

Dissertation submitted to

## THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY CHENNAI

IN PARTIAL FULFILMENT OF REQUIREMENT FOR THE AWARD OF DEGREE OF

MASTER OF SCIENCE IN NURSING

**APRIL 2014** 

Certified that this is the bonafide work of

Reg.No. 301211702

## MEDICAL SURGICAL NURSING THANTHAI ROEVER COLLEGE OF NURSING, PERMBALUR- 621 212

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### CHENNAI

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#### MASTER OF SCIENCE IN NURSING APRIL 2014

INTERNAL EXAMINER	EXTERNAL EXAMINER

**DECLARATION** 

I 301211702 hereby declare that this dissertation entitled "A STUDY

TO ASSESS THE EFFECTIVENESS OF SODIUM BICARBONATE

ORAL WASH ON REDUCTION OF ORAL MUCOSITIS AMONG

PATIENTS WITH HEAD AND NECK CANCER RECEIVING

RADIATION THERAPY IN GVN HOSPITAL, TRICHY" has been

prepared by me under the guidance and direct supervision of

Prof. R. Punithavathi.M.Sc. (N) Professor cum Principal, Thanthai Roever

College of Nursing, Perambalur, as a requirement for partial fulfilment of

M.Sc. Nursing degree course under The Tamilnadu Dr. M.G.R. Medical

University, Chennai – 32. This dissertation had not been previously formed

and this will not be used in future for award of any other degree/ diploma.

This dissertation represents independent original work on the part of the

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#### **ABSTRACT**

**Introduction:** Oral mucositis markedly influences the physical and psychosocial wellbeing of patients undergoing cancer therapy. Oral mucositis is one of the most frequent causes of treatment delay and dosage reductions in cancertherapy. Patients' quality of life can also be affected markedly by pain, infection, altered nutrition, and decrease in oral function.

**Objective**: To assess the effectiveness of sodium bicarbonate oral wash on reduction of oral mucositis among patients with head and neck cancer receiving radiation therapy in experimental group.

**Methodology:** Evaluative research approach with Quasi Experimetal Design was adopted for this study. Sixty patients with head and neck cancer receiving radiation therapy were recruited by nonprobability convenient sampling technique in the setting of GVN Hospital, Trichy, and divided into Experimental and Control groups. Experimental group (n=30) received sodium bicarbonate oral wash (5 gm of sodium bicarbonate in 250 ml of water) for two times a day for one week and control group (n=30) were not received intervention. The study tool was Oral Assessment Guide to assess the pre-test and post-test level of oral mucositis.

**Results:** Statistical findings revealed that the post test oral mucositis mean score is 10.83 in experimental group is less than the control group (13.90). The calculated 't' value 3.556 was significant at p<0.001 level. It is proved that the sodium bicarbonate oral wash was effective in reducing oral mucositis among patients with head and neck cancer receiving radiation therapy.

**Conclusion:** The study concluded that the effect of sodium bicarbonate oral wash is favorable in reducing oral mucositis and their economic burden and improving their quality of life.

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#### CHAPTER I

#### INTRODUCTION

Cancer is a rampant public health problem globally. There is an interesting emerging global trend in Cancer incidences and death rates. While the rates are decreasing in the United States and many other western countries, they are increasing in less developed and economically transitioning countries.

Cancer can be treated effectively with chemotherapy, radiotherapy or a combination of both. Unfortunately such therapy affects all rapidly dividing cells whether neoplastic or not. Consequently, the lining of the oral cavity is at high risk of side effects. Mucositis the medical term that is used to refer to oral complaints that can range in severity from a red, sore mouth to open sores that can be severe enough to prevent eating and drinking.

Mucositis is the painful irritation and ulceration of the mucous membrane inside layer the digestive tract is most of the times a cruel effect of different, therapies for the treatment of cancer such as chemotherapy and radiotherapy. The incidence of oral mucositis varies widely based on the specific type of cancer and the modality used for treatment.

Oral mucositis markedly influences the physical and psychosocial wellbeing of patients undergoing cancer therapy. Oral mucositis is one of the most frequent causes of treatment delay and dosage reductions in cancer therapy. Patients' quality of life can also be affected markedly by pain, infection, altered nutrition, and decrease in oral function

As oncology nurses play a critical role in improving patient outcomes related to oral mucositis, knowledge and research regarding oral

mucositis forms a crucial part of their activities. Managing oral mucositis is as important as managing fatigue, nausea and vomiting and many other side effects that affect patients with cancer.

Sodium bicarbonate is recommended in patients suffering from mucositis or erosion, due to its ability to increase salivary pH and suppress the growth of aciduric micro-organisms. Sodium bicarbonate can improve taste and it neutralizes acids and thus prevents erosion. It is bland and will not irritate the oral mucosa in patients with mucositis.

The effect of a sodium bicarbonate mouthwash solution is thought to aid in the formation of granulation tissue and to promote healing. Sodium bicarbonate mouthwash solution is safe and economical and has been used in cancer patients. Sodium bicarbonate has also been used as a cleansing agent because of its ability to dissolve mucus and loosen debris. The combination of salt and sodium bicarbonate raises oral pH and prevents overgrowth of aciduric bacteria.

#### **BACKROUND OF THE STUDY**

Cancer is a leading cause of death around the world. WHO estimates that 84 million people will die of cancer between 2005 to 2015 without intervention. Each year approximately 5,60,000 cases of head and neck cancer are diagnosed worldwide and 3,00,000 patients die annually. As many as 2,500 persons die every day due to tobacco-related diseases in India.

Cancer is a leading health problem in India, with approximately 1 million cases occurring each year. The prevalence of major Head and Neck Cancer is estimated to be 23.6 per 100,000 populations, which translates to 285,560 patients. It is the sixth most common cause of death in males and seventh in females. The use of tobacco, lime, betel and smoking are very

common unhealthy habit prevalent in India which may be one of the prominent causes of head and neck cancer.

In one study, it was reported that 303 of 599 patients (51 %) receiving chemotherapy for solid tumors or lymphoma developed oral mucositis. Oral mucositis developed in 22% of cycles of chemotherapy, GI mucositis in 7% of cycles and both oral and GI mucositis in 8% of cycles. An even higher percentage (approximately 75–80%) of patients who receive high-dose chemotherapy prior to hematopoietic cell transplantation develop clinically significant oral mucositis.

#### NEED FOR THE STUDY

Radiation-induced oral mucositis has a significant economic impact due to costs associated with pain management, liquid diet supplements, gastrostomy tube placement or total parenteral nutrition, management of secondary infections and hospitalizations. In one study of patients receiving radiation therapy for head and neck cancer, oral mucositis was associated with an increase in costs ranging from \$1700–\$6000 per patient, depending on the grade of oral mucositis <sup>2</sup>

The ulcerative lesions produced by mucotoxic chemo radiotherapy are painful, restrict oral intake and importantly, act as sites of secondary infection and portals of entry for the endogenous oral flora. The overall frequency of mucositis varies and is influenced by the patient's diagnosis, age, level of oral health, and type, dose, and frequency of drug administration. Some degree of mucositis occurs in approximately 40% of patients who receive cancer chemotherapy. Approximately one-half of those individuals develop lesions of such severity as to require modification of their cancer treatment and/or parenteral analgesia. Therapy for tumors of the head and neck associating concomitant chemotherapy and radiotherapy. Among

patients in the high-risk protocols, severe mucositis occurs with a frequency in excess of 60 %.

The treatment of radiation induced mucositis is not well established. However many agents like topical sucralfate, subcutaneous or topical granulocyte macrophages colony-stimulating factors, topical corticosteroids and parenteral radio protection aminofastine have been tried with varied response rates. Currently studies are attempting to find newer agents that are effective, safe and easy to use, Results have been conflicting inclusive or of limited benefit. Prevention of mucositis is still limited to reduction of its severity by relief of pain and discomfort, oral health care programs and strategies to eliminate microbes that are thought to be involved in the development or promotion of radiation mucositis,

Nurses have a critical role in all aspects of managing mucositis, including assessing it, teaching oral care, administering pharmacologic interventions, and helping patients cope with symptom distress. Mucositis can have a negative impact on the overall treatment experience, especially when severe pain or infections occur. Many interventions for managing mucositis exist; however, some are based in tradition or expert opinion and have not been studied in large randomized controlled trials. In addition, a variety of assessment tools are available, which create confusion and difficulties when comparing interventions across studies. Many reviews provided empirical evidence related to interventions for oral mucositis evaluating oral care, rinses, pharmacologic interventions and other techniques.

Hence the researcher was intended to assess the extended effectiveness of sodium bicarbonate oral wash in reducing oral mucositis among patients with head and neck cancer receiving Radiation Therapy.

