EFFECTIVENESS OF NORMAL SALINE MOUTH WASH VERSUS SODIUM BICARBONATE MOUTH WASH ON ORAL MUCOSITIS AMONG PATIENTS UNDERGOING RADIATION THERAPY IN ONCOLOGY WARD AT GOVERNMENT RAJAJI HOSPITAL MADURAI

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ABSTRACT

Title: Effectiveness of Normal saline mouth wash versus Sodium bicarbonate mouth wash on Oral mucositis among patients undergoing Radiation therapy in oncology ward at Government Rajaji Hospital Madurai. **Objectives:** Assess the level of Oral mucositis on patients undergoing Radiation therapy for Head and neck cancer.To evaluate the effectiveness of   Normal saline mouth wash in Experimental group I and Sodium bicarbonate mouth wash in Experimental Group II .To compare the effectiveness between Normal saline mouth wash and Sodium bicarbonate mouth wash on Oral mucositis among patients undergoing Radiation therapy for Head and neck cancer.To associate the level of Oral mucositis among patients undergoing Radiation therapy with selected demographic and clinical variables. **Hypotheses**: There is a significant difference between the pre and post test level of Oral mucositis among patients undergoing Radiation therapy for Head and neck cancer in Experimental group I and II.There is a significant difference between the post test level of Oral mucositis between Experimental group I and II.There is a significant association between the level of Oral mucositis with selected demographic and clinical variables. **Conceptual frame work**: Modified J.W Kenny's Open system model (1991). **Methodology:** Quantitative approach -True experimental-Comparative design was adopted.Sample size was 60(30 samples in Group I and 30 samples in Group II),assigned by Simple random sampling technique-lottery method.National Cancer Institute- Common toxicity criteria-Oral mucositis grading scale was used to measure the pre test level of Oral mucositis.The intervention was administration of Normal saline mouth wash to Group I and Sodium bicarbonate mouth wash to Group II for 1 minute, 3 times a day for about 2 weeks.On 3rd week, post test was done by using the same tool. **Findings:** By using Mann Whitney "u" test, the median difference between the post test score is 2. The obtained "Z" value is 4.445 at p-value 0.000 level of significance. **Conclusion:** The findings proved that Normal saline mouth wash is very effective than Sodium bicarbonate mouth wash to reduce the level of Oral mucositis.

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LIST OF ABBREVIATIONS

RT   : Radiation therapy

RT-AF   : Altered Fractionation Radiotherapy

cGy   : Centigray

WHO   : World Health Organization

EBT   : External Beam therapy

IMRT   : Intensity Modulated Radiation therapy

TNF   : Tumor Necrosis Factor

NCI-CTC   : National Cancer Institute-Common Toxicity Criteria

RIM   : Radiation induced Mucositis

HNC   : Head and Neck Cancer

OM   : Oral Mucositis

TPN   : Total Parenteral Nutrition

DNA   : Deoxyribo Nucleic acid

FUO   : Fever of unknown origin

NaCl   : Sodium Chloride

ICU   : Intensive Care Unit

Soda bicarb   : Sodium bicarbonate

CHX   : Chlorhexidine

Introduction

CHAPTER I

INTRODUCTION

"The block of granite which was an obstacle in the pathway of the weak, became a stepping-stone in the pathway of the strong."

-Thomas Carlyle

Cancer refers to a large group of potentially lethal disorders characterized by abnormal cell growth and metastasis .Because of its diversity and complexity, cancer has no single treatment nor it can be attributed to a single etiologic agent.The word Cancer came from the Greek words, carcinos and carcinoma to describe tumors, thus calling cancer "karkinos." The Greek terms actually were words to describe a crab, which Hippocrates thought a tumor resembled. Although Hippocrates may have named "Cancer," he was certainly not the first to discover the disease. The history of cancer actually begins much earlier.

Cancer, also known as a malignant tumor, is a group of diseases involving abnormal cell growth with the potential to invade or spread to other parts of the body. Not all tumors are cancerous; benign tumors do not spread to other parts of the body.

Cancer is a leading cause of disease worldwide. Approximately 70% of cancer deaths occur in low- and middle-income countries.30%of cancers could be prevented. In India, around 555000 people died of cancer in 2010, according to estimates published in March 28 ,2013. It is estimated that about 9 million new cancer cases are diagnosed every year and over 4.5 million people die from cancer each year in the world. In India the estimated number of new cancers in India per year is about 7 lakhs and over 3.5 lakhs people die of cancer each year. Out of these 7 lakhs new cancers

1

about 2.3 lakhs (33%) cancers are tobacco related. In Tamilnadu, there would be about 1.5 lakhs cancer cases at any given time and about 35,000 new cancer cases are added to this pool each year. (Jaypee International scientific Journal-vol 2.mar 2013).

In India, around 555 000 people died of cancer in 2010, according to estimates published in *The Lancet* today (March 28, 2012). The study, led by Dr Prabhat Jha, the Director of the Centre for Global Health Research at St. Michael's Hospital, Toronto, in a collaboration with Indian national institutions and the International Agency for Research on Cancer (IARC), used a unique method of projecting cancer deaths for the whole of India based on the patterns of cancer mortality in 2000-2003 in a sample of households. Cancer mortality is a key measure of the cancer burden in a given country and provides an important basis for implementing public health preventive measures.

From the Kidwai Memorial Institute of Oncology: The estimated number of new cancers in India per year is about 7 lakhs and over 3.5 lakhs people die of cancer each year. Out of these 7 lakhs new cancers about 2.3 lakhs (33%) cancers are tobacco related.

India officially recorded over half a million deaths due to cancer in 2011 – 5.35 lakhs as against 5.14 lakh (2009) and 5.24 lakh (2010). Uttar Pradesh recorded 89,224 deaths due to cancer, while Maharashtra saw 50,989 fatalities. The Union health ministry says there are about 28 lakh cases of cancer at any given point of time in India, with 10 lakh new cases being reported annually. The estimated cancer deaths in India are projected to increase to 7 lakh by 2015. (World Health Organization (WHO).

Tobacco use is the cause of about 22% of cancer deaths. Another 10% is due to obesity, a poor diet, lack of physical activity, and drinking alcohol. Other factors include certain infections, exposure to ionizing radiation, and environmental pollutants. In the developing world nearly 20% of cancers are due to infections such as hepatitis B, hepatitis C, and human papillomavirus. Approximately 5–10% of cancers are due to genetic defects inherited from a person's parents.

Warning signs of Cancer includes the following:

C change in bowel habits -sign of colorectal cancer

A sore that does not heal on the skin or in the mouth could be malignant

Unusual bleeding or discharge from rectum, bladder or vagina could be colorectal, prostate, bladder or cervical cancer

Thickening of breast tissue or a new lump in breast

Indigestion or trouble swallowing -cancer of the mouth thoart esophagus or stomach.

Obvious changes to moles or warts could be skin cancer

Nagging cough or hoarseness that persists for four to six weeks could be cancer of lung or throat cancer.

Overall 57.5% of global Head and Neck cancer occurs in Asia, especially in India. Head and neck cancer includes cancer of the paranasal sinuses, nasal cavity, oral cavity, tongue, salivary glands, larynx, and pharynx (including the nasopharynx, oropharynx, and hypopharynx). Head and Neck cancer in India accounted for 30% in all cancers. In India, 60-80% patients present with advanced disease as compared to 40% in developed countries.(10.5005/JP-Journals-10001-1132,Manik Rao Kulkarni)

Nearly all (90-97%) patients receiving radiotherapy in the head and neck develop some degree of mucositis. Of these patients treated with radiotherapy with or

without chemotherapy, 34 to 43% develop severe mucositis. The severity of oral mucositis increases in (1) patients with primary tumors in the oral cavity, oropharynx or nasopharynx, (2) treated with concomitant chemotherapy, (3) receiving a total dose over 5000 Centigray, and (4) treated with altered fractionation radiation schedules. (International Scientific Journals from Jaypee).

There are four standard methods of treatment for cancer: surgery, chemotherapy, radiation therapy, and immunotherapy/biologic therapy. When initially diagnosed with cancer, a cancer specialist (called an oncologist) will provide the patient withcancer treatment options.

Radiation therapy, radiotherapy, or radiation oncology, is therapy using ionizing radiation, generally as part of cancer treatment to control or kill malignantcells. Radiation therapy is commonly applied to the cancerous tumor because of its ability to control cell growth. Ionizing radiation works by damaging the cancerous tissue leading to cellular death. To spare normal tissues (such as skin or organs which radiation must pass through to treat the tumor), shaped radiation beams are aimed from several angles of exposure to intersect at the tumor, providing a much larger absorbed dose there than in the surrounding, healthy tissue.

Typically, one of the following radiation therapy procedures may be used to treat Head and Neck Cancer:

External beam therapy (EBT): a method for delivering a beam of high-energy x-rays to the location of the tumor. The beam is generated outside the patient (usually by a linear accelerator) and is targeted at the tumor site.

Intensity-modulated radiation therapy (IMRT): an advanced mode of high-precision radiotherapy that utilizes computer-controlled x-ray accelerators to deliver

precise radiation doses to a malignant tumor or specific areas within the tumor(2014-TexasOncology).

Aggressive treatment of malignant disease may produce unavoidable toxicities to normal cells. The mucosal lining of the gastrointestinal tract, including the oral mucosa, is a prime target for treatment-related toxicity by virtue of its rapid rate of cell turnover. The oral cavity is highly susceptible to direct and indirect toxic effects of cancer chemotherapy and ionizing radiation.

Oral mucositis is probably the most common, debilitating complication of cancer treatments, particularly chemotherapy and radiation.

Oral mucositis refers to erythematous and ulcerative lesions of the oral mucosa.   ~Davidson (2003)'

Incidence as well as severity may vary from patient to patient. The probability of developing mucositis is dependent upon the treatment. It is estimated that about 40% of patients treated with standard chemotherapy develop mucositis . The risk of developing mucosal injury increases with the number of chemotherapy cycles and previous episodes of chemotherapy-induced mucositis. There is a qualitative difference between the severity of oral mucositis induced by radiation and that of induced by chemotherapy.

Between 30% and 60% of patients receiving radiation therapy for cancer of the head and neck may develop oral mucositis, and greater than 90% of patients receiving concomitant chemotherapy and localized radiation therapy will be affected . The degree and duration of mucositis in patients treated with radiation therapy are related to radiation source, cumulative dose, dose intensity, volume of radiated

mucosa, smoking, alcohol consumption, and oral hygiene. Mucosal erythema occurs in the first week in patients treated with standard 200 Centigray of daily fractionated radiotherapy programs. With daily fractionated programs of <200 Centigray, the severity of mucositis is expected to be low.(Neoplasia. 2004 September; 6).

At Government Rajaji Hospital- Madurai, patients with Head and Neck cancer are receiving around 200-300 Centigray of daily fractionated dose of Radiotherapy.

A variety of patient-related factors appears to increase the potential for developing mucositis after chemoradiotherapy, including the age of the patient, nutritional status, type of malignancy, pretreatment oral condition, oral care during treatment, and pretreatment neutrophil counts.

Today, mucositis is recognized as an epithelial and sub epithelial injury and is thought to develop in a five-stage model: (1)initiation; (2) up-regulation with generation of messengers;(3) signaling and amplification; (4) ulceration with inflammation; and (5) healing (from Sonis ST. A Biological Approach to Mucositis. J Support Oncol 2004; 2:21–36).

1. Initiation of tissue injury: Radiation and/or chemotherapy induce cellular damage resulting in death of the basal epithelial cells. The generation of reactive oxygen species (free radicals) by radiation or chemotherapy is also believed to exert a role in the initiation of mucosal injury. These small highly reactive molecules are byproducts of oxygen metabolism and can cause significant cellular damage.

2. Upregulation of inflammation via generation of messenger signals: In addition to causing direct cell death, free radicals activate second messengers that

transmit signals from receptors on the cellular surface to the inside of the cell. This leads to upregulation of pro-inflammatory cytokines, tissue injury and cell death.

3. Signaling and amplification: Upregulation of proinflammatory cytokines such as tumor necrosis factor- alpha (TNF-α), produced mainly by macrophages, causes injury to mucosal cells, and also activates molecular pathways that amplify mucosal injury.

4. Ulceration and inflammation: There is a significant inflammatory cell infiltrate associated with the mucosal ulcerations, based in part on metabolic byproducts of the colonizing oral microflora. Production of pro-inflammatory cytokines is also further upregulated due to this secondary infection .

5. Healing: This phase is characterized by epithelial proliferation as well as cellular and tissue differentiation , restoring the integrity of the epithelium.

