Conclusion: The results showed that there is an effect of SB oral irrigation on oral mucositis in oral cancer patients.

Keywords: Mucositis, sodium bicarbonate, Chemotherapy, radiotherapy

Date of Submission: 18-01-2025
Date of Revision: 08-02-2025
Date of Acceptance: 28-02-2025

Access this article online
Website: https://innovationaljournals.com/index.php/ijns
ISSN No: 2581-463X
DOI: 10.31690/ijns.2025.v010i01.001

Introduction

"The most important thing in illness is never to lose heart hope"

~Nikolai Lenin.

Mucositis is the painful inflammation and ulceration of the mucous membranes lining the digestive tract, usually as an adverse effect of chemotherapy and radiotherapy treatment for cancer. Mucositis can occur anywhere along the gastrointestinal (GI) tract, but oral mucositis refers to

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the particular inflammation and ulceration that occurs in the mouth.[1] Oral mucositis is a common and often debilitating complication of cancer treatment. Oral and GI mucositis affects almost all patients undergoing high-dose chemotherapy and hematopoietic stem cell transplantation (HSCT), 80% of patients with malignancies of the head and neck receiving radiotherapy, and a wide range of patients receiving chemotherapy.

For most cancer treatments, about 5–15% of patients get mucositis. However, with 5-fluorouracil, up to 40% get mucositis, and 10–15% get Grade 3–4 oral mucositis. Inflammation is associated with severe GI mucositis in over 20% of patients.[2] Seventy-five to eighty percent of bone marrow transplantation recipients experience mucositis, of which oral mucositis is the most common and most debilitating, especially when melphalan is used. In Grade 3 oral mucositis, the patient is unable to eat solid food, and in Grade 4, the patient is unable to consume liquids as well. Radiotherapy to the head and neck or the pelvis or abdomen is associated with Grade 3 and Grade 4 oral or GI mucositis, respectively, often exceeding 50% of patients. Among patients undergoing head-and-neck radiotherapy, pain and decreased oral function may persist long after the conclusion of therapy. Fractionated radiation dosage increases the risk of mucositis to >70% of patients in most trials. Oral mucositis is particularly profound and prolonged among HSCT recipients who receive total-body irradiation.[3]

Chemotherapy is the specific treatment of cancer, where specific anti-neoplastic agents are used. These agents interfere with cellular function, including replication. It is used primarily to treat the systemic disease. It may be combined with surgery, radiation therapy, or both. Repeated doses of chemotherapy are necessary over a prolonged period. Cancer chemotherapy is used to destroy rapidly proliferating cells.[4] However, normal cells with high mitotic indexes are also affected by chemotherapy, particularly those in the oral and GI mucosa and the hemopoietic system. Ultimately, this may lead to certain oral complications of cancer chemotherapy such as mucositis, infection, hemorrhage, xerostomia, and neurologic and nutritional disorders. When using cytotoxic chemotherapeutic drugs, it is extremely important to keep patients free from the oral foci of infection and pain to minimize local infection and bacteremia and to enable them to maintain a nutritious diet.[5] The chemotherapeutic agents utilized to eradicate tumor production also adversely affect normal cells, particularly those that have relatively high turnover rates, such as oral epithelial tissues. The depressant effect of therapy on oral epithelial mitoses can result in thinning and ulceration of the tissues as well as salivary glands and taste dysfunctions.[6] The oral ulcerations may be due to direct cellular cytotoxicity from the chemotherapeutic agents, increased susceptibility to microorganisms due to neutropenia (bone marrow suppression), trauma, or a combination of these factors.[7] Oral mucositis is a frequent adverse effect of cancer chemotherapy and radiotherapy. Fluorouracil, radiotherapy, and conditioning regimens for hematopoietic stem cell grafting often cause severe oral mucositis, preventing patients from drinking and eating normally.[8] Complications can be attenuated by timely oriental care, such as extraction of damaged teeth, treatment of tooth decay, and care of trauma due to dentures. Effective approaches for the prevention or treatment of oral mucositis have not been standardized and vary considerably among institutions.[9] Prophylactic measures begin with an increased emphasis on improved oral status. Oral cryotherapy, the therapeutic administration of cold, is a prophylactic measure for oral inflammation.[10]