#### STATEMENT OF THE PROBLEM

A study to assess the effectiveness of sodium bicarbonate oral wash on reduction of oral mucositis among patients with head and neck cancer receiving radiation therapy in gvn hospital, trichy

#### **OBJECTIVES OF THE STUDY**

- 1. To assess the level of oral mucositis among patients with head and neck cancer receiving radiation therapy.
- 2. To assess the effectiveness of sodium bicarbonate oral wash on reduction of oral mucositis among patients with head and neck cancer receiving radiation therapy.
- 3. To find out the association between post-test level of oral mucositis and selected demographic variables of patients with head and neck cancer receiving radiation therapy in experimental group.

#### RESEARCH HYPOTHESES

- ❖ H₁: There will be a significant reduction in level of oral mucositis among patients with head and neck cancer receiving radiation therapy who receives sodium bicarbonate oral wash.
- ❖ H₂: There will be a significant association between post test level of oral mucositis and selected demographic variables of patients with head and neck cancer receiving radiation therapy who receives sodium bicarbonate oral wash.

#### **OPERATIONAL DEFINITIONS**

#### 1. Effectiveness

Producing favorable result.

It refers to the extent to which sodium bicarbonate oral wash becomes successful in reducing oral mucositis. It is measured by Oral Assessment Guide.

#### 2. Sodium bicarbonate oral wash

It refers to rinsing oral cavity of the patients with head and neck cancer with sodium bicarbonate solution (one tea spoon (5 grams) of sodium bicarbonate in 250 ml of water) twice a day for one week. One minute for each wash and ten minutes for 250 ml.

#### 3. Oral mucositis

Oral mucositis is the painful inflammation and/or ulceration of the oral mucosa, developed as an adverse effect of radiation therapy.

#### 4. Head and neck Cancer

The term head and neck cancers refer to a group of cancers found in the **Head**, **Neck and Oral cavity**.

**Head** for Brain, Mastoid, Maxilla, Thalamus.

**Neck** for Cervical esophagus, Vocal cord, Cricoids, Cervical spine, Hypo pharynx, Larynx, Thyroid.

**Oral cavity** for Buccal mucosa, Tongue, Cheek, Supraglottis, Hardpalate, Lacrimalgland.

#### 5. Patients

A client having head and neck cancer and having radiation induced oral mucositis.

#### 6. Radiation therapy

Radiation therapy is a high dose of electromagnetic waves to kill cancer cells and stop them from spreading.

#### ASSUMPTIONS

- Head and neck cancer patients receiving radiation therapy will develop oral mucositis.
- Oral mucositis will be reduced by sodium bicarbonate oral wash
- Sodium bicarbonate has cleansing action by loosening debris and reduce acidity of oral mucositis.

#### **DELIMITATIONS**

- The study is delimited for 60 samples only.
- The study is limited to head and neck cancer patients only.
- **\*** The data collection period is 4 weeks.
- **\*** The study setting is only one hospital.

#### PROJECTED OUTCOME

- 1. This study may help to understand the use of sodium bicarbonate oral wash in reduction of inflammation, pain, soften the scar tissue and to boost the body's immune system.
- 2. This study results may have the evidence to practice the use of sodium bicarbonate oral wash in order to promote comfort and there by improves quality of life of patients with head and neck cancer receiving radiation therapy.

#### **CHAPTER II**

#### **PART-I**

#### REVIEW OF LITERATURE

Review of literature is a systematic search of published work to gain information about a research topic (**Polit & Hungler**).

Conducting a review is a challenging experience. Through the literature review, researcher generates a picture of what is known about a particular framework, to proceed with the study. A literature review provides a background for current knowledge on the topic and illuminates the significance of the new study. Review of literature orients oneself with what is not known and known about an inquiry to ascertain what research can best make content to the existing base of evidence.

#### The review of related literature is organized under the following section.

- Literature related to radiation therapy induced oral mucositis.
- 2) Literature related to intervention for radiation induced oral mucositis.
- 3) Literature related to effect of sodium bicarbonate on radiation induced oral mucositis.

### 1. REVIEW OF LITERATURE RELATED TO RADIATION THERAPY INDUCED ORAL MUCOSITIS

Mi Hyang park et al., (2013) conducted an experimental study with 177 cancer patients. The Oral Assessment Guide (OAG) by observation and the Oral Mucositis Daily Questionnaire (OMDQ) by self-report were used to measure oral mucositis. The data were analyzed .Moderate to severe oral mucositis measured by OAG observation were 94.9% of hospitalized cancer patients receiving chemoradiotherapy were found to have moderate to severe oral mucositis.

M.Baharvand et al., (2013) conducted a cohort study in Tehran University of Medical Sciences Hospital, 22 patients with head and neck cancer were interviewed and examined before and 3 weeks after radiotherapy. Patients were given three consecutive concentrations of sugar, salt, citric acid and quinine sulfate solutions to evaluate their taste sensation by Whole Mouth Technique. Findings from this study were Head and neck radiotherapy causes impairment in taste perception, and life quality is influenced by dysgeusia.

Kristina Mang et al., (2013) conducted a Retrospective evaluation of the dental status of patients with oral cancer before radiotherapy with 90 patients who had undergone radiotherapy for oral cancer and concluded that a poor dental status, conventional fractionation and local tumour progression may enhance the risk of IORN which is in concordance with the literature.

**Sonis ST et al., (2009)** found that there is 90% incidence of mucositis in children under 12 years of age treated with standard chemotherapy. It seems likely that the high mitotic rate of oral mucosal cells in the age group in an adjuvant factor not withstanding its high prevalence.

**Susan.,** (2008) assessed the effect of treatment intensification on acute local toxicity during radiation therapy for head and neck cancer. Among 149 patients with head and neck cancer who were evaluated for local toxicity on a weekly basis 28% recorded mucositis, 33% dysphagia, 40% pain and 12% skin injury.

Rose., (2008) reviewed complications of radiation therapy for head and neck cancer. The individual described their treatment experience and identified the most troublesome and debilitating side effects of radiation therapy as overall lethargy, weakness, dry mouth, mouth sores and pain, taste changes, sore throat. The single most debilitating side effect was oropharyngeal mucositis.

### 2. REIEW OF LITERATURE RELATED TO INTERVENTION FOR RADIATION INDUCED ORAL MUCOSITIS

Khadija Muhamed ahmed et al., (2013) done an experimental study with 62 cancer patients receiving intensive chemotherapy were randomized to receive olive leaf extract, Benzydamine HCL or placebo local treatment for two weeks. The findings from this trial olive leaf extract was effective in reducing the incidence and decreasing the severity of oral mucositis when compared to benzydamine HCL and placebo groups.

Camila Samara Funk et al., (August 2013) Conducted a randomized clinical trial (RCT) to evaluate the impact of dental care program on the quality of life (QOL) of head and neck cancer patients under oncological treatment. 46 subjects with a diagnosis of head and neck primary neoplasty were randomly allocated to the control (CG) or test group (TG). Both groups received basic dental care but the TG received a complimentary care before and during, oncological therapy. The TG showed an improvement

in the general and specific QOL, while the CG showed a worsening in these indexes but without significant difference.

**Yen SH et al., (2012)** conducted a study with 36 HNC patients were randomized to standard oral care plus 5 mL of either phenylbutyrate 5% mouthwash (n = 17) or placebo (mouthwash vehicle, n = 19) taken four times daily (swish and spit). This pilot trial suggested that phenylbutyrate mouthwash significantly decreased the impact of OM in HNC patients receiving RT or chemoradiotherapy and did not confront the tumor control.

Bozana Loncar et al., (2011) conducted a study to investigate the effect of low-level laser irradiation on the secretory function of salivary glands in 34 patients with xerostomia (dry mouth). The results of the study indicate that the effects of low-level laser therapy on salivary glands are not only stimulating, but also regenerative to a degree since the glandular response to the same amount of applied laser energy increased linearly over time.

Lucia Helena et al., (2011) conducted a study about suggestion of a clinical oral care guidance for irradiated patients., high doses of radiation in large areas, including the oral mucosa, may result in several undesired reactions that manifest during or after the completion of therapy. The oral management protocol of head and neck irradiated patients suggested in this work aimed to improve the professionals. It is evident that the most important aspect to consider is the knowledge of radiation exposure, volume, modality, urgency, general state and prognosis of each case.

**M.Sarrafi et al., (2010)** conducted a, randomized, placebo-controlled clinical trial; twelve patients received phenytoin mouthwash (0.5%) or placebo for about two weeks. The quality of life improved dramatically in the phenytoin group with the healing process being more

evident in the first week. Furthermore, reduction in the wound area was greater in the phenytoin group than controls at the end of the first week of treatment.

## 3. REVIEW OF LITERATURE RELATED TO EFFECT OF SODIUM BICARBONATE ON RADIATION INDUCED ORAL MUCOSITIS

**So-Eun Choi et al., (2012)** compared the effectiveness of sodium bicarbonate (SB) solution with chlorhexidine (CHX) mouthwash in oral care of acute leukemia patients under induction chemotherapy. Forty-eight patients were randomly selected Patients were asked to rinse their mouth four times a day from the day before chemotherapy started until discharge. As a result of this study, it was found that oral care by SB solution for acute leukemia patients undergoing chemotherapy was an effective intervention to improve oral health.