The degree and extent of oral mucositis that develops in any particular patient and site appears to depend on factors such as age, gender, underlying systemic disease and race as well as tissue specific factors (e.g. epithelial types, local microbial environment and function).

Signs and symptoms of mucositis include:

-Red, shiny, or swollen mouth and gums

-Blood in the mouth

-Sores in the mouth or on the gums or tongue

-Soreness or pain in the mouth or throat

-Difficulty swallowing or talking

-Feeling of dryness, mild burning, or pain when eating food

-Soft, whitish patches or pus in the mouth or on the tongue

-Increased mucus or thicker saliva in the mouth

Diagnosis of Mucositis is based on the symptoms the patient is experiencing and the appearance of the tissues of the mouth following chemotherapy, bone marrow transplants or radiotherapy. Red burn-like sores or ulcers throughout the mouth is enough to diagnose mucositis.

Prophylactic measures and treatment options should be employed by practitioners for patients in the appropriate clinical settings. Specific recommendations for minimizing oral mucositis include the following:

- Good oral hygiene.

- Avoidance of spicy, acidic, hard, and hot foods and beverages.

- Use of mild-flavored toothpastes.

- Use of saline-peroxide mouthwashes 3 or 4 times per day.

- Prophylaxis, such as ice-chip cryotherapy, Palifermin (keratinocyte growth factor), and antiviral medications

Some mucosal pharmacologic alterations that have been tried include cryotherapy, Normal saline, Sodium bicarbonate, allopurinol, propantheline, and pilocarpine.

Focal topical application of anesthetic agents is preferred over widespread oral topical administration, unless the patient requires more extensive pain relief. Products such as the following may provide relief:

- 2% viscous lidocaine

- Diphenhydramine solution

- One of the many extemporaneously prepared mixtures combining the following coating agents with topical anesthetics:
  - Milk of magnesia.
  - Kaolin with pectin suspension.
  - Mixtures of aluminum.
  - Magnesium hydroxide suspensions (many antacids).

Systemic analgesics should be administered when topical anesthetic strategies are not sufficient for clinical relief. Opiates are typically used; the combination of chronic indwelling venous catheters and computerized drug administration pumps to provide Patient controlled analgesia has significantly increased the effectiveness of controlling severe mucositis pain while lowering the dose and side effects of narcotic analgesics.

Normal saline solution is also recommended to treat radiation induced mucositis.It can be prepared by adding approximately 1 teaspoon of table salt to 250ml of water. The solution can be administered at room or refrigerated temperatures, depending on patient preference. The patient should rinse and swish approximately 1 tablespoon, followed by expectoration; this can be repeated as often as necessary to maintain oral comfort. Sodium bicarbonate can be added, if viscous saliva is present. Saline solution can enhance oral lubrication directly as well as by stimulating salivary glands to increase salivary flow.

Sodium bicarbonate is a chemical compound, which is also often known as baking soda, bread soda, cooking soda and bicarbonate of soda also nicknamed sodium bicarbonate as sodium bicarb, bicarb soda. Sometimes it is also simply known

as bi-carb, for treating oral mucositis. The Latin name for sodium bicarbonate is Saleratus, which means, 'aerated salt'.

Toothpaste containing sodium bicarbonate has in several studies shown to have a better whitening and plaque removal effect than toothpastes without it. Sodium bicarbonate is also used as an ingredient in some mouthwashes. It works as a mechanical cleanser on the teeth and gums, neutralizes the production of acid in the mouth and also acts as an antiseptic to help prevent infections.(Oral complications of Chemotherapy and Head /Neck Radiation (PDQ/R-11-08-2013).

It is important that cancer patients be on the lookout for signs of mucositis, which should be treated as soon as possible once diagnosed. The consequences of mucositis can be mild, requiring little intervention, but they can also be severe--such as hypovolemia, electrolyte abnormalities, and malnutrition--and even result in fatality.

1.1 NEED FOR THE STUDY

>*"Every area of trouble gives out a ray of hope; and the one*
>*unchangeable certainty is that nothing is certain or unchangeable."*
>**-John Fitzgerald Kennedy**

Oral mucositis is an inflammation and ulceration of the oral mucosa with pseudomembrane formation; it is a potential source of infection which may lead to death. This condition is a frequent and painful debilitating effect of radiotherapy and chemotherapy for cancer, affecting over 40% of patients. The initial presentation is erythema followed by white desquamating plaques, which are painful when touched. Epithelial crusting and a fibrin exudate result in a pseudomembrane and ulceration, which is the more pronounced form of mucositis. Exposure of the richly innervated

underlying stromal connective tissue due to loss of epithelial cells is found in the most severe form of mucositis; this condition is usually seen 5 to 7 days following medication.

Oral mucositis is a distressing toxic effect of radiotherapy and systemic chemotherapy in cancer patients. Mucositis is characterized by atrophy of squamous epithelial tissue, vascular damage, and an inflammatory infiltrate concentrated at the basement membrane and is followed by ulceration. The erythematous atrophic and ulcerative lesions that develop are a consequence of epithelial damage and death mediated through a complex series of molecular and cellular events.It is associated with significant morbidity characterized by pain, odynodysphagia, dysgeusia, malnutrition, dehydration and it also increases the risk for systemic infections in immunocompromised patients.(International cancer of Head and Neck surgery, May-Aug 2010;(2):1-67).

Oral mucositis can occur with cumulative radiotherapy doses as low as 1000-2000 Centigray with therapy administered at a rate of 200 Centigray per day.In greater than half of patients with mucositis, the condition is of such severities so as to require parenteral analgesia, interruption of Radiotherapy, and hospitalization, all of which increase the cost of cancer therapy and have a negative impact on quality of life.

Oral mucositis (OM) induced by anti-neoplastic treatment is a very common side effect occuring in 75–99% patients. It is burdensome and can interfere with treatment administration at full dose. Oral Mucositis generally manifests with signs of erythema and ulceration along with pain and intolerance of hot, cold, acid and spicy foods. Such complications can compromise verbal communication, interfere with oral

drug assumption and require a particular diet. About 40% of patients treated with chemotherapy at standard doses develop mucositis and of these, around 50% develop lesions that require modifications or a suspension of the treatment programme. Oral care protocols are based on two levels of intervention: non-medicated vs medicated strategies. The non-medicated oral care protocol focuses on topical therapy and emphasizes frequent rinsing with 0.9% saline or sodium bicarbonate solutions. (Iranian Journal of Cancer prevention, Vol 5, No 4, Autumn 2012).

The severity of oral mucositis can be evaluated using several different assessment tools. Two of the most commonly used are the World Health Organization (WHO) Oral Toxicity score and the National Cancer Institute Common Toxicity Criteria (NCI-CTC) for Oral Mucositis. *World Health Organization (WHO) grading of mucositis:* This scoring system is widely used in routine clinical practice and clinical trials for the evaluation of mucositis. It is graded from 0 to 4. If the patient has no signs and symptoms, it is graded as 0. If the patient has painless ulcers, edema, or mild soreness, it is graded as 1. If there is painful erythema, edema, or ulcers but able to eat, it is graded as 2. If there is painful erythema, edema, or ulcers but unable eat, it is graded as 3. If there a requirement for parenteral or enteral support, it is graded as 4.

National Cancer Institute Common Toxicity Criteria (NCI-CTC) for Oral Mucositis. It is graded from 0 to 4. If the patient has no signs and symptoms, it is graded as 0. If the patient has Erythema of the oral mucosa, it is graded as 1. If there is patchy pseudomembranous reaction (patches generally ≤1.5cm in diameter and noncontiguous), it is graded as 2. If there is Confluent pseudomembranous reaction (contiguous patches generally ≥1.5cm in diameter), it is graded as 3 and if there is

Necrosis or deep ulceration; may include bleeding not induced by minor trauma or abrasion, it is considered as grade 4.

The morbidity of all mucositis can be profound. It is estimated that approximately 15% hospitalization for treatment-related complications . In addition, severe oral mucositis may interfere with the ability to deliver the intended course of therapy, leading to significant interruptions in treatment, and possibly impacting on local tumor control and patient survival.

Parulekar et al. have estimated that chemotherapy-induced mucositis varies from 40 to 76% in patients treated respectively with standard and high-dose chemotherapy.Nearly all (90% to 97%9,24) patients receiving radiotherapy in the head and neck will develop some degree of mucositis.[16] Of these patients treated with radiotherapy with or without chemotherapy, 34% to 43% will present severe mucositis. As a result, the patient's quality of life is affected, hospital admittance rates are higher, the use of total parenteral nutrition is increased and interruption of treatment is more frequent, all of which compromise tumor control. Mucositis causes 9% to 19% of chemotherapy and radiotherapy interruption.

Mucositis may limit the patient's ability to tolerate chemotherapy or radiation therapy, and nutritional status is compromised. It may drastically affect cancer treatment as well as the patient's quality of life. Thus, the treatment aimed to reduce the symptoms of mucositis should also aim to improve the quality of life.

The majority of patients receiving radiation therapy for head and neck cancer are unable to continue eating by mouth due to mucositis pain and often receive nutrition through a gastrostomy tube or intravenous line. It has been demonstrated that

patients with oral mucositis are significantly more likely to have severe pain and a weight loss of ≥ 5%.Approximately 16% of patients receiving radiation therapy for head and neck cancer were hospitalized due to mucositis. Further, 11% of the patients receiving radiation therapy for head and neck cancer had unplanned breaks in radiation therapy due to severe mucositis. Thus, oral mucositis is a major dose-limiting toxicity of radiation therapy to the head and neck region.(Inernational journal on head and neck surgery-Manik Rao Kulkarni).

The consequences of mucositis can be mild, requiring little intervention, but they can also be severe--such as hypovolemia, electrolyte abnormalities, and malnutrition--and even result in fatality. Oral mucositis can: -Cause pain -Restrict oral intake -Act as a portal of entry for organisms -Contribute to interruption of therapy -Increase the use of antibiotics and narcotics -Increase the length of hospitalization -Increase the overall cost of treatment. Patients with oral mucositis and neutropenia (a type of white blood cell deficiency) have a relative risk of septicemia (a systemic, toxic illness caused by the invasion of the bloodstream by virulent bacteria coming from a local infection) more than 4 times that of patients with neutropenia only. Mucositis is further complicated by the nausea and vomiting that often occur with treatment. Chemotherapy and radiation therapy can affect the ability of cells to reproduce, slowing healing of the oral mucosa, often extending the duration of present mucositis. Patients with damaged oral mucosa and reduced immunity are also prone to mouth infections. Taste loss tends to increase in proportion to the aggressiveness of treatment. Nausea, pain, vomiting, diarrhea, a sore or dry mouth may make eating difficult. Thus, maintaining adequate nutrition is an important challenge for oral cancer patients. Reduction of caloric intake can lead to weight loss, loss in muscle mass strength and other complications, including a decrease in immunity and a longer

healing time from treatments. Physical problems may interfere with food intake and proper nutrition. Patients with head and neck tumors may have mouth or throat pain that can interfere with chewing and compound difficulties in swallowing. Tooth and gum disease can also exacerbate issues.

Mucositis can have a negative impact on the overall treatment experience, especially when severe pain or infections occur. In general, mucositis should be treated conservatively to avoid further tissue irritation and damaging the remaining cells from which the epithelium will regenerate.Plaque control and oral hygiene should be maintained.Hence,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.

The researcher, during the clinical posting observed that the oral mucositis induced by cancer therapy can be reduced by the use of Normal saline or Sodium bicarbonate oral wash. Hence the researcher was intended to assess the extent of effectiveness of Normal saline and Sodium bicarbonate oral wash in reducing oral mucositis among cancer patient.

1.2 STATEMENT OF THE PROBLEM

A study to compare the effectiveness of Normal saline mouth wash versus Sodium bicarbonate mouth wash on Oral mucositis among patients undergoing Radiation therapy in oncology ward at Government Rajaji Hospital Madurai.

1.3 OBJECTIVES OF THE STUDY

- To assess the level of Oral mucositis among patients undergoing Radiation therapy for Head and neck cancer.

- To evaluate the effectiveness of Normal saline mouth wash in Experimental group I and Sodium bicarbonate mouth wash in Experimental Group II

- To compare the effectiveness between Normal saline mouth wash and Sodium bicarbonate mouth wash in Experimental group I and II

- To associate the level of Oral mucositis among patients undergoing Radiation therapy with selected demographic and clinical variables.

1.4 HYPOTHESES

- H_1: There is a significant difference between the pre and post test level of Oral mucositis among patients undergoing Radiation therapy for Head and neck cancer in Experimental group I and II

- H_2: There is a significant difference between the post test level of Oral mucositis between Experimental group I and II.