Objectives

- To assess the pre-intervention score of oral mucositis patients
- To assess the effectiveness of sodium bicarbonate (SB) oral irrigation to prevent oral infection among patients with post-intervention scores on oral mucositis patients
- To compare the reduction of oral mucositis between the experimental group and the control group
- To assess the association between the post-therapy score and selected demographic variables, such as age, gender, educational status, another disease besides cancer, and duration of chemotherapy.

Hypothesis

- H_1 – There will be a significant difference between pre- and post-therapy scores of oral mucositis patients
  - H_{01} – There will be no significant between pre- and post-therapy scores on oral mucositis patient
- H_2 – There will be a significant association between the post-therapy score and the selected demographic variable
  - H_{02} – There will be no significant association between the post-therapy score and the selected demographic variables.

Methods

This study has an evaluative research approach applied and the research design is quasi-experimental with experimental group pre-test, treatment and post-test and control group pre-test and post-test design. To assess the effectiveness of Sodium bicarbonate in cancer patients with a five-point rating scale. Only the experimental group took treatment.

The target population for the study was cancer patients who admitted in a cancer hospital and research institute, Gwalior, receiving a five-point rating scale related to oral mucositis during the period of study. The sample of the study comprises 60 (30 control group and 30 experimental group) cancer patients who underwent five-point rating scale, fulfilling the sample criteria. Non-probability convenient sampling technique was adopted to select the sample of this study.

Tools

A five-point rating scale was prepared to assess the effectiveness of SB oral irrigation on oral mucositis among cancer patients who were admitted at cancer hospital research institute, Gwalior (M.P.). The following steps were carried

out in preparing the tool: review of literature, such as books, journals, newspapers, articles, published and unpublished research studies, and internet search were used to develop the tool. The tool was prepared to have the following section:

- Section A: This section consists of demographic data, such as age, sex, educational status, general health status, and other diseases besides cancer; no score is allotted, but the data of the section were used for descriptive analysis
- Section B: This section deals with sign and symptoms of oral mucositis and complications with oral mucositis with the five-point rating scale for the assessment of effectiveness regarding SB oral irrigation on oral mucositis cancer patients.

Criterion measure

According to assessment, a five-point rating scale was used to assess the effectiveness of SB oral irrigation on oral mucositis among cancer patients.

Maximum score = 128.

Minimum score = 0.

Criterion measures to assess the effectiveness of SB oral irrigation on oral mucositis among cancer patients according to five-point rating scale assessment are as in Table 1.

Validity of tool

Content validity was obtained by the expert's opinion on the relevance of item. The content validity of the tool was established by submitting it to five experts from the field of nursing and medical. It includes medical-surgical nursing. Experts were requested to judge the items for their clarity, relatedness, meaningfulness, and content. Minor suggestions regarding rearranging of questions and difficult words were converted into simple words. As per their guidance and suggestions, amendments were made to tool. At last, final draft for the tool was prepared. The tool was translated into the English language.

Pilot study

A pilot study is the small-scale version, or trial run, done in preparation for a major study. The purpose of the pilot study is two-fold to make improvements in the research project and to detect a problem that must be eradicated before the major study is attempted.

A pilot study was conducted to ensure the reliability of the tool and feasibility of the study by taking 10th percentile of the total sample that is 6 subjects, 3 for the control group and 3 for the experimental group; to ensure the appropriateness of methods and procedure of data collection and to estimate the actual time and potential problems, researcher may encounter during the actual large study. The investigator took written permission from the concerned authority for the conduction of the study. The pilot study was conducted in the month of July 2017 on cancer patients after obtaining formal administrative permission from the HOD of the oncology unit at Jayarogy Hospital in Gwalior. This pre-interventional assessment was done with a self-structured rating scale of microsites, after that apply SB oral irrigation on the experimental group for 3 cycles in a day and subsequent 30 mL of oral irrigation on 1 cycle after the duration of 6 h every day and this process went on 1 week. Again post-interventional assessment was done. The analysis of the pilot study was done in accordance with the objectives of the study. The findings of the pilot study revealed that it was feasible to conduct the study and criterion measures were found to be effective. The plan for statistical analysis was also determined.