Gomathy Pratheepa J., (2011) conducted a quasi experimental pretest posttest two group study to assess the effectiveness of normal saline versus sodium bicarbonate mouth wash in reducing oral mucositis among patients receiving cancer treatment. The findings from this trial provided that both the mouth washes used for the study were effective where sodium bicarbonate was outweighing. Normal saline in reducing oral mucositis.

**Pratheepa., (2010)** conducted a one group pretest post test experimental design to assess the effectiveness of oral hygiene and saline soda gargle to prevent mucositis among the patients receiving radiation therapy. Oral mucositis assessment scale were used to assess the intended before and after administering the saline soda gargle and health education. The obtained 't' value for mucositis was 6.2 and that for oral hygiene was

45.03. It shows that oral hygiene and saline soda gargle had significant effect on preventing mucositis.

**Madan etal., (2008)** conducted a study to assess the effect of three alcohol-free mouthwashes on radiation-induced oral mucositis in patients with head and neck malignancies, scheduled to undergo curative radiotherapy, were randomly assigned to receive one of the three alcohol-free test mouthwashes (0.12% chlorhexidine, 1% povidone-iodine, or salt/soda) or a control. This study demonstrates that use of alcohol-free povidone-iodine or salt/soda mouthwash can reduce the severity and delay the onset of oral mucositis due to antineoplastic radiotherapy.

**Madankumar.**, (2008) done a comparative study to assess there is no difference in efficacy between two solutions saline soda and iodine on 76 patients. Results showed there is no difference in efficacy between two solutions. The study demonstrated the use of alcohol free solution could reduce the severity and delay the onset of oral mucositis due to anti neoplastic radiation therapy, thus improving the quality of life for patients. Hence alcohol free solution could be advocated for patient.

Macphail., (2008) assessed the effectiveness of micronized sucralfate versus salt soda mouthwashes on radiation induced mucositis. The purpose of the study was to compare the efficacy of both mouth washes in terms of severity of mucositis, related pain and the time required to heal radiation therapy induced mucositis in patients with cancer. The findings from this trial provided that there were no significant difference in efficacy between sucralfate and salt soda. The use of less costly salt soda is prudent and cost effective.

Potting et al., (2006) conducted a study to assess the effectiveness of commonly used mouthwashes for the prevention of chemotherapy-induced

oral mucositis. Daily chlorhexidine mouthwash is often recommended for preventing chemotherapy-induced oral mucositis. Povidone-iodine, NaCl 0.9%, water salt soda solution and chamomile mouthwash are also recommended. The results failed to detect any beneficial effects of chlorhexidine as compared with sterile water or NaCl 0.9%. The severity of oral mucositis was shown to be reduced by 30% using a povidone-iodine mouthwash and salt soda.

Salvador PT., (2005) conducted a retrospective descriptive study documented the frequency of oral mucositis and examined the impact of certain variables in the development of oral mucositis in autologous stem cell transplants. Sodium bicarbonate mouthwash is commonly used intervention; 72.92% of the interventions were used as secondary prevention. The results reported that oral mucositis was significantly associated and level of prevention (secondary) were independent predictors of oral mucositis.

Carl W, Havens J., (2000) conducted a study to reduce the intensity of pain and prevent systemic infection via the compromised mucosa, agents such as antiseptic mouthwashes, anti-ulcer compounds, sodium bicarbonate, saline, and allopurinol have been traditionally used with limited success. The results reported from different testing centers are often contradictory and confusing. Basic requirements in prevention and control of mucositis are good oral hygiene, mechanical débridement of the oral tissues and hydration.

#### **PART II**

#### **CONCEPTUAL FRAMEWORK**

Conceptual framework and model adapted for present study was based on WIEDENBACH'S HELPING ART OF CLINICAL NURSING THEORY.

Wiedenbach views nursing as an art based on goal directed care.

Factual and speculative knowledge, judgment and skills necessary for effective nursing practice.

Wiedenbach's vision of nursing practice closely parallels the assessment, implementation and evaluation steps of the nursing process.

#### She identifies seven level of awareness

- Sensation- Reception Of Stimulus.
- Perception- Reaction To How Stimulus Is Viewed.
- Assumption- Over View of The Stimulus.
- Realization- Gathering of Resource To Control Actions.
- Insight- Use of Reason To Gain More Information About The Situation.
- Design- formulation of a plan.
- Decision- action that furthers the plan.

#### According to theory the nurse involve to three components

- ldentifying a need for help
- Ministering needed help
- Validating that need for help was met.

In this study the nurse investigator attaining the goal through three steps of Wiedenbach's perspective theory.

#### STEP-I

#### **Identifying a need for help**

The nurse perceives the patients behavior as consistent or inconsistent with the nurses concept of comfort or capability.

#### General information;

For collecting general information the investigator collect information, generally through demographic variables. And through pre-test, get information about severity of oral mucositis mild, moderate and severe.

#### The central purpose

According to the theory the central purpose to what the nurse wants to accomplish. It is the overall plan towards nurse strives, it transcends the immediate intent of the assignment are task by specifically directing activities towards the patients good.

In this study the central purpose was to reduce the symptoms of level of mucositis.

#### The prescription

According to the theory, the prescription refers to the plan of care for patients. It specifies the nature of the action that will fulfill the nurse's

central purpose and the rationale for that action. After the prescription of established, the nurse can implement it through the nursing care plan.

In this study the prescription for the oral mucositis was sodium bicarbonate oral wash.

#### STEP-II

#### Ministering the needed help

The nurse formulates a plan for meeting the patients need for help based on available resources: what the patients thinks, knows, can do, and has done plus what the nurse thinks, knows, can do, and has done; the nurse presents the plan to the patients and the patients response to it.

#### Realities

Realities refers to the, physical, physiologic, emotional and spiritual factors that come in to play in situation involving nursing action. Wiedenbach identified the five realities as agent, recipient, goal, means and framework.

The agent is the practicing nurse or a designee who has the personal attributes, capacities, capabilities, commitment, and competence to provide nursing care. In this study it refers to the researcher, direct all action toward the goal.

The recipient is the patient who has personal attributes, problems, capabilities, aspirations and abilities to cope with the concerns or problems being experience. The recipient, who receives the nurses action or on whose behalf action are taken, the recipient is vulnerable and dependent. In this study the recipient are patients with head and neck cancer receiving radiation therapy with oral mucositis.

The goal is the nurse's desired outcome the nurse wishes to achieve. In this study it refers to reduction of severity of oral mucositis.

The mean comprise the activities and devices used by the nurse to achieve the goal. This includes specific skills procedure techniques and devices that may be used to facilitate nursing practice. In this study 5 gram of sodium bicarbonate in 250ml of water.

The frame work consists of the human, environment, professional, and organizational facilities. In this study the patients with head and neck cancer receiving radiation therapy with oral mucositis are selected in GVN Hospital at Trichy.

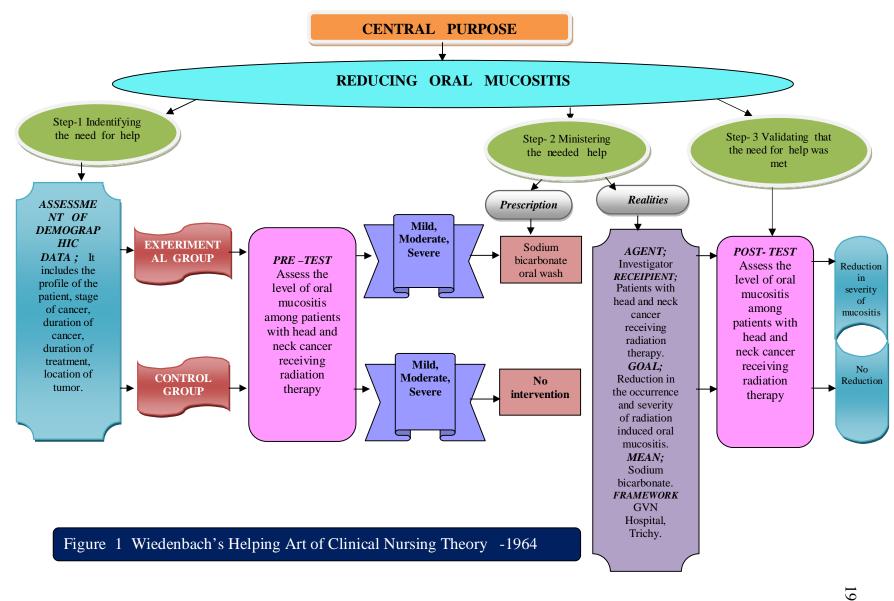
#### STEP-III

#### Validating that the need for help was met

The nurse perceives the patients behaviour consistent or inconsistent with the nurse's concept of comfort of capability.