- H_3: There is a significant association between the level of Oral mucositis with selected demographic and clinical variables.

1.5 OPERATIONAL DEFINITIONS

1. EFFECTIVENESS:

In this study, it refers to the process of comparing the outcome of Normal saline and Sodium bicarbonate mouth wash on Radiation induced mucositis among patients undergoing Radiation therapy for Head and Neck cancer as measured by National Cancer Institute-Common Toxicity Criteria- Oral Mucositis grading scale.

2. NORMAL SALINE MOUTH WASH:

In this study, it refers to rinsing oral cavity of patients with Oral mucositis by using 40 ml of Normal saline solution, which is prepared by adding 1teaspoon of salt (6grams) in 250 ml of water which contains Sodium 150mmol/litre and chloride 150mmol/litre) for 1 minute , thrice a day (8am, 2 pm and 8 pm) for 2 weeks.

3. SODIUM BICARBONATE MOUTH WASH:

In this study, it refers to rinsing oral cavity of patients with Oral mucositis by using 40 ml of Sodium bicarbonate solution, which is prepared by adding 1teaspoon of Sodium bicarbonate (1.3 grams) in 250 ml of water for 1 minute , thrice a day (8am, 2 pm and 8 pm) for 2 weeks.

4. ORAL MUCOSITIS:

In this study it refers to redness, swelling, pain and ulceration that occurs in the oral mucosa as a side effect of Radiation therapy for Head and Neck cancer which can be measured by National Cancer Institute-Common Toxicity Criteria- Oral Mucositis grading scale.

5. PATIENTS UNDERGOING RADIATION THERAPY:

In this study, it refers to patients with Head and Neck Cancer receiving Radiation therapy in Radiation oncology ward at Government Rajaji Hospital Madurai.

6. ONCOLOGY WARD:

In this study, it refers to the ward where the Cancer patients are treated with Radiation therapy.

1.6 ASSUMPTION

The study assumes that,

1. The patients receiving radiation therapy for Head and Neck Cancer develops varying level of Oral mucositis

2. Oral mucositis patients will cooperate for the Normal saline and Sodium bicarbonate mouth wash.

3. Normal saline and sodium bicarbonate mouth wash has no side effects and it helps to heal Oral mucositis.

1.7 DELIMITATIONS

The study is limited to:

1. Patients receiving Radiation therapy for Head and Neck Cancer at Radiation oncology ward, Government Rajaji Hospital Madurai.

2. The sample size is limited to 60 patients with Radiation induced Oral mucositis

3. Data collection period is limited to 4-6weeks

1.8 PROJECTED OUTCOME

This study will yield the expected outcome of the researcher that Radiation induced oral mucositis can be healed by the administration of Normal saline and sodium bicarbonate mouth wash.

Review of Literature

CHAPTER -II

REVIEW OF LITERATURE

"For the creation of a masterwork of literature two powers must concur, the power of the man and the power of the moment, and the man is not enough without the moment".

-James Allen

A review of relevant literatures was collected to generate a picture of what is known about a particular situation. Relevant literature to those sources that are important in providing in depth knowledge related to make changes in practice or to study a selected problem.

This chapter is divided into two parts:

PART I:

Review of related literature on the study

PART II:

Conceptual Framework

PART I

REVIEW OF RELATED LITERATURE

A literature review is a text written by someone to consider the critical points of current knowledge including substantive findings, as well as theoretical and methodological contributions to a particular topic.

-BT Basavanthappa(2012)

A literature review is the process of reading, analyzing, evaluating, and summarizing scholarly materials about a specific topic.

-Polit (2010)

Literatures relevant for this study reviewed and have been organized under the following headings.

1. Review related to the prevalence of Oral mucositis

2. Review related to the effectiveness of Normal saline mouth wash on other conditions

3. Review related to the effectiveness of Sodium bicarbonate mouth wash on other conditions

4. Review related to the effectiveness of Normal saline mouth wash on Oral mucositis

5. Review related to the effectiveness of Sodium bicarbonate mouth wash on Oral mucositis

1. REVIEW RELATED TO THE PREVALENCE OF ORAL MUCOSITIS:

Bjarnason.,(2012).A prospective observational study was conducted at Boston University to examine the burden of mucositis and risk of complications in head and neck cancer patients receiving radiation with or without chemotherapy at Chicago. Oral mucositis was assessed two, four and six weeks by using questionnaire for head and neck cancer. A 12 team instrument was used to measuring mouth and throat soreness and pain and limitation in oral functions. Data was collected at every weeks and results showed that oral mucositis was initially developed who is with radiation therapy and severe mucositis and throat soreness occurred in 76 percent of patients.

David I. Rosenthal, et al;(2013).conducted a Randomized control trial at Mumbaito identify the toxicity associated with Radiation therapy.Radiation-induced mucositis (RIM) is a common toxicity for head and neck cancer (HNC)patients. The frequency has increased because of the use of more intensive altered radiation fractionation and concurrent chemotherapy regimens. The extent of the injury is directly related to the mucosal volume irradiated, anatomic subsite exposed, treatment intensity, and individual patient predisposition.

Fayed,L;(2009).conducted a retrospective study on the various modalities of cancer therapies at California and identified that Chemotherapy and radiation therapy are the most effective treatments of cancer. Both will damage the cancerous and normal cells, which leads to systemic adverse effect. It works by targeting rapidly multiplying cancer cells. Unfortunately, other types of cells in bodies also multiply at high rates. This is why both can cause side effects like hair loss and mucosal damage. Radiation therapy uses certain types of energy to shrink tumors or eliminate cancer

cells. It works by damaging a cancer cell's DNA, making it unable to multiply. Cancer cells are highly sensitive to radiation and typically die when treated. Nearby healthy cells can be damaged and leads to complications such as Mucositis.

Fayed, L.,(2010).A study was conducted to explore the relationship between oral mucositis and selected clinical and economic outcomes of patients with radiation and chemotherapy. Subjects who were participated in this study consisted of 92 patients from eight centers. Oral mucositis scoring system (Oral Mucositis Assessment Scale) was used to assess oral mucositis and examined the relationship between patients peak oral mucositis scores and days with fever, the occurrence of infection, days of total parenteral nutrition (TPN), and days of injectable narcotic therapy, days in hospital, total hospital charges for the index admission, and vital status at 100 days. Results showed that Patients' peak oral mucositis scores reached the full range of possible values (0 to 5) and were significantly (P<0.05) correlated with all of the outcomes and it revealed that oral mucositis is associated with significantly worse clinical and economic outcomes in cancer treatment.

Floyd; (2011). conducted a Randomized clinical trial at Boston and found out tissues with a larger blood supply or a higher cell turnover rate respond more intensely to radiation. In the oral cavity, these areas are the lateral borders and ventral surface of the tongue as well as the soft palate and floor of the mouth. Large amounts of fine vasculature exist in these areas, and radiation leads to vascular congestion and increased interstitial permeability. Within the irradiated fields, mucositis can occur anywhere in the oral cavity. However, it may be found more frequently on the uvula and soft palate because these sites have a higher cell turnover rate than other area. Mucositis is common at the tumor site, especially when the irradiated fields include

the salivary glands or metallic dental restorations. Extensive irradiation of the salivary glands leads to production of glycoproteins and an increased acidity of saliva all of which render patients at higher risk for mucositis.

Jai prakash Agarwal;(2012). conducted a Randomized control trial at Mumbai on the prevalence of Radiation induced oral mucositis among patients undergoing radiation terapy for head and neck cancer.Oral mucositis is one of the debilitating and dose-limiting acute toxicity during (chemo) radiation or for HNC having a major impact on the patient daily functioning, well-being and quality of life. The unplanned interruption of treatment secondary to mucositis may compromise the treatment and the outcomes if not adequately addressed.

John Henry;(2010).A retrospective study was done in the department of Clinical Oncology, Netherlands, to assess the incidence and severity of Radiotherapy-associated oral mucositis on 150 subjects. Mucositis was scored using the World Health Organization (WHO) criteria. Eighty-seven episodes of mucositis occurred in 47 (31%) patients. Twenty-six patients each experienced only one episode, whereas 21 patients had up to eight episodes of mucositis. The 1,281 Radiotherapy cycles that have been analyzed included 87 cycles in which mucositis was observed. In 16 patients (11%) only slight oral mucosal changes were recorded (maximum WHO score 1), while 25 patients (17%) experienced mild to moderate mucositis (maximum WHO score 2), and in 6 patients (4%) mucositis was moderate to severe (maximum WHO score 3). No grade 4 mucositis developed. It was concluded that almost one-third of patients receiving chemotherapy for solid tumors experienced one or more episodes of mild to more severe oral mucositis.

Kumar;(2009).conducted a study to identify the prevalence of Radiation induced oral mucositis among patients receiving Receiving radiotherapy or chemotherapy for Head and Neck cancer. Patients receiving radiotherapy or chemotherapy for Head and Neck cancer will develop some degree of oral mucositis. The incidence of oral mucositis was especially high in patients: (i) With primary tumors in the oral cavity, oropharynx, or nasopharynx; (ii) who also received concomitant chemotherapy; (iii) who received a total dose over 5,000cGy; and (iv) who were treated with altered fractionation radiation schedules. Radiation-induced oral mucositis affects the quality of life of the patients and the family concerned.

Loyd V. Allen;(2011). conducted a Bibliographical review on Oral mucositis.Oral mucositis is a widespread and potentially serious consequence of high-dose chemotherapy and radiotherapy. It seems to be particularly associated with fluorouracil, doxorubicin, and methotrexate. Symptoms, which may include altered taste perception, sores, and varying degrees of pain, usually appear 4 to 5 days after treatment initiation. Treatment is mainly supportive, involving both nonpharmacologic and pharmacologic methods. For compounded preparations such as mouthwashes, there are various formulations that pharmacists can use based on the experience and needs of the individual physician and patient, respectively.

Naidu.R;(2012).conducted a study and concluded that Oral mucositis remain a major source of illness despite the use of a variety of agents to prevent them. Oral mucositis is defined as inflammation and ulceration of the mouth mucosa with pseudo membrane formation; it is a potential source of infection which may lead to death. It manifests first by thinning of oral tissues leading to erythema. As these tissues

continue to thin, ulceration eventually occurs. It is at this stage that the primary symptom of severe debilitating oral pain is most severe.

Napenas J;(2007)conducted a study and identified that the incidence and severity of cancer radiotherapy-associated mucositis is caused in part by changes in the oral bacterial microflora. This systematic review examined the role of oral bacterial microflora changes in the development of oral mucositis during radiotherapy. Thirteen prospective clinical trials were identified, involving 300 patients with 13 different cancer diagnoses.The most frequent Gram-negative species isolated during chemotherapy were from the Enterobacteriaceae family, Pseudomonas sp. and E. coli.

Ramana.V;(2010). conducted a study on the prevalence of Oral mucositis.It occurs secondary to radiotherapy for various solid tumors, the exact pathophysiology of development is not known, but it is thought to be divided into direct and indirect mucositis.Chemotherapy or radiation therapy will interfere with the normal turnover of epithelial cells, leading to mucosal injury; subsequently, it can also occur due to indirect invasion of gram-negative bacteria and fungal species because most of the cancer therapy will cause changes in blood counts.

Ronald., (2011)conducted aprospective studyto assess the toxicity on patients who receives high-dose therapy. Two recently published retrospective analyses of patient complaints following radiotherapy have identified,oral mucositis as the worst toxicity reported by patients, and what is more important is that patients indicated that oncology healthcare team members do a poor job of managing and providing methods of symptom relief. Twenty percent of patients surveyed indicated they received no symptom relief at all.

Steven;(2012). A prospective study was conducted in the Cancer Institute Hospital of Japanese Foundation for Cancer Research, Tokyo, Japan to evaluate of incidence and severity of oral mucositis induced by Radiotherapy in solid tumors and malignant lymphomas.Two hundred twenty-seven patients who received chemotherapy for head and neck cancer, esophageal cancer, colorectal cancer, breast cancer, and malignant lymphomas at the Cancer Institute Hospital between January 2011 and December 2012 were recruited. It was found that OM frequently occurs in patients with various tumors receiving Radiotherapy. Despite low-grade OM, they might cause gastrointestinal adverse events.