Table 1: Five-point rating scale

Score	Grade
0–25	Grade 0
26–50	Grade 1
51–75	Grade 2
76–100	Grade 3
100 to above	Grade 4

Data collection procedure

Data collection is the precise, systematic gathering of information relevant to the research purpose. Data collection was done in the month of July 2017. Non-probability convenient sampling technique was used to select 60 patients who have cancer with oral mucositis, out of which 30 were in the control group and 30 were in the experimental group. Formal permission was obtained from the Cancer Hospital and Research Institute at Gwalior. Participants of the research study were explained about the purpose of research and the objective of the study. Written consent was taken from them for their participation in the study. The patient continued to receive usual care in both the control group and the experimental group.

Results

Objective 1

To assess the pre-intervention score of oral mucositis patients in the control group and experimental group.

Objective 2

To assess the effectiveness of SB oral irrigation to prevent oral infection among patients with post-intervention scores on oral mucositis patients.

Objective 3

To compare the reduction of oral mucositis between the experimental group and the control group.

The pre- and post-test mean oral mucositis score of the control group was 72 and the standard deviation was 25.69. In the experimental group, pre-test mean oral mucositis score was 78.69 and standard deviation score was 18.64 and post-test mean score was 53.43 and the standard deviation was 16.63. The "*t*" test score of the control group was 0 and the probability was 2.05 according to the degree of freedom was 29, which indicates that it is no significant score. In the experimental group, "*t*" test score was 30.07 and the probability was 2.05, according to degree of freedom were 29, which indicates that it is a significant score.

Objective 4

To assess the association between the post-therapy score and selected demographic variables, such as age, gender, other diseases beside cancer, and general health status.

Discussion

Figure 1 illustrates the frequency distribution of mucositis levels during cancer in the pretest phase of the control group. The distribution was as follows: 2 patients (6.66%) were in Grade 0, 3 patients (10%) in Grade 1, 9 patients (30%) in Grade 2, 11 patients (36.66%) in Grade 3, and 5 patients (16.66%) in Grade 4. In the experimental group, 0 (0%) were in Grade 0, 2 (6.66%) were in Grade 1, 10 (33.33%) were in Grade 2, 12 (40%) were in Grade 3, and 6 (20%) were in Grade 4.

Figure 2 illustrates the frequency distribution of mucositis levels during the post-test in the control group, without any treatment. The distribution was as follows: 2 patients (6.66%) were in Grade 0, 2 patients (6.66%) in Grade 1, 12 patients (40%) in Grade 2, 10 patients (33.33%) in Grade 3, and 4 patients (13.33%) in Grade 4. In the experimental group, after giving SB oral irrigation that is 2 (6.66%) was in Grade 0, 10 (33.33%) were in grade 1, 11 (36.66%) were in grade 2, 7 (23.33%) were in grade 3, and 0 (0%) were in Grade 4.

Figure 3 shows the difference between the pre- and post-test mean and standard deviation and "*t*" test, oral mucositis score of the control group and experimental group was statistically significant at $P < 0.05$ level.