It refers to the collection of evidence that shows whether the patient's needs have been met and that his/her functional ability has been restored as a direct result of the research action. It is based on patients oriented evidence. This step involves the post-test assessment and that score after ministering analysis inter the outcome.

In this study the post-test was done through Oral Assessment Guide. According to the result of the pre-test score described the mild, moderate, severe oral mucositis of experimental group was improved to no mucositis, mild, moderate mucositis score.



#### **CHAPTER III**

#### RESEARCH METHODOLOGY

This chapter deals with the brief description of different steps undertaken by the investigator for the study. It includes the research approach, research design, variables, setting of the study, population, criteria for sample selection, sample and sampling technique, validity, reliability, pilot study, description of tool, procedure for data collection, plan for data analysis and protection for human rights.

#### RESEARCH APPROACH AND DESIGN

#### Research approach

Evaluative Approach was the research approach.

#### Research design

In this study the Quasi Experimental Study –Non-Equivalent control group design.

#### PRETEST POSTTEST DESIGN

GROUP	PRETEST	INTERVENTION	POSTTEST
Е	O1	X	O2
С	O1	-	O2

**E** - Experimental Group

**C** - Control Group.

O1 - Pre-test assessment of level of oral mucositis.

**X** - Intervention of sodium bicarbonate oral wash.

O2 - Post-test assessment of level of oral mucositis.

#### **VARIABLES**

#### The variables included in the study were

- 1. **Independent variable:** Sodium bicarbonate oral wash.
- 2. **Dependent variable:** Oral mucositis.

#### SETTING OF THE STUDY

The setting for the study is outpatient and inpatient departments of GVN Hospital Trichy. It is a cancer institute which provides all modalities of cancer treatment under one roof.

#### **POPULATION**

#### Target population

The target population of the study is patients with head and neck cancer with oral mucositis receiving radiation therapy.

#### Accessible population

The patients with head and neck cancer receiving radiation therapy having oral mucositis in GVN Hospital, Trichy.

#### **SAMPLE**

Patients with head and neck cancer receiving radiation therapy in GVN Hospital, Trichy.

#### SAMPLE SIZE

The sample size was 60. (30 patients in control group and 30 patients in experimental group).

#### SAMPLING TECHNIQUE

Non probability convenient sampling technique.

#### CRITERIA FOR SAMPLE SELECTION

#### **INCLUSION CRITERIA**

- ❖ Patients with head and neck cancer in the age group of 21 to 70 years.
- ❖ Both female and male patients with head and neck cancer receiving radiation therapy.
- Patients with head and neck cancer receiving radiation therapy and having oral mucositis
- Patients who understand and speak Tamil.

#### **EXCLUSION CRITERIA**

- **Cancer patients with chemotherapy or surgical therapy.**
- Clients who are having other co morbid conditions.
- Clients who are not willing to participate in the study.

#### **DESCRIPTION OF THE TOOL**

#### Section A

A structured interview schedule to collect information regarding demographic variables such as age, gender, religion, personal habits, location of tumor, diet pattern, stage of cancer, duration of treatment, duration of cancer.

#### Section B

Standardized Oral Assessment Guide (Eilters et al:1998) was used to assess the oral mucositis. It consists 8 category of assessment. The levels of oral mucositis are mild, moderate and severe. Total score is 24.

#### **GRADING PROCEDURE**

ORAL MUCOSITIS STATUS	SCORE
MILD	1 -8
MODERATE	9 -16
SEVERE	17-24

#### **DESCRIPTION OF INTERVENTION**

5 grams of sodium bicarbonate dissolved in 250 ml of boiled and cooled water. Oral wash was started after one week of radiation therapy and it was continued for twice a day for one week. (1 minute for each wash and 10 minutes for 250ml).

#### VALIDITY

The content of the tool was validated by one radiologist, one physician, three medical surgical nursing experts. The expert's suggestions were incorporated and a standardized Oral Assessment Guide was used for the main study.

#### **PILOT STUDY**

The pilot study was carried out from 11<sup>th</sup> June to 17<sup>th</sup> June at GVN hospital Trichy. The study was conducted after obtaining permission from the concern authorities. 3 samples for control group and 3 samples for experimental group was taken. Oral cavity was assessed with Oral Assessment Guide (Elites et all) for both groups. Sodium bicarbonate oral wash was given for one week for experimental group.

The effectiveness of sodium bicarbonate oral wash on reduction of oral mucositis is assessed after 1 week in experimental group and compared with control group. Pilot study was feasible and it was planned to proceed on conduct main study without any modification.

#### DATA COLLECTION PROCEDURE

The data collection procedure was carried out for a period of one month. Samples were selected according to inclusion criteria of the study. Informed written consent obtained from the samples. Patients with oral mucositis are recruited by convenient sampling technique, for both experimental and control group. Oral cavity was assessed with Oral Assessment Guide (Eiltes et al). Sodium bicarbonate oral wash was provided twice a day to the experimental group for one week. Post-test was done after 1 week for both the groups.

#### PLAN FOR DATA ANALYSIS

It was planned to analyze the data using descriptive statistics and inferential statistics.

#### **Descriptive statistics**

\* Frequency, percentage, mean and standard deviation will be used to describe the pre-test and post-test level of oral mucositis.

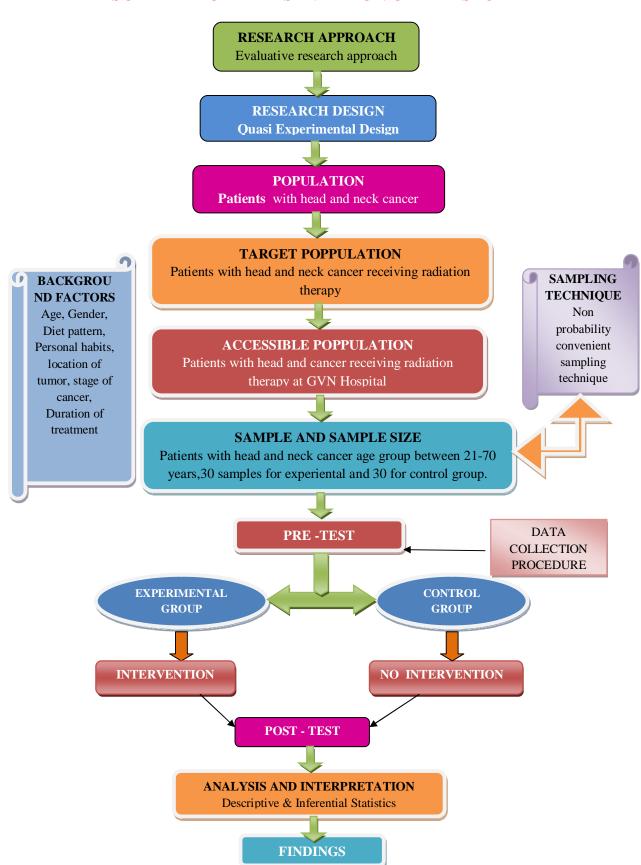
#### **Inferential statistics**

- \* Paired `t` test will be used to determine the difference between pre-test and post-test level of oral mucositis among both groups.
- \* Independent `t` test will be used to determine the difference between post-test level of oral mucositis between two groups.
- \* Chi-square will be used to determine the association between the post-test level of oral mucositis and selected demographic variables in experimental group.

#### PROTECTION OF HUMAN SUBJECTS

The study was conducted after the approval of the dissertation committee. Permission was obtained from the administration. Consent was obtained from the samples before data collection and assurance was given to the samples regarding the confidentiality of the data collection.

#### SCHEMATIC REPRESENTATION OF THE STUDY



#### **CHAPTER IV**

#### DATA ANALYSIS AND INTERPRETATION

This chapter deals with the classification, analysis and interpretation of the data to determine the effectiveness of sodium bicarbonate oral wash on reduction of oral mucositis among patients with head and neck cancer receiving radiation therapy.

The finding of the study were grouped, tabulated, organized, analyzed & interpreted under the following sections.

#### SECTION A

Frequency and percentage distribution of demographic variables of patients with head and neck cancer receiving radiation therapy.

#### **SECTION B**

- a) Pre-test and post-test level of oral mucositis among patients with head and neck cancer receiving radiation therapy in experimental group.
- b) Pre-test and post-test level of oral mucositis among patients with head and neck cancer receiving radiation therapy in control group.

- a) Comparison of mean mucositis score in pre-test and posttest among patients with head and neck cancer receiving radiation therapy in experimental group.
- b) Comparison of the mean mucositis score in pre-test and post-test among patients with head and neck cancer receiving radiation therapy in control group.
- c) Comparison of the mean mucositis score in post-test among patients with head and neck cancer receiving radiation therapy in experimental and control group.

#### **SECTION D**

a) Association of post test level of oral mucositis among patients with head and neck cancer receiving radiation therapy in experimental group with their selected demographic variables.

#### **SECTION A**

TABLE 1

Frequency and percentage distribution of demographic variables among the patients with head and neck cancer receiving radiation therapy in experimental group and control group.