Stokman M A, Spijkervet F K, et al;(2009).conducted a cross sectional study which aim to evaluate the effectiveness of interventions for the prevention of oral mucositis in cancer patients treated with head and neck radiotherapy and/or chemotherapy, with a focus on randomized clinical trials,the aim of which was the prevention of mucositis in cancer patients undergoing head and neck radiation, chemotherapy, or chemoradiation. The control group consisted of a placebo, no intervention, or another intervention group. Mucositis was scored by either the WHO, the National Cancer Institute-Common Toxicity Criteria (NCI-CTC) score, or the absence or presence of ulcerations, or the presence or absence of grades 3 and 4 mucositis. The meta-analyses included 45 studies fulfilling the inclusion criteria, in which 8 different interventions were evaluated: i.e., local application of chlorhexidine; iseganan; PTA (polymyxin E, tobramycine, and amphotericin B); granulocyte macrophage-colony-stimulating factor/granulocyte colony-stimulating factor (GM-CSF/G-CSF); oral cooling; sucralfate and glutamine; and systemic administration of amifostine and GM-CSF/G-CSF. Four interventions showed a significant preventive effect on the development or severity of oral mucositis: PTA

with an odds ratio (OR) = 0.61 (95% confidence interval [CI], 0.39-0.96); GM-CSF, OR = 0.53 (CI: 0.33-0.87); oral cooling, OR = 0.3 (CI: 0.16-0.56); and amifostine, OR = 0.37 (CI: 0.15-0.89).

Suman. A;(2010).conducted a study on the incidence and severity of oral mucositis. It will vary from patient to patient, and treatment to treatment. Approximately 400,000 patients per year may develop acute or chronic oral complications during chemotherapy and radiation therapy. It is estimated that there is 40 percent incidence of mucositis in patients treated with chemotherapy, patients receiving radiation have 30 to 60 percent chance and patients receiving radiation therapy in particular to head and neck have chance of 98%.Severe mucositis is commonly seen in patients who receive radiation therapy for cancer of the oral cavity and surrounding structures.

Trotti A, Bellm L A;(2013).conducted a Randomized clinical trial on patients with head and neck cancer receiving RT with or without chemotherapy that reported one or more outcomes of interest. Thirty-three studies (n=6181 patients) met inclusion criteria. Mucositis was defined using a variety of scoring systems. The mean incidence was 80%. Over one-half of patients (56%) who received altered fractionation RT (RT-AF) experienced severe mucositis (grades 3-4) compared to 34% of patients who received conventional RT. Rates of hospitalization due to mucositis, reported in three studies (n=700), were 16% overall and 32% for RT-AF patients. Eleven percent of patients had RT regimens interrupted or modified because of mucositis in five studies (n=1267) reporting this outcome. It gives a conclusion that Mucositis is a frequent, severe toxicity in patients treated with RT for head and neck cancer.

Verdi.,(2011). A descriptive study was conducted to find out the incidence of oral mucositis in cancer treatment. Patients receiving radiation therapy and chemotherapy were included in the study. Patients oral cavity was assessed weekly and identified that patients receiving chemotherapy, oral mucositis usually develops from 10 to 12 days of administration and in radiation therapy mucositis occurred after 7 to 10 days of administration, the incidence and severity was high in patients receiving both.

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2. REVIEW RELATED TO THE EFFECTIVENESS OF NORMAL SALINE MOUTH WASH ON OTHER CONDITIONS

Boston, Denman;(2011) conducted a comparative evaluation of 0.9% Normal saline mouthwash with 0.2% chlorhexidine gluconate in prevention of plaque and gingivitis at department of Periodontology, Pune, Maharashtra, to assess the efficacy of 0.9% Normal saline mouthwash as an anti-plaque agent and its effect on gingival inflammation and to compare it with 0.2% chlorhexidine gluconate by evaluating the effect on plaque and gingival inflammation and on microbial load on 60 subjects. Group A-30 subjects were advised chlorhexidine gluconate mouthwash. Group B-30 subjects were advised experimental Normal saline mouthwash. Parameters were recorded for plaque and gingival index at day 0, on 14th day, and 21st day. On comparison between chlorhexidine and Normal saline mouthwash, percentage reduction of the Plaque Index between 0 and 21st day were 64.207 and 69.072, respectively (P=0.112), percentage reduction of Gingival Index between 0 and 21st day were 61.150 and 62.545 respectively (P=0.595) and percentage reduction of BAPNA values between 0 and 21st day were 42.256 and 48.901 respectively [P=0.142].

Einberg. Stephen;(2012) conducted a systematic review to assess the effectiveness of mouthwashes in preventing and ameliorating chemotherapy-induced oral mucositis at Boston University. Based on study quality, three out of five randomized controlled trials were included in a meta-analysis. The results failed to detect any beneficial effects of chlorhexidine as compared with sterile water, or NaCl 0.9%. Patients complained about negative side-effects of chlorhexidine, including teeth discoloration and alteration of taste in two of the five studies on chlorhexidine. The severity of oral mucositis was shown to be reduced by 30% using 0.9% normal saline mouthwash as compared with sterile water in a single randomized controlled trial.

Felix. Fernandes (2012). A study was conducted to evaluate the oral care of patients with cancer at Pune.The effects of povidone-iodine and normal saline mouthwashes on oralmucositis after high dose chemotherapy on 132 patients who were randomized to use normal saline (n=65) or povidone-iodine diluted 1:100 (n=67) mouthwashes for oral mucositis prophylaxis and treatment after high-dose chemotherapy followed by autologous peripheral stem cell transplantation. No significant difference was found between the groups in respect of oral mucositis characteristics, fever of unknown origin and other infections.

Hadi Darvishi Khezri. Mohammad Ali Haidari Gorji.et al;(2013)conducted a double blinded clinical trial atMazandaran University of Medical Sciences, Sari, Mazandaran, Iran.This study is aimed to determine and compare anti-bacterial effects of the chlorhexidine gluconate 0.2%, herbal mouthwash of matrica (chamomile extracts) 10%, Persica^{TM} 10% and normal saline in intensive care unit patients. In this clinical trial, 80 patients who were admitted in ICU divided

into four groups of 20 patients each one. Researchers applied Persica™ to group one, chlorhexidine gluconate mouthwash 0. 2% to group two and third group received matrica, finally in the control group, normal saline were used. In order to culturing of *Staphylococcus aureus* and *Streptococcus pneumoniae,* salivary samples were obtained without any stimulation after six minimums oral rinsing. The result showed that decreased rate of bacterial colonies after intervention in the whole four groups was significant ($p < 0.001$). The mouthwash of chlorhexidine ($p < 0.001$), Persica™ ($p = 0.008$) and Normal saline($p = 0.01$) had a significant antibacterial effect on *S. aureus* and *S. pneumoniae* ($p < 0.001$). Hence it is concluded that Herbal oral mouthwash of Persica™ and Normal saline has the effect on *S. pneumoniae and S. aureus* of oropharynx area in mechanical ventilation patients.

Muskan. Ronald et al;(2013) conducted a study at Lansdowne, Uttrakhand, India to compare the efficacy of 3 mouth washes such as Aloe vera, Chlorhexidine and Normal saline on Dental plaque. A total of 300 systemically healthy subjects were randomly allocated into 3 groups: Aloe vera mouthwash group (n=100), control group (=100)-chlorhexidene group and saline water-Placebo (n=100). To begin with, Gingival index (GI) and plaque index (PI) were recorded. Then, baseline plaque scores were brought to zero by professionally cleaning the teeth with scaling and polishing. After randomization of the participants into three groups, Subjects were asked to swish with respective mouthwash (Aloe vera mouthwash, 0.2%chlorhexidine gluconate mouthwash, or normal saline) as per therapeutic dose for 4 days. There was a significant reduction on plaque in Normal saline and chlorhexidine groups and no statistically significant difference was observed among them ($p>0.05$). Normal saline mouthwash showed no side effects. The results of the present study indicated that

Normal saline may prove an effective mouthwash due to its ability in reducing dental plaque.

Parwani SR.Parwani RN. et al; (2013) conducted a Comparative evaluation of anti-plaque efficacy of herbal and 0.2% chlorhexidine gluconate mouthwash in a 4-day plaque re-growth study at Modern Dental College campus, Bijasan road, Madhya Pradesh.In this clinical trial, 90 pre-clinical dental students with gingival index (GI) ≤1 were enrolled.The baseline plaque scores were brought to zero by professionally cleaning the teeth with scaling and polishing. After that, randomized 3 groups were made (of 30 subjects each - after excluding the drop-outs) who were refrained from regular mechanical oral hygiene measures. Subjects were asked to swish with respective mouthwash (0.2% chlorhexidine gluconate mouthwash, herbal mouthwash, or normal saline) as per therapeutic dose for 4 days. Then, GI and PI scores were re-evaluated on 5 th day by the same investigator, and the differences were compared statistically by ANOVA and Student's '*t*'- test. It was concluded that 0.2% chlorhexidine gluconate and Norml saline mouthwash remains the best anti-plaque agent. However, when socio-economic factor and/or side-effects of chlorhexidine need consideration, presently tested normal saline mouthwash may be considered as a good alternative.

Rahn,Adamietz *et al*; (2011)conducted a comparative study at University of Caulifornia on 60 subjects. The present study demonstrated that rinsing with salt and soda reduced the incidence and severity of Dental plaque, when compared to Chlorhexidine and other control mouthwashes. It has given the conclusion that rinsing with salt and soda, in addition to a standard prophylaxis regimen, reduced the incidence, severity, and duration of Dentalplaque.

Samuel Vokurka.Eva Bystrická et al; (2012) conducted a randomized multicentre study on chemotherapy induced oral mucositis at Department of Haemato-oncology, University Hospital, Alej Svobody. In this study, 132 patients were randomized to use normal saline (n=65) or povidone-iodine diluted 1:100 (n=67) mouthwashes for OM prophylaxis and treatment after high-dose chemotherapy comprising BEAM or HD-L-PAM. The study groups were well balanced in respect of age, sex, chemotherapy and the number of CD34+ cells in the graft. No significant difference was found between the groups in respect of OM characteristics, fever of unknown origin (FUO) and other infections. The antimicrobial solution was less tolerable for patients. OM occurred significantly more often in females than in males (86% vs 60%, P=0.0016).The mechanical effect of mouthwashes might have a certain importance in FUO prevention. When indicating oral rinses, the patient's individual preference and tolerance of solutions offered should be considered.

Shabanloei. Ahmadi et al; (2011) conducted a randomized, double-blind clinical trial on 83 patients receiving chemotherapy to determine and compare the efficacy of Alloporinol, Chamomile and normal saline mouthwashes in the prevention of chemotherapy-induced Stomatitis, Tarbiat Modares University of Tehran-(Iran). Significant differences were found between Alloporinol, Chamomile and normal saline groups in the scores of the severity of Stomatitis (P=0.017), Stomatitis pain (P=0.027) and in the persistence of Stomatitis. No significant differences were noted among the mean Stomatitis (P=0.59), Stomatitis pain (0.071) and the severity scores of the Alloporinol and Normal saline groups. These findings indicate the equal efficacy of Alloporinol and Normal saline in the prevention of chemotherapy-induced Stomatitis as compared to the Chamomile group. Considering the cost and easy accessibility of Normal saline and its potential therapeutic applicability in the

reduction of the severity of chemotherapy-induced Stomatitis, it has been implied for the prevention of the same.

Zohreh Taraghi. Hadi Darvishi Khezri. et al;(2011)conducted a randomized clinical trial at Imam Khomeini Hospital, Sari, Iran to determine and compare the antibacterial effects of persica® mouthwash 10% (*miswak extract*) and chlorhexidine gluconate 0.2% and 0.9% normal saline in mechanically ventilated patients in intensive care unit (ICU). In this trial, 60 patients who were admitted in a surgical ICU and met the inclusion criteria were randomly divided in two equal intervention and one control groups. In the first intervention group, chlorhexidine gluconate mouthwash 0.2% was used, in the second one, the researchers used persica® herbal mouthwash 10% and finally in the control group, normal saline was used. Data were analyzed using Chi-square and ANOVA tests in SPSS 17 software. Decrease of bacterial counts was significant in all three groups after intervention (p<0.001). The findings of this study indicated that herbal persica® mouthwash and normal saline can be considered as an effective mouth wash in ICU patients due to high resistance of the bacteria to synthetic mouthwashes and side effects of these drugs.

3. REVIEW RELATED TO THE EFFECTIVENESS OF SODIUM BICARBONATE MOUTH WASH ON OTHER CONDITIONS

Berry.Davidson et al; (2011) conducted a single blind randomised comparative study in a 20-bed adult intensive care unit in a university hospital. Patients with an expected duration of mechanical ventilation more than 48 h were eligible. Patients were randomised to one of three study regimens (Group A control, second hourly oral rinse with sterile water, Group B sodium bicarbonate mouth wash

second hourly, and Group C twice daily irrigations with chlorhexidine 0.2% aqueous oral rinse and second hourly irrigations with sterile water).Data from a total of 109 patients were analyzed. Group A 43, Group B 33 and Group C 33 (mean age: 58 ± 17 years, simplified acute physiology score II: 44 ± 14 points). On admission no significant differences were found between groups for all clinical data. While Group B showed a greater trend to reduction in bacterial colonization,(p=0.302). The incidence of ventilator associated pneumonia was evenly spread between Groups A and C (5%) while Group B was only 1%.