The pre-test mean oral mucositis score of the control group was 72 and the standard deviation was 25.69. In the experimental group, pre-test mean oral mucositis score was 78.69 and the standard deviation score was 18.64. The post-test mean oral mucositis score of the control group was 72 and the standard deviation was 25.69. In the experimental group, post-test mean score was 53.43 and the standard deviation was 16.63. The "*t*" test score of the control group was 0 and the probability was 2.05 ($P < 0.05$) according to the degree of freedom was 29, which indicates that it is no significant score. In the experimental group, "*t*" test score was 30.07 and the probability was 2.05 ($P < 0.05$) according to the degree of freedom was 29, which indicates that it is the significant score. Hence, null hypothesis was rejected and the research hypothesis (H_1) was accepted as the control group, "*t*" value 0 indicates that the calculated "*t*" value is less than tabulated "*t*" value, according to this experimental group, "*t*" value of 30.07 indicates that calculated "*t*" value is more than tabulated "*t*" value. It was calculated that there was an impact of SB oral irrigation on oral mucositis in cancer patients.

Mohammadi *et al.*, (2022)[11] conducted the study "Effectiveness of SB and zinc chloride mouthwashes in the treatment of oral mucositis and quality of life in patients with cancer under chemotherapy;" the results of the Freidman's test showed that the effect of time on oral mucositis severity of oral mucositis was significant in the SB accordingly, the severity of mucositis in the SB decreased from end of the 1st week to the 3rd week.

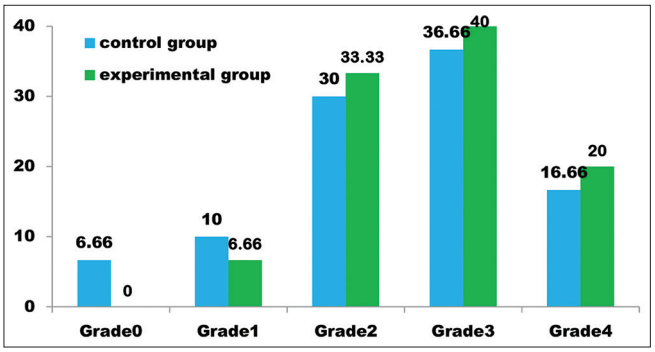

Figure 1: Frequency and percentage distribution of mucositis patients in the control group and experimental group according to pre-test grade of mucositis in five-point rating scale assessment

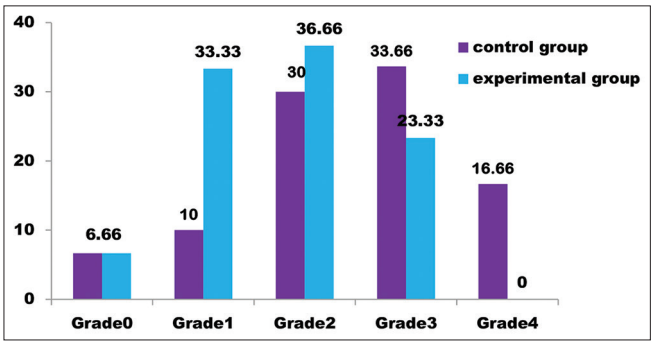

Figure 2: Frequency and percentage distribution of mucositis patients in the control group and experimental group according to post-test grade of mucositis in five-point rating scale assessment

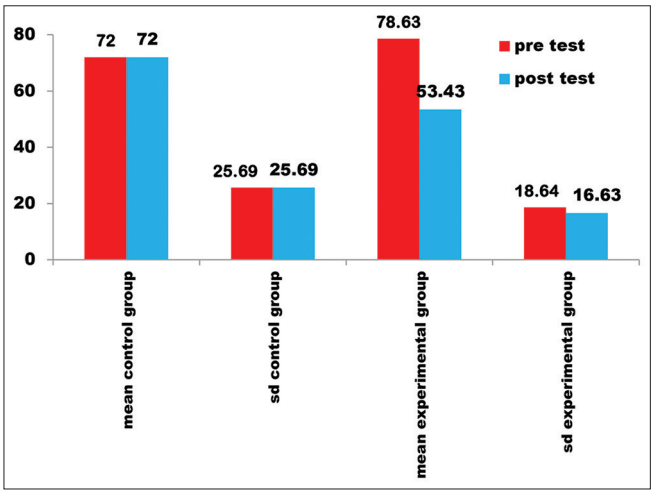

Figure 3: Frequencies and percentage distribution of pre- and post-test mean and standard deviation of mucositis patients in the control group and experimental group

Table 2 shows finding related to the association between the post-therapy score and selected demographic variables, such as age, gender, other diseases beside cancer, and general health status.