N=60

C M	Domo avankia Variablas	Experimen	ntal Group	<b>Control Group</b>	
S.No	Demographic Variables	F	%	F	
1	Age in years				
	21 - 30	2	6.67	2	6.67
	31 – 40	2	6.67	6	20.00
	41 – 50	8	26.67	4	13.33
	51 – 60	10	33.33	13	43.33
	61-70 years	8	26.67	5	16.67
2	Gender				
	Male	19	63.33	17	56.67
	Female	11	36.67	13	43.33
3	Religion				
	Hindu	23	76.67	24	80.00
	Muslim	4	13.33	2	6.67
	Christian	3	10.00	4	13.33
4	Diet pattern				
	Vegetarian	7	23.33	11	36.67
	Non vegetarian	23	76.67	19	63.33

CN	Demographic Variables	Experimen	ntal Group	<b>Control Group</b>	
S.No		F	%	F	%
5	Personal habits				
	Cigarette smoking	2	6.67	2	6.67
	Alcohol consumption	4	13.33	4	13.33
	Tobacco chewing	7	23.33	8	26.67
	Cigarette & Alcohol	7	23.33	10	33.33
	None	10	33.33	6	20.00
6	Location of tumor				
	Head	6	20.00	10	33.33
	Neck	12	40.00	14	46.67
	Oral cavity	12	40.00	6	20.00
7	Stage of cancer				
	I stage	3	10.00	9	30.00
	II stage	15	50.00	12	40.00
	III stage	8	26.67	5	16.67
	IV stage	4	13.33	4	13.33
8	<b>Duration of cancer</b>				
	<1 Year	22	73.33	20	66.66
	1-2 Years	4	13.33	6	20.00
	> 2 years	4	13.33	4	13.33
9	<b>Duration of treatment</b>				
	<1 Year	22	73.33	20	66.66
	1-2 Years	4	13.33	6	20.00
	> 2 years	4	13.33	4	13.33

The data in the table shows that,

Majority of the samples 10(33.33%) in experimental group and 13(43.33%) in control group belongs to the age group of 51-60 years.

Majority of the samples 19(63.33%) in experimental group and 17 (56.67%) in control group were male.

Majority of the samples 23 (76.67%) in experimental group and 24 (80%) in control group were Hindu.

Majority of the samples 23(76.76%) in experimental group and 19 (63.33%) in control group consume non-vegetarian.

Majority of the samples 10(33.33%) in experimental group do not have bad habits and 10(33.33%) in control group had habit of cigarette smoking and alcohol.

Majority of the samples 12 (40%) in experimental group had tumor in neck and oral cavity and 14 (46.67%) in control group had tumor in neck.

Majority of the samples 15(50%) in experimental group and 12 (40%) in control group had II stage of cancer.

Majority of the samples 22 (73%) in experimental group and 20(66.66%) in control group have duration of cancer less than 1 year.

Majority of the samples 22(73%) in experimental group and 20(66.66%) in control group were receiving treatment for less than 1 year.

FIGURE 2 a Percentage distribution of age of the patients with head and neck cancer receiving radiation therapy in experimental and control group

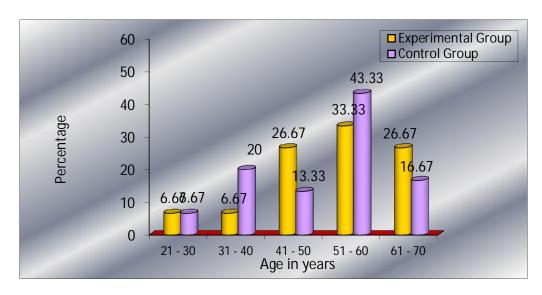


FIGURE 2 b Percentage distribution of gender of the patients with head and neck cancer receiving radiation therapy in experimental and control group

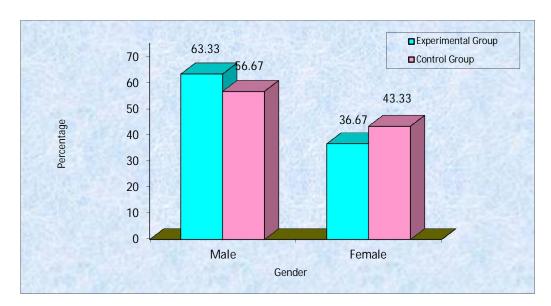


FIGURE 2 c Percentage distribution of diet pattern of the patients with head and neck cancer receiving radiation therapy in experimental and control group

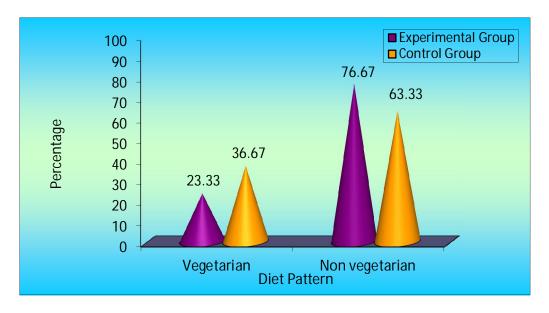


FIGURE 2 d Percentage distribution of personal habits of the patients with head and neck cancer receiving radiation therapy in experimental and control group

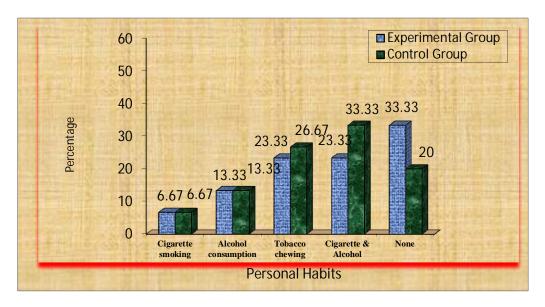


FIGURE 2 e Percentage distribution of location of tumor of the patients with head and neck cancer receiving radiation therapy in experimental and control group

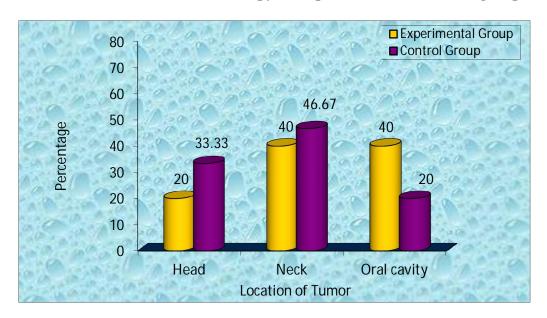


FIGURE 2 f Percentage distribution of stage of cancer of the patients with head and neck cancer receiving radiation therapy in experimental and control group.

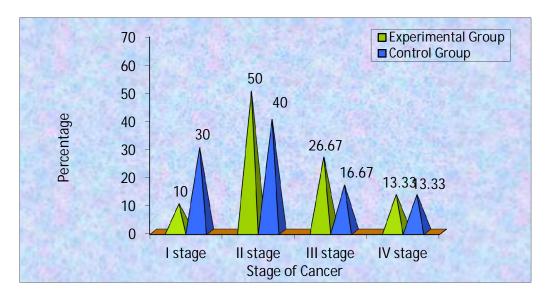
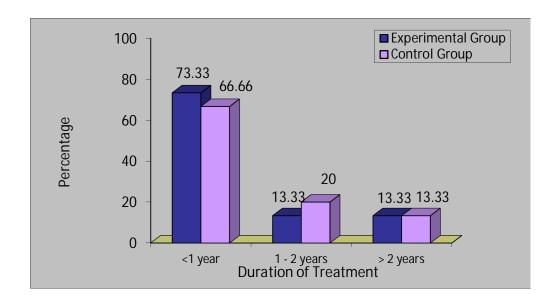


FIGURE 2 g Percentage distribution of duration of treatment of the patients with head and neck cancer receiving radiation therapy in experimental and control group



#### **SECTION B**

TABLE 2

Pre-test and post-test level of oral mucositis among patients with head and neck cancer receiving radiation therapy in experimental group

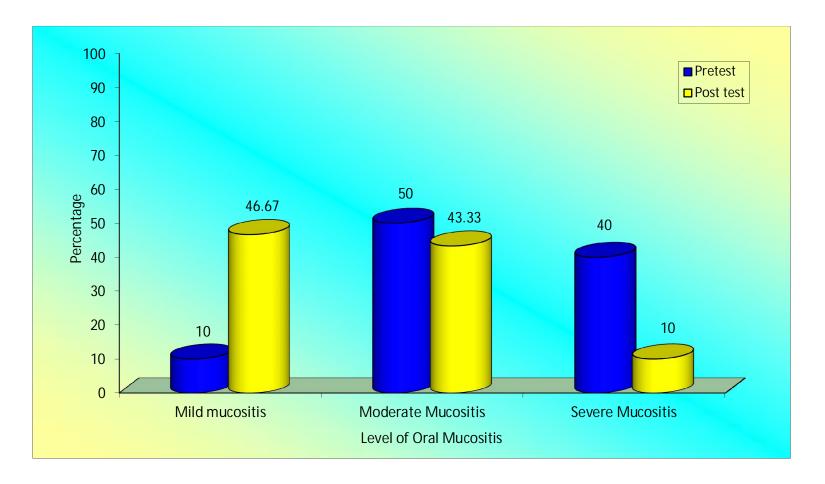
N=30

Mucositis Status	Pre-test		Post-test		
	F	%	F	%	
Mild mucositis	3	10	14	46.67	
Moderate mucositis	15	50	13	43.33	
Severe mucositis	12	40	3	10	

In pre-test, Majority 15(50%) were having moderate mucositis and the next majority 12(40%) were having severe mucositis, only 3(10%) had mild mucositis.