Dixon.Berlin et al; (2013) A Study was conducted to see the effect of three test mouthwashes and a control were studied. 0.12% chlorhexidine, 1% povidone-iodine, Salt/sodium bicarbonate, Plain water (control) Coloring agents, sweeteners, and flavoring agents were added to the mouthwashes so that all had identical color and taste. All were alcohol free, 76 completed Compliance was assessed weekly by WHO Stomatis scale. Significant difference in mean Stomatitis scores were observed among all four groups. Post hoc analysis for repeated measure showed a statistically significant difference between the povidone group and control group (p = 0.013) at the end of week 1.At the end week 4, significant difference also were observed between the povidone and salt/soda groups (p =0.16). Thus the study concluded that all the 3 mouthwashes were effective in reduction of Stomtitis.

Eun Choi ;(2011) conducted a randomized controlled trial study at Department of Nursing, Nambu University, Gwangju, South Korea was to compare 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 and assigned to an SB solution group or

CHX-based product group according to acute myelogenous leukemia or acute lymphoblastic leukemia. Patients were asked to rinse their mouth four times a day from the day before chemotherapy started until discharge. The oral microbial count was assessed on a weekly basis from the 1st day of chemotherapy started to the 28th day or to the day of discharge from the hospital. Of all the patients in the SB group, 25.0% developed ulcerative oral mucositis, whereas 62.5% in the CHX group did. 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.

Irwin;(2010) conducted a randomized clinical trial to compare the effectiveness of two different durations of Soda bicarb mouth wash for prevention of 5- Fluorouracil related stomatitis at New york. The trial involved patients who were receiving their first course of a treatment regimen– Fluorouracil plus leucoverin chemotherapy. These patients were randomized to receive Soda bicarb mouth wash twice a day. Evaluation was done using physician judgement of Stomatitis and patient interview. Out of the total 178 patients evaluated it was found that both Soda bicarb groups had less degrees of Stomatitis.

Janjan,N.A et al., (2010) conducted a study to compare the effectiveness of povidone iodine mouthwash and Soda bicarb mouthwash on Stomatitis. The result of the study which reveal that both povidone iodine mouthwash and Soda bicarb mouth wash have effect in reducing the grade of stomatis, but need more evidence for to identify the more effective mouthwash on Stomtitis and need to integrate into health practice.

Kumar,M., (2012) conducted a randomized clinical trial on the effectiveness of povidone iodine mouthwash and Soda bicarb mouth wash on stomatitis at University of Lucknow. Eighty patients with Stomatitis were randomly assigned to receive one of the two alcohol-free test mouthwashes (1% povidone-iodine and Soda bicarb). The patients were instructed to rinse with 10 ml of the mouthwash, twice a day, for a period of 6 weeks. Mucositis was assessed at baseline and at weekly intervals during radiation therapy, using the World Health Organization criteria for grading of mucositis. Among the 76 patients who completed the study, patients in the Soda bicarb group had significantly lower scores when compared to the povidone iodine group. This study shows that use of Soda bicarb mouthwash can reduce the severity and delay the onset of Stomatitis.

Lewin;(2012) A study was conducted on client to see the effect of baking soda oral rinse in reducing the severity of stomatitis. The patient presented with a change in his voice, weight loss, and pain in his throat for two months. Nurse planed (a) rinsing his mouth with baking soda several times a day, (b) using abioadherent oral gel mixed with water every eight hours, and (c) applying the patient already had been prescribed nystatin to rinse with and expectorate. As the treatment sessions continued, performance status remained at 90 and his stomatitis scale wavered from 2.0–3.0 (on a scale from0 = no stomatitis to 4 = tissue necrosis, significant bleeding, and life-threatening consequences).Through the use of multiple interventions during his therapy, the client was able to reduce his pain, maintain a good performance status, and maintain his lifestyle without severe changes. The study concluded that oral rinse with baking soda are aimed at preventing minimizing Stomatitis.

Michael;(2011) conducted a systematic review to assess the effectiveness of mouthwashes on chemotherapy-induced Stomatitis at British University. Based on study quality, three out of five randomized controlled trials were included. The results failed to detect any beneficial effects of chlorhexidine as compared with Soda bicarb, or NaCl 0.9%. Patients complained about negative side-effects of chlorhexidine, including teeth discoloration and alteration of taste in two of the five studies on chlorhexidine. The severity of oral mucositis was shown to be reduced by 30% using Soda bicarb mouthwash as compared with Chlorhexidine in a single randomized controlled trial.

Ramkumar.D.N.Kapoor et al; (2013) conducted a randomized clinical trial at Department of Orthodontics, Lucknow , to compare the microbicidal and clinical effectiveness of various mouth washes in controlling Gingival disease and dental cries during fixed orthodontic treatment. Fourty four patients aged between 11-18 years were divided into four groups according to the type of mouth wash used. Trial of 2% Chlorhexidine, essential oil mouth wash and soda bicarb mouth wash. The result of the study revealed that that the Soda bicarb showed maximum potential for the control of pathogenic organism and controlling disease and plaque accumulation.

Reimer;(2012) conducted a randomized controlled trial double blind was conducted to assess the effectiveness of commonly used mouthwash for the prevention and treatment of dental plaque for the patients undergoing orthodontic treatment at Marthas Hospitl Ludhiana. Patients undergoing orthodontic procedures were included in this study. The severity of dental plaque was assessed daily, weekly or less often. The mouthwashes used for this study were chlorhexidine mouthwash, povidone iodine mouthwash and Soda bicrb mouthwash. A result shows that

chlorhexidine mouthwash was not found to be more effective than povidone iodine mouthwash and with Soda bicarb mouthwash.

4.REVIEW RELATED TO THE EFFECTIVENESS OF NORMAL SALINE MOUTH WASH ON ORAL MUCOSITIS.

Dodd.Dibble et al; (2012). Randomized clinical trial of the effectiveness of 3 commonly used mouthwashes to treat chemotherapy-induced mucositis. The effectiveness of 3 mouthwashes to treat chemotherapy-induced mucositis was comparable; salt and soda, chlorhexidine, and "magic" mouthwash (lidocaine, Benadryl and Maalox) -as comparable results were obtained, authors suggest to use salt and soda as is the least costly mouthwash -non significant differences for pain ratings among the mouthwashes was observed .This study concludes that given the comparable effectiveness of the mouthwashes, the least costly was salt and soda mouthwash.

Eli Lilly;(2014)conducted a clinical trial at United states on the effects of povidone-iodine and normal saline mouthwashes on oral mucositis was compared in patients after high dose chemotherapy. In the study, 132 patients were randomized to use normal saline (n=65) or povidone-iodine diluted 1:100 (n=67) mouthwashes for oral mucositis prophylaxis and treatment after high-dose chemotherapy followed by autologous peripheral stem cell transplantation. The study groups were well balanced in respect of age, sex, chemotherapy and the number of CD34+ cells in the graft. No significant difference was found between the groups in respect of oral mucositis characteristics, fever of unknown origin and other infections. The antimicrobial solution was less tolerable for patients. Oral mucositis occurred significantly more often in females than in males (86% vs 60%, P=0.0016) and was worse and of longer

duration. This study concluded that frequent mechanical cleansing of the mouth by a simple saline solution is more effective compared to more sophisticated mouthwashes which can be harmful.

Fernandes;(2013).conducted a study on topical agents which include topical anesthetics such as viscous lidocaine are frequently combined with other agents to make mouthwashes. Other commonly used ingredients include dyphenhydramine, milk of magnesia, and chlorhexidine. A randomized clinical trial performed with 142 patients to evaluate the effectiveness of three different mouthwashes for chemotherapy-induced mucositis, and found evidence to support only routine oral hygiene, and the use of the inexpensive salt and soda mouthwash was effective. Other topical agents that may demonstrate a role in pain management include doxepin, a trycyclic antidepressant, topical morphine sulphate, topical capsaicin and sucralfate.

Goodman.M;(2009).conducted a study on various agents which are used in order to reduce the incidence and severity of oral mucositis. Normal saline is an agent that appears to be effective in controlling infection. Sodium bicarbonate also appears to be beneficial in controlling radiation or chemotherapy induced oral mucositis. An ideal oral rinse for patients with radiation or chemotherapy induced oral mucositis should reduce the oral microflora, promote reepithelization of soft tissue lesion, normalize the pH of oral fluids and be nontoxic.Normal saline and Sodium bicarbonate mouthwash have all these qualities, Patients with radiation or chemotherapy induced oral mucositis were rinse their mouth with 10 ml of mouthwash, twice a day for healing of oral mucositis.

Gulavita. S et al., 2012).A randomized double blind study was conducted to determine whether Normal saline mouthwash could alleviate radiation induced oral mucositis. Patients were scheduled to receive radiation therapy to include greater than one third of oral cavity mucosa were selected for the study. Twenty five patients were randomized to receive the mouthwash, while twenty four received placebo mouthwash. The result showed that Normal saline mouthwash provided benefit to patient receiving radiation therapy to the oral mucosa and suggesting that Normal saline mouthwash is determental in clinical situation.

John Dew;(2012).A clinical trial was conducted at Spainto evaluate the effectiveness of ice chips and normal saline to prevent or reduce oral mucositis in patients treated with high doses of Alkeran. The trial included 40 patients with multiple myeloma. Twenty-one patients received ice chips (cryotherapy) 30 minutes prior to treatment and continued to use the ice chips for six hours. Nineteen patients received normal saline instead of ice chips. Severe oral mucositis occurred in 74% of patients treated with ice chips, compared with 14% of patients treated with saline. Individuals treated with normal saline received fewer narcotics and nutrition through a vein than those treated with ice chips.The researchers concluded that normal saline significantly reduces the incidence of severe oral mucositis in patients receiving treatment with high doses of Alkeran.

Kumar Madan P. D. Sequeira;(2010).A Randomized clinical trial was done with micronized sucralfate verses normal saline mouth washes on oral mucositis All patients in this randomized clinical trial carried out a systematic oral hygiene protocol called the PRO-SELF: Mouth Aware (PSMA) Program. Patients who developed Radiation Therapy-induced mucositis anytime during their course of Radiation

Therapy were randomized to one of the two mouthwashes and followed to the completion of Radiation Therapy and at one month following Radiation Therapy. Thirty patients successfully completed the study. At the one-month follow-up assessment no significant differences were found between the mouthwashes in MacDibbs scores or pain ratings (upon swallowing. The findings from this trial provide important clinical that there is no significant difference in efficacy between micronized sucralfate and normal saline, but use of the less costly normal saline is prudent and cost-effective.

Marylin J. Suzanne L et,al;(2010). Conducted a Randomized control trial at Sanfrancisco to test the effectiveness of 3 mouthwashes used to treat chemotherapy-induced mucositis. The mouthwashes were as follows: salt and soda, chlorhexidine, and "magic" mouthwash (lidocaine, Benadryl, and Maalox).A randomized, double-blind clinical trial was implemented in 23 outpatient and office settings. Participants were monitored from the time they developed mucositis until cessation of the signs and symptoms of mucositis, or until they finished their 12-day supply of mouthwash. All participants followed a prescribed oral hygiene program and were randomly assigned a mouthwash.In 142 of 200 patients, there was a cessation of the signs and symptoms of mucositis within 12 days. This study yield the conclusion that given the comparable effectiveness of the mouthwashes, the least costly was salt and soda mouthwash.

Potting.C;(2006). performed a systematic review at Japan,to assess the effectiveness of mouthwashes in preventing and treating chemotherapy-induced oral mucositis. Based on study quality, three out of five randomized controlled trials were included in a meta-analysis. 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 NaCl 0.9% mouthwash as compared with povidone-iodine mouthwash in a single randomized controlled trial. These results do not support the use of chlorhexidine mouthwash to prevent and treat oral mucositis.But cost effective NaCl 0.9% is effective for reducing the severity of Oral mucositis.