Table 2: Finding related to the association between the post-therapy score and selected demographic variables, such as age, gender, other diseases beside cancer, and general health status.

Demographic variables	Chi-Square value	Degree of freedom	Table value	Level of significant
Age	42.8**	12	21.03	Significant
Sex	8.205*	4	9.49	Non-significant
Educational status	15.93*	12	21.03	Non-significant
Income of family (monthly)	32.21**	12	21.03	Significant
General health status of a person	46.77**	12	21.03	Significant
People have other diseases besides cancer	32.86**	12	21.03	Significant
Type of diet	19.83*	12	21.03	Non-significant
Any habits of person	37.83**	12	21.03	Significant
Treatment of chemotherapy by	21.2**	8	15.51	Significant
Duration of hospitalization	36.9**	12	21.03	Significant
Prosthesis (denture)	18.77**	4	9.49	Significant

Table value>calculated value (*non-significant), Table value<calculated value (**significant)

The association between the post-therapy score and demographic variables, such as age, gender, educational status, and income of family, was statistically significant $P < 0.05$.

The association was done between post-therapy score and demographic variables, such as age, Chi-square score was 42.8, degree of freedom was 12, and probability was 21.03 ($P < 0.05$). It is significant in level.

The association was done between post-therapy score and demographic variables, such as gender, Chi-square score was 8.205, degree of freedom was 4, and probability was 9.49 ($P < 0.05$). It is no significant in level.

The association was done between post-therapy score and demographic variables, such as educational status, Chi-square score was 15.93, degree of freedom was 12, and probability was 21.03 ($P < 0.05$). It is no significant in level.

Choi and Kim (2012),[12] conducted a randomized trial "SB Solution versus Chlorhexidine (CHX) Mouthwash in Oral Care of Acute Leukemia Patients Undergoing Induction Chemotherapy" in this study 48 patients recruited and being treated with chemotherapy to compare a mixture of CHX and SB mouthwash versus SB mouthwash alone. The results revealed that the incidence rate of ulcerative OM in the SB group (25.0%) was significantly lower than in the CHX group (62.5%). However, no significant differences were observed in the randomized controlled trial randomized controlled trial study by Cabrera-Jaime *et al*., in which 45 patients undergoing chemotherapy were divided into three arms and tested for SB 5% aqueous solution plus *Plantago major* extract, SB 5% aqueous solution plus CHX 0.12%, or SB 5% aqueous solution plus SB 5% aqueous solution.

The association was done between post-therapy score and demographic variables, such as income of family (monthly), Chi-square score was 32.21, degree of freedom was 12, and probability was 21.03 ($P < 0.05$). It is significant in level.

The association was done between post-therapy score and demographic variables, such as general health status of a person, Chi-square score was 46.77, degree of freedom was 12, and probability was 21.03 ($P < 0.05$). It is significant in level.

The association was done between post-therapy score and demographic variables such as person have other disease besides cancer, Chi-square score was 32.86, degree of freedom was 12, and probability was 21.03 ($P < 0.05$). It is significant in level.

The association was done between post-therapy score and demographic variables, such as type of diet, Chi-square score was 19.83, degree of freedom was 12, and probability was 21.03 ($P < 0.05$). It is no significant in level.

The association was done between post-therapy score and demographic variables such as person have any habits, Chi-square score was 37.83, degree of freedom was 12, and probability was 21.03 ($P < 0.05$). It is significant in level.

The association was done between post-therapy score and demographic variables such as treatment of chemotherapy by Chi-square score was 21.2, degree of freedom was 8, and probability was 15.51 ($P < 0.05$). It is significant in level.

The association was done between post-therapy score and demographic variables such as duration of hospitalization of patient, the Chi-square score was 36.9, degree of freedom was 12, and probability was 21.03 ($P < 0.05$). It is significant in level.