In post test, Majority 14(46.67%) were having mild mucositis and the next majority 13(43.33%) were having moderate mucositis, only 3(10%) had severe mucositis.

FIGURE 3 Percentage distribution of pre-test and post- test level of oral mucositis among patients with head and neck cancer receiving radiation therapy in experimental group.



#### **SECTION B**

TABLE 3

Pre-test and post-test level of oral mucositis among patients with head and neck cancer receiving radiation therapy in control group

N=30

Mucositis Status	Pre	-test	Post-test		
	F	%	F	%	
Mild mucositis	3	10	3	10	
Moderate mucositis	10	33.33	20	66.67	
Severe mucositis	17	56.67	7	23.33	

In pre-test, Majority 17(56.67%) were having severe mucositis and the next majority 10(33.33%) were having moderate mucositis, only 3(10%) had mild mucositis.

In post test, Majority 20(66.67%) were having moderate mucositis and the next majority 7(23.33%) were having severe mucositis, only 3(10%) had mild mucositis.

FIGURE 4 Percentage distribution of pretest and post test level of oral mucositis among patients with head and neck cancer receiving radiation therapy in control group

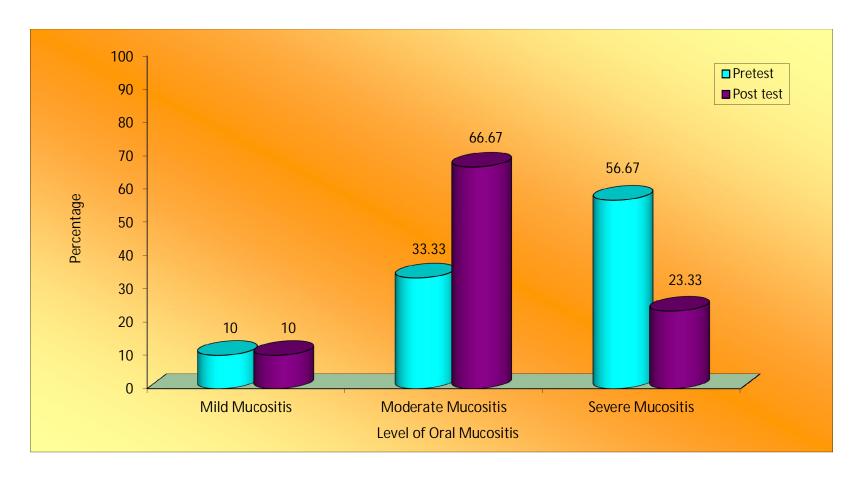


TABLE 4

Comparison of mean mucositis score and standard deviation in the pre-test and post-test of Patients with head and neck cancer receiving radiation therapy in experimental group.

N=30

Test	Maximum score	Mean	S.D	Mean Diff	't' Value
Pretest	24	15.00	4.42	4.17	T=9.259***
Post test	24	10.83	3.47	- 4.17	P=0.001, S

\*\*\*p<0.001, S – Significant

**Table 4 reveals,** the calculated pre-test mucositis mean score was 15.00 with standard deviation of 4.42 and the post-test mucositis mean score was 10.83 with standard deviation of 3.47. The mean difference was 4.17 and the calculated 't' value 9.259 was a significant at p<0.001 level.

TABLE 5

Comparison of mean mucositis score and standard deviation in the pre-test and post- test of Patients with head and neck cancer receiving radiation therapy in control group.

N=30

Test	Maximum score	Mean	S.D	Mean Diff	't' Value
Pretest	24	16.07	4.02	2.17	T=5.981***
Post test	24	13.90	3.19	_ =	P=0.001, S

\*\*\*p<0.001, S Significant

**Table 5 reveals,** the calculated pre-test level of mucositis mean score was 16.07 with the standard deviation of 4.02 and the post-test mucositis mean score was 13.90 with the standard deviation of 3.19. The mean difference was 2.17 and the calculated 't' value 5.981 was significant at P<0.001 level.

**TABLE 6** 

Comparison of mean mucositis score and standard deviation in the post-test of patients with head and neck cancer receiving radiation therapy in experimental and control group.

N=60

Groups	Maximum score	Mean	S.D	Mean Diff	't' Value
Experimental	24	10.83	3.47	3,07	T=3.556***
Control	24	13.90	3.19	- /	P=0.001, S

\*\*\*p<0.001, S – Significant

**Table 6 shows,** In experimental group level of mucositis mean score was 10.83 with the standard deviation of 3.47. In control group level of mucositis mean score was 13.90 with standard deviation of 3.19. The mean difference was 3.07 and the calculated 't' value 3.556 was significant at P<0.001 level.

## **SECTION D**

TABLE 7

Association of the post-test level of oral mucositis among patients with head and neck cancer receiving radiation therapy in experimental group

with their selected demographic variables.

N=30

Demographic Variables	Mild Mucositis (1-8)	Moderate Mucositis (9-16)	Severe Mucositis (17-24)	Chi- Square Value
	F	F	F	· value
Age in years				
21 - 30	1	1	0	
31 - 40	1	1	0	$\chi^2 = 8.584$
41 - 50	1	6	1	N.S
51 - 60	5	3	2	
61 -70 years	6	2	0	
Gender				2 0.020
Male	9	8	2	$\chi^2 = 0.038$
Female	5	5	1	N.S
Religion				
Hindu	11	9	3	$\chi^2 = 1.555$
Muslim	2	2	0	N.S
Christian	1	2	0	
Diet pattern				$\chi^2 = 0.197$
Vegetarian	3	3	1	
Non vegetarian	11	10	2	N.S
	Age in years  21 – 30  31 – 40  41 – 50  51 - 60  61 -70 years  Gender  Male Female Religion Hindu Muslim Christian Diet pattern Vegetarian	Demographic Variables         Mucositis (1-8)           F         Age in years           21 - 30         1           31 - 40         1           41 - 50         1           51 - 60         5           61 - 70 years         6           Gender         9           Female         5           Religion         11           Muslim         2           Christian         1           Diet pattern         3	Demographic Variables         Mucositis (1-8)         Mucositis (9-16)           F         F           Age in years         Image: Property of the content of the con	Demographic Variables         Mucositis (1-8)         Mucositis (9-16)         Mucositis (17-24)           F         F         F           Age in years         Image: Property of the pattern variables of the pattern v

S. No	Demographic Variables	Mild Mucositis (1-8)	Moderate Mucositis (9-16)	Severe Mucositis (17-24)	Chi- Square Value
		F	F	F	
5	Personal habits				
	Cigarette smoking	2	0	0	_
	Alcohol consumption	1	3	0	$\chi^2 = 10.010$
	Tobacco chewing	4	1	2	N.S
	Cigarette & Alcohol	2	4	1	
	None	5	5	0	
6	<b>Location of tumor</b>				
	Head	3	1	2	$\chi^2 = 6.937$
	Neck	7	5	0	N.S
	Oral cavity	4	7	1	
7	Stage of cancer				
	I stage	3	0	0	$\chi^2 =$
	II stage	5	10	0	27.713
	III stage	5	3	0	S***
	IV stage	1	0	3	
8	<b>Duration of cancer</b>				2 0.401
	<1 Year	10	11	1	$\chi^2 = 9.481$
	1-2 Years	2	2	0	N.S
	More than 2 years	2	0	2	
9	<b>Duration of</b>				
9	treatment				$\chi^2 = 9.481$
	<1 Year	10	11	1	N.S
	1-2 Years	2	2	0	
	More than 2 years	2	0	2	

\*\*\*p<0.001, S – Significant,

N. S – Not Significant

**Table 7 reveals,** the Calculated Chi-square value is greater than tabulated value (at 0.001 Level) for stage of cancer. So there was a significant association exist between stage of cancer and post test level of oral mucositis.

The Chi-square value is less than the tabulated value (at 0.001 Level) for age, gender, religion, diet pattern, personal habits, location of tumor, duration of cancer, duration of treatment and post test level of oral mucositis among patients with head and neck cancer receiving radiation therapy. So there was no significant association found between Post test level of oral mucositis and demographic variables such as age, gender, religion, diet pattern, personal habits, location of tumor, duration of cancer, duration of treatment in experimental group.