Satheeshkumar PS. Chamba MS;(2011).conducted a study at Trivandrum on twenty-four patients who underwent radiation therapy for oral cancer and subsequently developed oral mucositis were included in the study. They were randomly allocated into two groups on noticing grade I mucositis (erythema). The study group was advised to use Normal saline mouthwash and sodium bicarbonate mouth wash for the control group. A weekly follow-up evaluation of body weight, food intake, pain and grading of mucositis were made during the radiation treatment period and post radiation treatment period. Both the groups were statistically identical. All the 24 patients in both the groups passed through grade 3 mucositis on the last day of radiotherapy. However, 10 patients in the control group and only one patient in the study group entered to grade 4 mucositis. The control group took more than 45 days to resolve while the study group took only less than 28 days. The results of the study were evaluated and tried to formulate a hypothesis so as to explain the less severity and early resolution of mucositis in the study group.

Setiawan.S; (2004). A randomized control trail was done to assess the effectiveness of Normal saline mouthwash on oral mucositis in patients receiving Radiotherapy, total of 130 patients were participated in a clinical trial with pre-post design and single blind system. Subjects were divided into two groups using Normal saline mouthwash and placebo as control group. Patients in two groups received daily oral hygiene instructions and were examined daily until the mucositis heal. The results showed that mucositis and its related pain were disappeared after 8 to 14 days and 13 to 14 days respectively.

Sonis.et al;(2001). Conducted a study on 35 patients, all receiving radiation therapy, 12 of them received both chemotherapy and radiation therapy concurrently, for confirmed squamous cell or adenocarcinoma cancer. They were evaluated utilizing NeutraSal® against the standard of care salt and soda rinses. Historical degrees of the side effects using the standard of care option and the NeutraSal®. End points were patients performance status pain level using 0-10 dysphagia ability to eat orally weight loss control and mucosities degree 0-10. Taste return after treatment completed 0 to 2 months.Patients were evaluated weekly during treatment and approx. 4-6 weeks for the acute toxicities and subquent follow up every 4-8 week for 9 months post treatment. Among the 35 patients evaluated, it was found that the oral toxicities was found that the oral toxicities associated with radiation therapy were significantly lower than historical averages when salt and soda was utilized.

5. REVIEW RELATED TO THE EFFECTIVENESS OF SODIUM BICARBONATE MOUTH WASH ON ORAL MUCOSITIS

Calwin;(2011)conducted a comparative study at Spain, to determine the efficacy of a mouthwash in relieving mucositis-induced discomfort in patients receiving radiotherapy, (lidocaine, diphenhydramine and sodium bicarbonate mouthwash) when they developed mucositis of any severity. The response to the mouthwash was reported on a self-assessment scale. Patients' response data were analyzed with reference to: (1) relief throughout the duration of mucositis and (2) relief during the worst stage (for each episode) of mucositis. The average duration of mucositis was 7.9 days (range 3–23 days), and the mean duration of the worst stage of mucositis was 4.81 days (range 2–13 days). The mean mucositis severity score was 1.9 (range 1–4), and the average self-assessment (response) score was 0.81 (range 0–2). The mean mucositis score during the worst stage of mucositis was 2.25 (range 1–4), and the average self-assessment (response) score during the worst stage of mucositis was 0.91 (range 0–2.7). These results suggest that this three mouthwash provides effective symptomatic relief in patients with chemotherapy-radiotherapy induced oral mucositis.

Chamba;(2010). A Bibliographical review was conducted in the School of nursing, University of California, San Francisco on Review of the current treatments for Radiation Induced Oral Mucositis in Patients with head and neck cancer with the purpose to review the research studies on current treatment for radiation therapy- (RT) induced mucositis in patients with head and neck cancer. Four types of agents have been evaluated for the management of RT-induced oral mucositis in patients with head and neck cancer and it was concluded that oral mucositis remains the most common complication among patients with head and neck cancer. The most effective

measure to treat RT-induced mucositis in patients with head and neck cancer is frequent oral rinsing with a bland mouthwash, such as saline or a sodium bicarbonate rinse, to reduce the amount of oral microbial flora.

Cheng. K.F.,(2003).A prospective randomized cross over study was conducted at California to assess the effectiveness of two oral care protocols differing in the type of mouthwashes. The mouthwashes used for this study were soda versus turmeric. Forty patients undergoing chemotherapy were allocated to receive soda first and then turmeric protocol. Subjects were evaluated in intervals of 3 to 4 days by using WHO grading for mucositis and 10cm visual analogue scale for oral symptom evaluation. The results showed that a significant difference in mean area of oral mucositis grade for subjects received soda mouthwash compared to those received turmeric and revealed that saline may be helpful in palliating mucositis symptoms in chemotherapy.

Delwin;(2012).A cohort study was conducted in the School of nursing, University of California, San Francisco on Review of the current treatments for Radiation Induced Oral Mucositis in Patients with head and neck cancer with the purpose to review the research studies on current treatment for radiation therapy- (RT) induced mucositis in patients with head and neck cancer. Four types of agents have been evaluated for the management of RT-induced oral mucositis in patients with head and neck cancer and it was concluded that oral mucositis remains the most common complication among patients with head and neck cancer. The most effective measure to treat RT-induced mucositis in patients with head and neck cancer is frequent oral rinsing with a bland mouthwash, such as saline or a sodium bicarbonate rinse, to reduce the amount of oral microbial flora.

Hee-Seung Kim;(2012).conducted a randomized controlled trial at Korea. Forty-eight patients were randomly selected and assigned to an Sodium bicarbonate solution group or Chlorhexidine-based product group according to acute myelogenous leukemia or acute lymphoblastic leukemia. Patients were asked to rinse their mouth four times a day from the day before chemotherapy started until discharge. The World Health Organization mucositis grade, patient-reported Oral Mucositis Daily Questionnaire, and clinical signs associated with infection were assessed on a daily basis. The oral microbial count was assessed on a weekly basis from the 1st day of chemotherapy started to the 28th day or to the day of discharge from the hospital. The onset of oral mucositis was later in the SB group than the Chlorhexidine group. As a result of this study, it was found that oral care by Sodium bicarbonate group solution for acute leukemia patients undergoing chemotherapy was an effective intervention to improve oral health.

Janjan,N.A et al., (2000).conducted a comparative study on comparing the effectiveness of on radiation or chemotherapy induced oral mucositis. There are studies which reveal that both Normal saline and Sodium bicarboanate mouthwash have effect in reducing radiation or chemotherapy induced oral mucositis but need more evidence for to identify the more effective mouthwash on radiation or chemotherapy induced oral mucositis and need to integrate into health practice.

Jenmick;(2011).A retrospective study was conducted toinvestigate whether medicated mouthwashes are effective in the prevention of oral mucositis among patients undergoing radiotherapy. The severity of mucositis was scored using a World Health Organization (WHO) instrument (or an adaptation of this scale), The instructions for use ranged from a 20 second rinse twice daily to a one minute rinse

four times daily. The intervention mouthwashes were sodium bicarbonate mouthwash without the active ingredient (chlorhexidine or chamomile), amine-stannous fluoride or water. Two authors independently performed the study selection. Disagreements were resolved through discussion with a third reviewer. Chlorhexidine mouthwash was not found to be more effective than control, the results do not support the use of chlorhexidine mouthwash in the prevention of oral mucositis, and hence the author concluded that the use of sodium bicarbonate rather than chlorhexidine mouthwash for the prevention of oral mucositis associated with radiotherapy is effective.

Laurie MacPhail.Ai-Shan Shih;(2003).conducted a study to compare the efficacy of micronized sucralfate (Carafate R) mouthwash and salt & soda mouthwash in terms of the severity of the mucositis, the severity of mucositis-related pain, and the time required to heal RT-induced mucositis in patients with HNC. Severe mucositis and related pain can interfere with the ingestion of food and fluids, so patients' body weights were measured as well. All patients in this randomized clinical trial carried out a systematic oral hygiene protocol called the PRO-SELF: Mouth Aware (PSMA) Program. Thirty patients successfully completed the study. The typical participant was male (70%), married/partnered (70%), White (63%), not working or retired (73%), and had an average of 14.5 years of education (SD = 3.7). T-tests and Chi-square analyses with an alpha set at 0.05 were used to compare differences between the two mouthwashes. No significant differences were found in the number of days to onset of mucositis (i.e., 16 +/- 8.4 days). The findings from this trial provide important clinical information regarding no significant difference in efficacy between micronized sucralfate and salt & soda, use of the less costly salt & soda is prudent and cost-effective.

Linda. Derwik;(2010).A prospective Study was conducted to see the effect of three test mouthwashes and a control were studied. 0.12% chlorhexidine, 1%

povidone-iodine, sodium bicarbonate, Plain water (control) Coloring agents, sweeteners, and flavoring agents were added to the mouthwashes so that all had identical color and taste. All were alcohol free, 76 completed Compliance was assessed weekly by WHO oral assessment scale .Significant difference in mean mucositis scores were observed among all four groups. Post hoc analysis for repeated measure showed a statistically significant difference between the povidone group and control group (p = 0.013) at the end of week 1.At the end of week 2, povidone, chlorhexidine and soda groups differed significantly from the control group at end of week 4, significant difference also were observed between the povidone,chlorhexidine and soda groups (p =0.16). Thus the study concluded that all the 3 mouthwashes were effective in reduction of mucositis.

Linda;(2012).A cohort study was conducted on client to see the effect of baking soda oral rinse in reducing chemotherapy and radiation therapy induced stomatitis and mucositis The patient presented with a change in his voice, weight loss, and pain in his throat for two months. Following biopsy, he was diagnosed with infiltrating moderately differentiated carcinoma of the right tonsil; he was started with treatment, which consisted of chemotherapy and radiation therapy (40 sessions). He developed mucositis and stomatitis. Identified his pain as a 10+ on the visual analog scale, and he had extremely thick saliva and xerostomia. Nurse planed (a) rinsing his mouth with baking soda intrepid water several times a day, (b) using abioadherent oral gel mixed with water every eight hours, and (c) applying the patient already had been prescribed nystatin to rinse with and expectorate. As the treatment sessions continued, performance status remained at 90 and his stomatitis scale wavered from 2.0–3.0 (on a scale from0 = no stomatitis to 4 = tissue necrosis, significant bleeding, and life-threatening consequences).The study concluded that oral rinse with baking soda are aimed at preventing or minimizing oral mucositis.

PART II

CONCEPTUAL FRAME WORK

A conceptual frame work can be a set of concepts and assumptions that integrate them into a meaningful configuration (Fwcett, 2012); the concept is a thought, idea or mental image framed in mind in response to learning something new. A frame work is a basic structure supporting anything.

A conceptual framework deals with abstraction (concept), which is assembled by nature of their relevance to a common theme (Chris tension J Paula and Kenny Janet W, 2013).

To describe the relationship of concepts in the study, **open system model** by **J.W.Kenny's (**1991) is used. Open system model serves as a model for reviewing people as interacting with the environment. Theoretical framework provides a certain frame work of reference for clinical practice, research and education.

"Open systems model is a set of related definitions, assumptions and prepositions which deals with reality as an integrated hierarchy." systems model focuses in each system as a whole, but pays particular attention to the interaction of its part or subsystems. A system is a group of elements that interact with one another in order to achieve a goal.

The following are the major concepts of the theory.

INPUT:

Input is the matter, energy and transformation that enter the system. In the present study, the input is the characteristics of the patients with Radiation induced oral mucositis like Age, gender, marital status, educational status, occupation, family monthly income, duration of illness, stage of cancer, nutritional status, history of co-morbidity, frequency of taking oral hygiene, past history of cancer treatment, lifestyle habits, and past history of using any dentures. In this open system model, the level of Radiation induced oral mucositis was assessed and measured using National cancer Institute- common toxicity criteria- Radiation induced oral mucositis grading scale.The level of Radiation induced oral mucositis can be graded as 0,1,2,3 and 4 based on the severity of patient condition.

THROUGHPUT:

Throughput is the use of biologic, psycho logic and socio-cultural sub systems to transform the inputs.The present study considers throughput was the administration of Normal saline and sodium bicarbonate mouth wash for patients with Radiation induced oral mucositis .

OUTPUT:

Output is the return of matter, energy and information to the environment in the form of both physical and psychosocial behavior. The expected outcome was obtained by assessing the level of Radiation induced oral mucositis through National cancer Institute- common toxicity criteria- Radiation induced oral mucositis grading scale.The output was considered in times of change in post test level of Radiation induced oral mucositis by using National cancer Institute- common toxicity criteria- Radiation induced oral mucositis grading scale.

FEEDBACK:

Differences in pre and post test scores were observed from the subjects by using National cancer Institute- common toxicity criteria- Radiation induced oral mucositis grading scale. In the present study, the feedback was considered as a process of effectiveness of Normal saline and sodium bicarbonate mouth wash on Radiation induced oral mucositis . It was assessed by comparing the pre and post test scores, through Wilcoxon signed rank test. The effectiveness between both interventions were assessed through Mann Whitney "u" test and the association between the level of Radiation induced oral mucositis with their demographic variables were assessed through chi-square test.