The association was done between post-therapy score and demographic variables, such as prosthesis (denture), Chi-square score was 18.77, degree of freedom was 4, and probability was 9.49 ($P < 0.05$). It is significant in level. Hence, it can be calculated from the above finding that our research hypothesis (H_2) is proven and the null hypothesis (H_{02}) is rejected.

Conclusion

This study was done to evaluate the effectiveness of SB oral irrigation on oral mucositis on cancer patients. The results of this study showed that there is an effect of SB oral irrigation on oral mucositis on oral cancer patients. The five-point rating scale plan prepared for this study will help to oncology nurses to help for understand signs and symptoms and reduce oral mucositis.

Recommendation

Recommendations are made on the basis of the study as follows:

- The study can be replicated on a large sample to validate and for better generalization
- To assess the condition of the patient mouth daily. While there is no evidence to suggest any one assessment tool is better than others, below is the World Health Organization grading of mucositis as an example of a typical tool
- To assess the knowledge and attitude of oncology nurses on complementary and alternative therapies for oral mucositis management
- To assess the effectiveness of other nursing measures, such as coconut, ice, curd, and clove oil, for effective ulcer management during oral cancer.

Acknowledgment

"You can get horses ready for battle, but it is the Lard who gives victory."

Great and mighty is the Lard to who all glory, honor, thanks, and praise is due in every effort, which led to the completion of this work. His mighty presence was ever felt.

I am very fortunate to have the valuable guidance, help, and support of all those who were my advisors, experts, friends well-wishers, and family members. I convey my personal and individual heartfelt thanks to all those who have been associated with the present study and have contributed to it in one way or the other. This thanksgiving is an emotional indebtedness and appreciation. With immense sincerity and gratefulness, I thank to my guide Prof. MRS. SUNEETA RANA MAM H.O.D MEDICAL SURGICAL NURSING, P.G. College of Nursing who in spite of her busy schedule helped me, without which this dissertation would not have been in the present from and shape, and which helped me to say a strong foundation for the study. I owe my gratitude and sincere thanks to my research co-guide, Mrs. SHEULI SARKAR mam P.G. College of Nursing, for his valuable guidance, inspiring discussion, kind encouragement, patient correlation, and valuable suggestions throughout my Endeavor. His reassuring glance and inspiring words will never be forgotten.

It's my privilege to convey my sincere thanks to the experts who have validated the research tool and have guided me with their valuable suggestions and corrections. I express my special thanks to Dr. B.R. Shrivastav sir owner of the Cancer Hospital and Research Institute who allowed me to conduct my final study at the Cancer Hospital and Research Institute, Gwalior, and all the nurses of the hospital for their cooperation in conducting the study.

The librarian, Mr. Prem Kumar Sharma of P.G. College of Nursing, I thank him for his cooperation and assistance toward procuring relevant texts and references for the study.

I extremely thankful to all teaching faculties for their cooperation and the help they have rendered during this study.

I am very thankful and indebted to my Father Mr. RAMSEVAK PRAJAPATI and my Mother Mrs. MANJU PRAJAPATI who gave meaning to my life in so many ways. They made me what I am now, I am grateful to them for showing their immeasurable love and blessing upon me, and for their constant encouragement, prayer, and support.

Last but not least, I am thankful to the members who consented to be the subject of my study, without whom this project could never have become a reality.

Above all, I thank God Almighty for abundant blessing and continuous support during this project.

Miss Varsha Prajapti

Funding

Self-funding research study.

Conflicts of Interest

Self-interested study.

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How to cite this article: Prajapati V, Khan F. A Quasi-Experimental Study to Assess the Effectiveness of Sodium Bicarbonate Oral Irrigation on Oral Mucositis among the Cancer Patients Who admitted at Cancer Hospital and Research Institute, Gwalior City (Madhya Pradesh). Indian J Nurs Sci 2025;10(1):1-6.