#### **CHAPTER V**

#### **DISCUSSION**

This chapter high lights the discussion of the data analysed based on the objectives and hypothesis of the study. The problem stated is, "a study to assess the effectiveness of sodium bicarbonate oral wash on reduction of oral mucositis among patients with head and neck cancer receiving radiation therapy" in GVN HOSPITAL, TRICHY.

The first objective of the study was to assess the level of oral mucositis among patients with head and neck cancer receiving radiation therapy.

In experimental group, Pre-test assessment revealed 15(50%) had moderate mucositis, 12(40%) had severe mucositis and 3(10%) had mild mucositis. Post test assessment showed that 14(46.67%) had mild mucositis, 13(43.33%) had moderate mucositis and 3(10%) had severe mucositis.

In control group, Pre-test assessment revealed 17(56.67%) had severe mucositis, 10(33.33%) had moderate mucositis and 3(10%) had mild mucositis. Post-test assessment showed that 20(66.67%) had moderate mucositis, 7(23.33%) had severe mucositis and 3(10%) had mild mucositis.

The second objective of the study was to assess the effectiveness of sodium bicarbonate oral wash on reduction of oral mucositis among patients with head and neck cancer receiving radiation therapy.

In experimental group, the post test oral mucositis mean score was 10.83 with the standard deviation of 3.47 and in control group the post test oral mucositis mean score was 13.90 with the standard deviation of 3.19. The

calculated 't' value was 3.556. Calculated 't' value was less than the table value which revealed that there was a significant difference in post test score of oral mucositis in experimental and control group at p<0.001 level. Hence the stated hypothesis  $\mathbf{H}_1$ 

"There will be a significant reduction in level of oral mucositis among patients with head and neck cancer receiving radiation therapy, who receives sodium bicorbanate oral wash" is accepted

The third objective of the study was to find out the association between post-test level of oral mucositis and selected demographic variables of patients with head and neck cancer receiving radiation therapy who receives sodium bicarbonate oral wash.

The association revealed that, there was a significant association found between stage of cancer and post test level of oral mucositis.

There was no significant association found between the post test level of oral mucositis and demographic variables of age, gender, religion, personal habbits, location of tumor, duration of cancer, duration of treatment of participants in experimental group with their demographic variables at p<0.001 level. Hence the stated hypothesis  $\mathbf{H}_2$ 

"There will be a significant association between post test level oral mucositis and selected demographic variables of patients with head and neck cancer receiving radiation therapy in experimental group" is not accepted.

#### **CHAPTER VI**

# SUMMARY, MAJORFINDINGS, IMPLICATIONS, LIMITATIONS, RECOMMENDATIONS AND CONCLUSION

This chapter is divided into two sections, in the first section summary of the study, findings and conclusion is presented. In the second section implication in various areas of nursing practice, nursing education, nursing administration, nursing research and recommendations for further study are present.

#### SUMMARY OF THE STUDY

The objective of the study were to evaluate the effectiveness of sodium bicarbonate oral wash on reduction of oral mucositis among patients with head and neck cancer receiving radiation therapy and to find out the association between post test level of oral mucosists in an experimental group with their selected demographic variables.

The research approach adapted for this study was evaluative in nature. The present study was an experimental study, Quasi Experimental study design. Independent variable was sodium bicarbonate oral wash and dependent variable was oral mucosists. The conceptual frame work adopted for the present study was based on Wiedenback's Helping Art of Clinical Nursing Theory. The tool used in this study was Oral Assessment Guide to assess the level of oral mucosists. The tool was found reliable and feasible.

The pilot and main study was conducted in GVN Hospital Trichy, with 60 samples. Samples were recruited through non probability convenient

sampling technique. Pre test was done to assess the level of oral mucositis. The sodium bicarbonate oral wash was given from the seventh day of radiation therapy for experimental group. Post test was done after 1 week for both groups respectively. Descriptive statistics (frequency, percentage, mean, standard deviation) and inferential statistics (un paired `t' test, paired `t' test & chi-square) were used to analyze the data and to test the hypotheses. The findings revealed that, there is a reduction in level of oral mucositis after the sodium bicarbonate oral wash, as the mean mucositis score 10.83 of experimental group was lesser than the mean mucositis score 13.90 of control group. The obtained 't' value was 3.556, The mean difference was 4.17, significant at p<0.001 level.

There was a significant association between stage of cancer and post test level of oral mucositis and there was no significant association between the post test and age, gender, religion, diet pattern, personal habits, location of tumor, duration of cancer, duration of treatment.

So it is concluded that the sodium bicarbonate oral wash is effective on reduction of oral mucositis among patients with head and neck cancer receiving radiation therapy.

#### MAJOR FINDINGS OF THE STUDY

Majority of the samples (33.33%) in experimental group and (43.33%) in control group belongs to the age group of 51-60 years.

Majority of the samples (63.33%) in experimental group and (56.67%) in control group were male.

Majority of the samples (76.76%) in experimental group and (63.33%) in control group consume non-vegetarian.

Majority of the samples (33.33%) in experimental group were having no bad habits and (33.33%) in control group were having habit of cigarette smoking and alcohol.

Majority of the samples (40%) in experimental group had tumor neck and oral cavity and (46.67%) in control group had tumor in neck.

Majority of the samples (50%) in experimental group and (40%) in control group were in II stage of cancer.

Majority of the samples (73%) in experimental group and (66.66%) in control group have duration of cancer for < 1 year.

Majority of the samples (73%) in experimental group and (66.66%) in control group were receiving treatment for < 1 year.

#### FINDING RELATED TO PLANNED INTERVENTION

- 1. In pre-test, (50%) were having moderate mucositis, (40%) were having severe mucositis, and (10%) had mild mucositis in experimental group. In post-test, (46.67%) were having mild mucositis, (43.33%) were having moderate mucositis, and (10%) had severe mucositis in experimental group.
- 2. In Pre-test (56.67%) were having severe mucositis, (33.33%) were having moderate mucositis, only (10%) had mild mucositis. In Post- test (66.67%) were having moderate mucositis, (23.33%) were having severe mucositis only (10%) had mild mucositis in control group.
- 3. In experimental group, pre-test mean mucositis score was 15.00 and in post-test mean mucositis score was 10.83. The

- calculated 't' value 9.259 was significant a t p<0.001 level.
- 4. In control group, pre-test mean mucositis score was 16.07 and in post-test mean mucositis score was 13.90. The calculated 't' value 5.981 was significant at p<0.001 level.
- 5. Post- test mean mucositis score of experimental group was 10.83 and of control group was 13.90, the calculated 't' value 3.556, was significant at p<0.001 level. It revealed that the sodium bicarbonate oral wash effective in reducing the oral mucositis among patients with head and neck cancer receiving radiation therapy.
- 6. The association of post- test level of oral mucositis and stage of cancer was significant while the age, gender, religion, diet pattern, personal habits, location of tumor, durational of cancer, duration of treatment had no significant association.

#### **IMPLICATIONS**

The following implications, which are of vital concern in the field of nursing practice, nursing education, nursing administration and nursing research is derived from the study.

#### **Implications for nursing practice**

This can be facilitated by motivating the nurse to,

 Develop the skill in providing efficient nursing care for effective reduction of oral mucositis and promote quality of life

- Teach the head and neck cancer patients during radiation therapy about the effectiveness of various measures for oral mucositis.
- 3) The nurses can give care through 'Evidence Based Practice' to the radiation induced oral mucositis.
- 4) The radiation therapy nurses can follow the practice of sodium bicarbonate oral wash to patients regularly.

## Implications for nursing education

- 1) Ensure that the students learn the physiological changes during radiation therapy.
- 2) Provide adequate clinical exposure for the students to give effective and safe nursing care for head and neck cancer patients with reduction of oral mucositis.
- 3) Make use of available literatures and studies related to measures for oral mucositis during radiation therapy.
- 4) Educate the students about various complementary evidence based therapies for oral mucositis in head and neck cancer patients.
- 5) Encourage the students for effective utilization of research based practices.

#### **Implications for nursing administration**

1) Collaborates with governing bodies to formulate standard policies and protocols to emphasize nursing care during radiation therapy.

- Conduct in-service education programme and continuing nursing education programme for effective management for radiation therapy induced oral mucositis.
- Update their knowledge about current practices and treatment through workshops. Conferences, seminars on different methods to reduce oral mucositis.

#### **Implications for nursing research**

- As a nurse researcher, promote more research on effective management of oral mucositis during radiation therapy in other settings.
- 2) Disseminate the finding of the research through conferences, seminars and publishing nursing Journal.
- Promote effective utilization of research findings on oral mucositis during oral mucositis management for patients with cancer in other site. ( Eg- Lungs, Stomach, pancreas, etc)

#### RECOMMENDATIONS FOR FUTURE RESEARCH

The study recommends the following future research,

- \* The similar study can be conducted with larger samples for better generalization.
- \* A study can be conducted to assess the effectiveness of other measures such as chlorehexidine, sesame oil, bensadamine and honey application for reduction of oral

mucositis among patients with head and neck cancer receiving radiation therapy.