INPUT

THROUGH PUT

OUTPUT

Demographic variables:
Age, Gender, Religion Marital status, Educational status, Occupation, Monthly family income

Clinical variables:
Duration of Cancer Stage of Cancer, Nutritional status History of co-morbid conditions, Frequency of taking oral hygiene, Past history of chemo/Radiation therapy, Life style habits, Fractionated dosage of Radiotherapy, History of using any dentures

P R E T E S T

Assessment of samples by National Cancer Institute – common toxicity criteria - oral mucositis grading scale and allotting the samples in Experimental group I and II

Experimental Group I

Administration of normal saline mouth wash for 1 minute, thrice a day for two weeks.

- It can enhance oral lubrication
- Increase salivary flow

Thus it promotes the healing of oral mucositis

Experimental Group II

Administration of sodium bicarbonate mouth wash for 1 minute, thrice a day for two weeks.

- It can maintains a healthy PH in mouth
- It promotes clean and fresh oral environment

Thus it promotes the healing of oral mucositis

P O S T T E S T

Oral mucositis symptoms effectively reduced

EVALUATION
Grade 0 – No Oral Mucositis
Grade 1 – Mild Oral Mucositis
Grade 2 – Moderate oral Mucositis
Grade 3 – Severe oral Mucositis
Grade 4 – Life Threatening

Oral mucositis symptoms considerably reduced

FEED BACK

FIGURE.1. MODIFIED J.W KENNYS OPEN SYSTEM MODEL (1991)

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Methodology

CHAPTER - III

RESEARCH METHODOLOGY

Research methodology is a pathway by which the researcher intends to solve the problem systematically. It involves the series of procedures in which the Investigator starts from initial identification of the problem to its final conclusion.

Methodology is an investigation of the ways of obtaining, organizing and analysis of data. This chapter deals with the description of the methods and different steps used for collecting and organizing data. It includes research approach, research design and setting of the study, sample and sampling technique. It further deals with development and description of tool, procedure for data collection and plan for data analysis. This study was done to compare the effectiveness of Normal saline mouth wash versus Sodium bicarbonate mouth wash on Oral mucositis among patients undergoing Radiation therapy in Oncology ward at Government Rajaji Hospital Madurai.

3.1 RESEARCH APPROACH:

In this study, a Quantitative approach was adopted by the Researcher to compare the effectiveness between Normal saline mouth wash and Sodium bicarbonate mouth wash on Oral mucositis among patients undergoing Radiation therapy in oncology ward at Government Rajaji Hospital Madurai.

3.2 RESEARCH DESIGN:

Research design is the Researchers overall plan for obtaining answers to the research questions or for testing the research hypothesis.

The Researcher adopted True experimental-Comparative design for this study.

	GROUP	PRE TEST	INTERVENTION	POST TEST
R	Experimental group I	O_1	X	O_2
	Experimental group II	O_1	X	O_2

R   : Random assignment

Experimental Group I : Subjects receiving Normal saline mouth wash

Experimental Group II : Subjects receiving Sodium bicarbonate mouth wash

O_1 : Observation before intervention

O_2 : Observation after intervention

X   : Intervention

3.3 RESEARCH VARIABLE:

 INDEPENDENT VARIABLE

An independent variable is the one that is believed to cause or influence dependent variable. It stands alone and does not depend on another (Polit, Hunger1999).

In this study, the independent variable is Normal saline and Sodium bicarbonate mouth wash administered to the patients with Oral mucositis.

DEPENDENT VARIABLE

A dependent variable is the outcome variable of interest, the variable that is hypothesized to depend on or caused by another variable. In this study dependent variable is the level of Oralmucositis.

DEMOGRAPHIC VARIABLE

Age, gender, religion, marital status, educational status, occupation and family monthly income.

CLINICAL VARIABLES:

Duration of illness,stage of cancer, nutritional status, history of co-morbidity frequency of taking oral hygiene, past history of Chemo/Radiation therapy, lifestyle habits and past history of using any dentures.

3.4 SETTING OF THE STUDY:

Setting is the physical location and condition in which data collection takes place. The study was conducted in the Radiation oncology ward at Government Rajaji Hospital, Madurai. It is the second biggest medical college hospital in Tamil nadu. It has all specialty departments and caters to the health needs of the people of the southern Tamil nadu. The Oncology department has three wings- Medical, Surgical and Radiation, each with the bed strength of 50,60 and 43 respectively, with an annual census of 7000 patients. Average of 500 new cases and 700 old cases are attending the Out-patient per month and an average of 300 patients admitted in oncology wards\month. This hospital is selected because of the researcher doing her post graduation in the College of Nursing, Madurai Medical College, Madurai.

3.5 POPULATIONOF THE STUDY:

TARGET POPULATION:

Target population were Head and Neck cancer patients with Radiation induced oral mucositis.

ACCESSIBLE POPULATION:

The study populations were Head and Neck cancer patients with Radiation induced oral mucositis admitted in Radiation oncology ward at Government Rajaji Hospital Madurai.

3.6 SAMPLE:

Head and neck cancer patient's with Radiation induced oral mucositis and who fulfill the inclusion criteria in the Radiation Oncology ward at Government Rajaji hospital, Madurai.

3.7 SAMPLE SIZE:

The total sample size was 60. Among the sixty samples, 30 samples were allotted for Experimental group I and 30 samples were allotted for Experimental group II.

3.8 SAMPLING TECHNIQUE:

The sample for this study was selected through Simple random sampling technique-lottery method.

3.9 CRITERIA FOR SAMPLE SELECTION:

INCLUSION CRITERIA:

- Subjects of Head and neck cancer with Radiation induced oral mucositis at Radiation oncology ward in Government Rajaji Hospital Madurai.

- Subjects with both gender

- Subjects came under the age group of 20 -60 years

- Subjects receiving Radiation therapy for more than a week

- Subjects who are all conscious and able to follow the instructions.

- Subjects who can speak and understand Tamil.

EXCLUSION CRITERIA:

- Subjects who are not willing to give consent.

- Subjects who are critically ill

- Patients who are receiving Chemotherapy.

3.10 DEVELOPMENT AND DESCRIPTION OF THE TOOL:

The tool used in the study consists of two sections:

SECTION A

Semi structured interview questionnaire, which is prepared by the Researcher and validated by the Experts. It comprises 7 number of items of Demographic variables such as Age, gender, religion, marital status, education, occupation and family income and 9 number of items of Clinical variables like Duration of illness, stage of cancer, nutritional status, history of co-morbidity, frequency of taking oral hygiene, past history of chemo/radiation therapy, lifestyle habits, fractionated dosage of Radiation therapy per day and history of using any dentures.

SECTION B

The second tool was assessment of the level of oral mucositis by using National Cancer Institute-Common toxicity criteria-Oral mucositis grading scale. It is a Standardized tool.

SCORING KEY

SECTION A

No scoring was allotted for the baseline variables.

SECTION B

High score of the National Cancer Institute-Common toxicity criteria-Oral mucositis grading scale will be life threatening .The grading are as follows:

SL.NO	GRADE	LEVEL OF MUCOSITIS
1	0	No mucositis
2	1	Mild mucositis
3	2	Moderate mucositis
4	3	Severe mucositis
5	4	Life threatening condition

3.11 CONTENT VALIDITY

The tools used for this study was given to five experts in the field of nursing and one Physician for content validity. Suggestions were considered and appropriate changes were made and found valid. Tool was translated in Tamil and retranslated by experts to confirm language validity.

For measuring the level of Oral mucositis, National Cancer Institute-Common toxicity criteria-Oral mucositis grading scale was used. It is a standardized tool.

3. 12 RELIABILITY

The reliability of an instrument is the degree of consistency with which it measures the attribute, and it is supposed to   measure over a period of time. Reliability of the tool was established by test-retest method. The tool is administered in 2 different occasions and by using Karl pearson co-relation co-efficient , the obtained 'r' value is 0.84. Hence the tool was reliable and used in this study.

3.13 REPORT OF PILOT STUDY:

A pilot study was conducted to find out the reliability of the tool and feasibility of conducting the study. The study was conducted in Radiation oncology ward of Government Rajaji Hospital Madurai for patients with Oral mucositis in the period of one week from 01-08-2014 to 07-08-2014.Initially the patients were explained about the study and informed consent was obtained. According to the inclusion criteria, samples are selected and pre test was conducted by using National Cancer Institute-Common toxicity criteria-Oral mucositis grading scale. It is a standardized tool. By simple random sampling technique,10 subjects- 5 subjects for experimental group I and 5 for experimental group II were selected. Normal saline mouth wash for Experimental group I and Sodium bicarbonate mouth wash for Experimental group II was given to rinsing oral cavity for 1minute, 3 times a day (8am, 2pm and 8 pm) for about 7 days. On the seventh day post test was done for both the groups. Unpaired "t" test was used to compare the effectiveness. Unpaired "t" test value of Experimental Group I is 1.9 and Experimental Group II is 1.1.The value of Experimental Group I is greater than that of Experimental Group II. This indicated

that the Normal saline mouth wash is more effective than Sodium bicarbonate mouth wash.

3.14 DATA COLLECTION PROCEDURE:

The investigator obtained formal permission to conduct the study from respective authorities and Dissertation committee of Madurai Medical College Madurai. Data collection period is from 12-08-2014 to 15-09-2014.Initially the patients were explained about the study and informed consent was obtained. The data has been collected from the subjects who were willing to participate in the study and who have met the selection criteria among 60 patients with Oral mucositis.Pre test was conducted by using Semi- structured interview schedule for the Demographic and Clinical variables and Observational check list (National- Cancer Institute-Common Toxicity Criteria-Oral Mucositis grading scale) for assessing the level of Oral Mucositis. By using simple random sampling-lottery method, the samples were equally assigned to both the groups. 30 samples in experimental group I and other 30 samples in experimental group II. Normal saline mouth wash for Experimental group I and Sodium bicarbonate mouth wash for Experimental group II was administered for rinsing oral cavity for 1minute, 3 times a day (8am, 2pm and 8 pm) for 2 weeks for each group. Post test was conducted for both the groups on third week by using the same tool.

3.15 PLAN FOR DATA ANALYSIS

The data collected was subjected to statistical analysis using descriptive statistics and inferential statistics.

DESCRIPTIVE STATISTICS

The descriptive statistical analysis includes frequency, percentage, mean and standard deviation to assess the demographic and clinical variables.

INFERENTIAL STATISTICS

- Wilcoxon signed rank test were used to compare the pre test and post test difference

- Mann Whitney 'u' test were used to compare the difference between both interventions.

- Chi-square test were used to determine the association between the level of oral mucositis among Experimental group I and group II with selected demographic and clinical variables.

The findings were expressed in the form of figures and tables.

3.16 ETHICAL CONSIDERATION

The proposed study was conducted after the approval of research committee of College of nursing, Madurai Medical College ,Madurai. Written informed consent was obtained from each subject before starting the data collection. Confidentiality was maintained for each subject. The formal approval was obtained from the head of the department of Radiation oncology ward, Government Rajaji Hospital Madurai. Assurance was given like, they can withdraw from the study at anytime. The possible benefit of participating in the study was explained to all subjects and anonymity was maintained throughout the study.

FIGURE 2.SCHEMATIC REPRESENTATION OF THE STUDY

Research approach-Quantitative approach

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Research design-True experimental -Comparative design

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Settings-Radiation oncology ward , Government Rajaji Hospital Madurai

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Target population: Head and Neck cancer patients with Radiation induced Oral mucositis

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Accessible population: Head and Neck cancer patients with Radiation induced oral mucositis admitted in Radiation oncology ward at Government Rajaji Hospital Madurai

↓

Sample: Head and neck cancer patient's with Radiation induced oral mucositis in Radiation Oncology ward at Government Rajaji Hospital, Madurai and who fulfill the inclusion criteria

↓

Sample size:n=60 (30-Experimental group I and 30-Experimental group II

↓

Sampling technique: Simple random sampling-lottery method

↓

Pre assessment-Level of Oral mucositis by using National cancer Institute common toxicity criteria -Oral mucositis grading scale

↓ ↓

Experimental Group I-Normal saline mouth wash

Experimental Group II-Sodium bicarbonate mouth wash

↘ ↙

Post assessment - Level of Oral mucositis by using National cancer Institute common toxicity criteria-Oral mucositis grading scale

↓

Data Analysis and interpretation of the findings (Descriptive and Inferential statistics)

↓

Dissemination of the Research findings and Recommendations

Data Analysis And Interpretation

CHAPTER – IV

DATA ANALYSIS AND INTERPRETATION

James A Fain (2013) defines data analysis as the systematic organization and synthesis of research data and the listing of research hypothesis using those data.