- \* A study can be conducted to the patients receiving chemotherapy.
- \* The similar study can be conducted in other settings.

#### **CONCLUSION**

The purpose of the study was to assess the effectiveness of sodium bicarbonate oral wash on reduction of oral mucositis among patients with head and neck cancer receiving radiation therapy in GVN Hospital at Trichy. The intentional study proved that there is a reduction of oral mucositis among patients with head and neck cancer receiving radiation therapy. The findings of the present study agree with the findings of the previous clinical study, regarding sodium bicarbonate oral wash. The pre-test and post-test mean and standard deviation were calculated. The reduction of oral mucositis was statistically significant at 0.001 level. From the above findings, it is evident that sodium bicarbonate oral wash was found to be effective in reducing oral mucositis among patients with head and neck cancer receiving radiation therapy.

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#### **ANNEXURE I**

# LETTER SEEKING EXPERT'S OPINION FOR CONTENT VALIDITY

#### **From**

301211702

M.Sc (Nursing) II Year,

Thanthai Roever College of Nursing,

Perambalur.

To

#### Respected Sir/madam,

**Sub:** Requisition for content validity of tool.

I am doing M.Sc (Nursing) II Year in Thanthai Roever College of Nursing, Perambalur, Under the Tamilnadu, Dr.M.G.R. Medical University Chennai. As a partial fulfillment of my M.Sc (Nursing) Degree Programme, I am conducting a research on ,"A study to assess the effectiveness of sodium bicarbonate oral wash on reduction of oral mucositis among patients with head and neck cancer receiving radiation therapy". A tool has been developed for the research study. I am sending the above stated for your expert and valuable opinion, I will be thankful for your kind consideration. Kindly return it to the Undersigned.

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Place:	Yours sincerely
Date:	(301211702)

#### **ANNEXURE II**

## LIST OF EXPERTS OPINION FOR CONTENT VALIDITY

#### OF RESEARCH TOOL

1. Prof. Dr. S. Rajina Rani. M.Sc (N), Ph.D,

Prof. Med. Surg. (N) & research guide,

Doctor's college of nursing,

Pudukkottai-622 203.

2. Prof. R. Punithavathi. M.Sc (N),

Principal,

Thanthai Roever College of Nursing,

Perambalur

3. Mrs. KS. Pushpalatha. M.Sc (N), Ph.D,

Asso. Professor,

Shanmuga College of Nursing,

Salem-636 007.

4. Mrs. Angel Priya. M.Sc (N), Ph.D,

Principal,

The Salvation Army Catherine Booth College of Nursing,

Nagarcoil -629 001.

5. Mrs. P. Jasmine Parimala. M.Sc (N), Ph.D,

Principal,

CSI Eliza Caldwel college of nursing,

Thirunelveli.

6. Dr.Xavier.MD. DMRD

Oncologist

**GVN** Hospital

Trichy.

#### ANNEXURE III

# EVALUATION CRITERIA CHECK LIST FOR VALIDATION

#### INTRODUCTION

The expert is requested to go through the following criteria for evaluation. Three columns are given for responses and a column for remarks. Kindly place tick mark in the appropriate column and give remarks.

Interpretation of column

Column I : Meets the criteria

Column II : Partially meet the criteria Column III : Does not meet the Criteria

S.	Criteria	1	2	3	Remarks
No					

- 1 Scoring
  - Adequacy
    - Clarity
  - Simplicity
- 2 Content
  - Logical sequence
  - Adequacy
  - Relevance
- 3 Language
  - Appropriate
  - Clarity
  - Simplicity
- 4 Practicability
  - It is easy to score
  - Does it precisely
  - Utility

Any other suggestion

Signature : Name : Designation : Address :

#### **ANNEXURE IV**

# LETTER FOR SEEKING PERMISSION TO DO THE DISSERTATION WORK IN GVN HOSPITAL TRICHY

#### From

301211702,

M.Sc (N) II year,

Thanthai Roever College of Nursing,

perambalur.

To

The Managing Director,

GVN Hospital,

Trichy.

**Through**: The principal

Thanthai Roever College of Nursing, Perambalur.

Sub: Seeking permission to do the project in GVN Hospital.

#### Respected sir,

I am doing M.SC (N) II year in Thanthai Roever college of Nursing, Perambalur, Under The Tamilnadu, Dr.M.G.R. Medical University Chennai. As a partial fulfillment of my M.sc (N) Degree programme, I am conducting a research among patients who are receiving radiation therapy. I request you to kindly allow me to do the project work in your esteemed institution.

**STATEMENT OF THE PROBLEM**: A study to assess the effectiveness of sodium bicorbanate oral wash on reduction of oral mucositis among patients with head and neck cancer receiving radiation therapy.

I would be deeply grateful if you permit me.

Thanking you

Date: Yours sincerely, Place: (301211702)

#### **ANNEXURE V**

# CERTIFICATE OF ENGLISH EDITING

#### TO WHOMSOEVER IT MAY CONCERN

This is to certify that the dissertation work **A study to assess the effectiveness of sodium bicarbonate oral wash on reducing oral mucositis among patients with head and neck cancer receiving radiation therapy.**Done by 301211702 II year M.sc Nursing, in Thanthai Roever College of Nursing, Perambalur is edited for English language appropriateness by Mr.P.Thangamani MA.B.ed.MPhil, PG Asst(English).

Signature:

## **ANNEXURE VI**

# ஒப்புதல் படிவம்

தந்தை ரோவர் செவிலியர் கல்லூரியில் பயிலும் 301211702 அவர்களால் நடத்தப்படுகின்ற ஆராய்ச்சி நோக்கத்தினைப் பற்றி எனக்கு தெளிவாக தெரிவிக்கப்பட்டது. இதில் பங்கேற்பதற்கு எனக்கு எந்த ஆட்சேபனையும் இல்லை. மேலும் இந்த விவரங்களை வெளியிடுவதற்கும், அச்சிடுவதற்கும் முழு சம்மதம் அளிக்கிறேன்.

கையெழுத்து:

பெயர் :

தேதி :

இடம் :

# ANNEXURE VII

# DATA COLLECTION TOOL

# SECTION: A - DEMOGRAPHIC VARIABLES

			rnish the following details by plac	ing a [ ✓ ]
mark	in appr	opriate choice.		
				Sample no:
1.	Age i	n years		
	a)	21-30		
	b)	31-40		
	c)	41-50		
	d)	51-60		
	e)	61-70		
2.	Gend	er		
	a)	Male		
	b)	Female		
3.	Relig	ion		
	a)	Hindu		
	b)	Muslim		
	c)	Christian		

4.	Diet	Diet pattern			
	a)	Vegetarin			
	b)	Non vegetarian			
5.	Pers	onal habits			
	a)	Cigarette smoking			
	b)	Alcohol consumption			
	c)	Tobacco chewing			
	d)	Cigarette & Alcohol			
	e)	None			
6.	Loca	ation of tumor			
	a)	Head			
	b)	Neck			
	c)	Oral cavity			
7.	Stag	e of cancer			
	a)	I stage			
	b)	II stage			
	c)	III stage			
	d)	IV Stage			

8.	Duration of cancer			
	a)	< 1 year		
	b)	1 – 2 Years		
	c)	> 2 Years		
9.	Dur	ation of Treatment		
	a)	< 1 year		
	b)	1-2  yrs		

c) > 2 yrs

## **SECTION B: ORAL ASSESSMENT GUIDE (EILTERS et al: 1998)**

## OAG scale assists in determining oral health and functions:

- 1. score of 8 indicate mild mucositis (level-1)
- 2. score of 9-16 indicates moderate mucositis (level-2)
- 3. score of 17-24 indicates severe mucositis (level-3)

A category	Mild mucositis(1)	Moderate Mucositis (2)	Severe Mucositis (3)	Score
Voice	Normal	Deeper or raspy	Unable to talk	
Swallow	Normal	Some pain on swallow	Unable to swallow	
Lips	Smooth pink & moist	Dry or cracked	Ulcerated or bleeding	
Tonge	Pink & moist with papillae present	Coated or loss of papillae with shiny appearance with or without redness	Blistered or cracked	
Saliva	Watery	Thick or raspy	Absent	
Mucous membrane	Pink & moist	Reddened coated without ulceration	Ulcerations with or without bleeding	
Gingival	Pink & firm	Edematous	Spontaneous bleeding	
Teeth	Clean or no debris	Plaque or debris in localized area	Generalized plaque or debris along gumline TOTAL SCORE	

OAG scale assists in determining oral health and functions:

# Oral assessment guide

# Item score

Category	Mild mucositis (1)	Moderate mucositis (2)	Moderate sever mucositis (3)
1.	1	2	3
2.	1	2	3
3.	1	2	3
4.	1	2	3
5.	1	2	3
6.	1	2	3
7.	1	2	3
8.	1	2	3