This chapter deals with the analysis and interpretation of the data collected. Analysis is a method for rendering quantitative, reliable, meaningful and providing intelligible information. So that the research problem can be studied and tested which including the relationship between the variables.

The purpose of the data analysis is to translate information collected during the course of the study into an interpretable form so that the research questions could be answered.Master sheet was prepared and the data was analyzed based on the objectives and hypothesis using descriptive and inferential statistics.

ORGANIZATION OF THE FINDINGS

In order to assess the effectiveness of Normal saline and Sodium bicarbonate mouth wash on Oral mucositis, data were tabulated, analyzed and interpreted using descriptive and inferential statistical method. The data were presented under the following headings.

SECTION-I

- Description of subjects according to Demographic and Clinical variables

SECTION-II

- Description of Pre test level of Oral mucositis among subjects undergoing Radiation therapy for Head and neck cancer

SECTION-III

- Effectiveness of Intervention in Experimental group I and Experimental group II.

SECTION-IV

- Comparison between the effectiveness of Normal saline and Sodium bicarbonate mouth wash in Experimental group I and II

SECTION-V

- Association of the level of Oral mucositis in Experimental group I and II with selected demographic and clinical variables

SECTION I

DESCRIPTION OF THE DEMOGRAPHIC CHARCTER AND CLINICAL PROFILE OF THE SUBJECTS

Table-1

DISTRIBUTION OF SUBJECTS ACCORDING TO THEIR DEMOGRAPHIC VARIABLES

n=30+30

S. No	DEMOGRAPHIC VARIABLES	GROUP I NORMAL SALINE MOUTH WASH		GROUP II SODIUM BICARBONATE MOUTH WASH	
		f	%	f	%
1.	**Age (in years):**				
	a. 21-30	2	6.7	1	3.3
	b. 31-40	0	0	2	6.7
	c. 41-50	6	20	13	43.3
	d. 51-60	22	73.3	14	46.7
2.	**Gender :**				
	a. Male	27	90	26	86.7
	b. Female	3	10	4	13.3
3.	**Religion:**				
	a. Hindu	30	100	29	96.7
	b. Christian	0	0	1	3.3
	c. Muslim	0	0	0	0
	d. Others, if specify	0	0	0	0
4.	**Marital status**				
	a. Unmarried	7	23.3	2	6.7
	b. Married	23	76.7	28	93.3
	c. Widow/Widower	0	0	0	0
	d. Divorced	0	0	0	0
	e. Separated	0	0	0	0
5.	**Education:**				
	a. No formal education	14	46.7	17	56.7
	b. Primary	15	50	10	33.3
	c. Secondary	1	3.3	2	6.7
	d. Higher secondary	0	0	1	3.3
	e. Graduate and above	0	0	0	0
6.	**Occupation:**				
	a. Unemployed	1	3.3	20	66.7
	b. Daily wages	20	66.7	6	20
	c. Business	6	20	3	10
	d. Salaried	1	3.3	1	3.3
	e. House wife	2	6.7	0	0

S. No	DEMOGRAPHIC VARIABLES	GROUP I NORMAL SALINE MOUTH WASH		GROUP II SODIUM BICARBONATE MOUTH WASH	
		f	%	f	%
7.	**Family monthly income:** a. Below 3000 b. 3001-4000 c. 4001-5000 d. Above 5000	1 11 17 1	3.3 36.7 56.7 3.3	0 14 13 3	0 46.7 43.3 10

With regard to the age, majority of the participants, 22 (73.3%) and 14 (46.7%), in experimental group I and experimental group II were between the age group of 51-60 years.6 (20%) and 13 (43.3%) in experimental group I and experimental group II were between the age group of 41-50 years.0 (0%) and 2 (6.7%) were between the age group of 31-40 years and 2 (6.7%) and 1 93.3%) were between the age group of 21-30 years in experimental group I and experimental group II respectively.

In the aspect of gender, most of the participants ,27 (90%) and 26 (86.7%) in experimental group I and experimental group II were males and only 3 (10%) and 4 (13.3%) were females in experimental group I and experimental group II respectively.

Regarding the religion, all the participants, 30 (100%) in experimental group I and most of the participants in experimental group II,29 (96.7%) were Hindus and only 1 (3.3%) belongs to Christian in experimental group II.

In the aspect of marital status, majority of the participants ,23 (76.7%) and 28 (93.3%) were married , remaining 7 (23.3%) and 2 (6.7%) participants were unmarried in experimental group I and experimental group II respectively.

With regard to the educational status, most of the participants, 14 (46.7%) and 17 (56.7%) in experimental group I and experimental group II were not having any formal education.15 (50%) and 10 (33.3%) in experimental group I and experimental group II were having primary education.1 (3.3%) and 2 (6.7%) in experimental group I and experimental group II were studied upto secondary education, no one had higher secondary education and no graduate as well in experimental group I. Only 1 (3.3%) participant in experimental group II were educated upto higher secondary and no graduate in this group.

In the aspect of occupational status, most of the participants ,20 (66.7%) in experimental group I were daily wages and experimental group II were unemployed.Only 1 (3.3%) in experimental group I were unemployed and experimental group II were salaried , 6(20%) %) in experimental group I were daily wagesand experimental group II were business respectively, 3 (10%) in experimental group II were business and 2(.7%) participants in experimental group I were housewives.

With regard to the family income, majority of the participants, 17 (5.7%) and 14 (4.7%) in experimental group I and experimental group II were having the family income between Rs4001-5000 and Rs3001-4000 respectively.11 (36.7%) participants in experimental group I had family income between Rs 3001-4000 and 13 (43.3%) in experimental group II were between the range of Rs 4001-5000 and only 1 (3.3%) and 3 (10%) in experimental group I and experimental group II had above Rs 5000 and only 1 (3.3%) in experimental group I and no participants in experimental group II had family income of below Rs 3000.

DISTRIBUTION OF SUBJECTS ACCORDING TO THEIR AGE
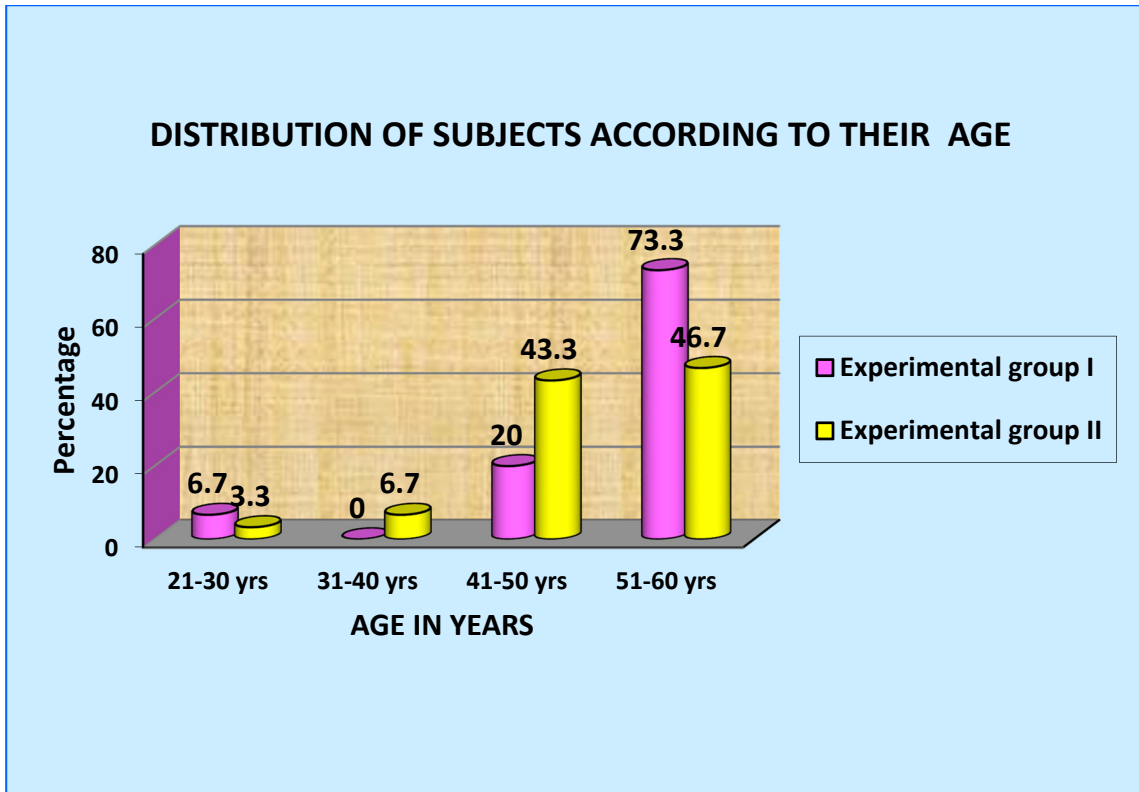
FIGURE.3.PERCENTAGE WISE DISTRIBUTION OF PATICIPANTS ACCORDING TO THEIR AGE

The above cylinder diagram shows that majority of participants, 22 (73.3%) and 14 (46.7%) were 51-60 years of age group and least 0 (0%) and 2 (6.7%) were between the age group of 31-40 years in experimental group I and experimental group II respectively.
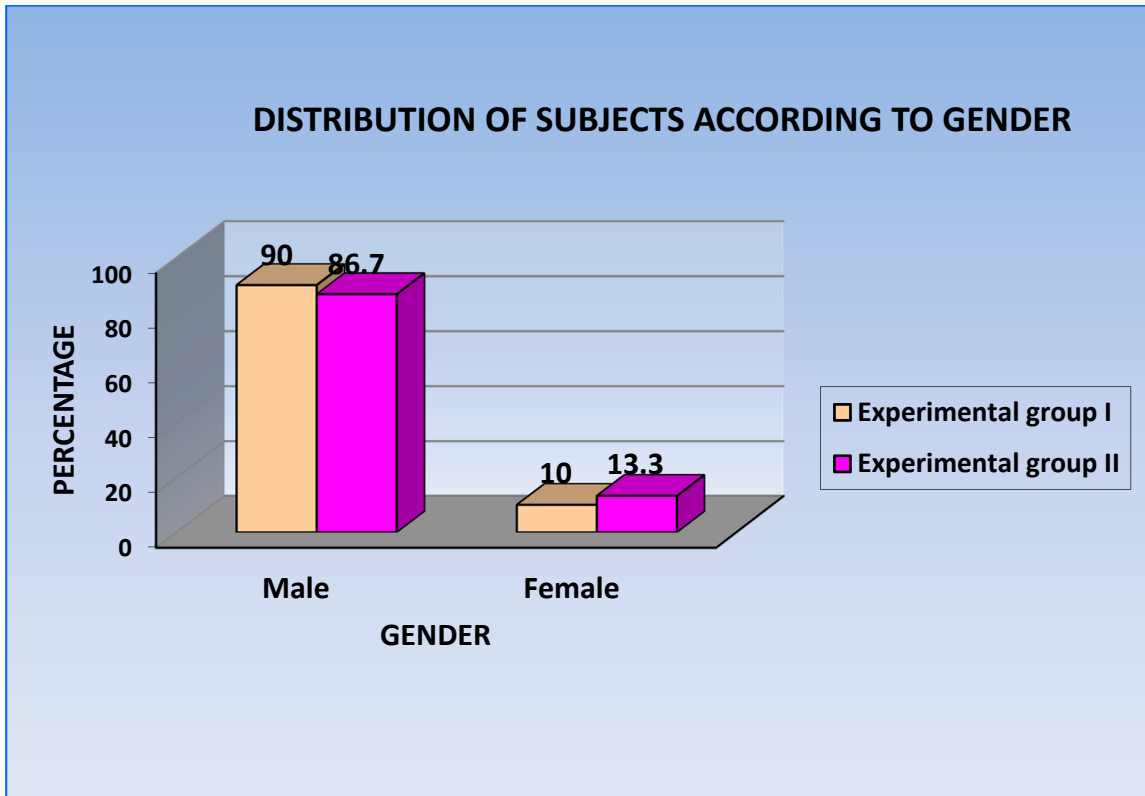
FIGURE.4.PERCENTAGE WISE DISTRIBUTION OF SUBJECTS ACCORDING TO THEIR GENDER

The above 3-D clustered column diagram shows that majority,27 (90%) and 26 (86.7%) participants were maleand only 3 (10%) and 4 (13.3%) were females in experimental group I and experimental group II respectively.

DISTRIBUTION OF SUBJECTS ACCORDING TO THEIR OCCUPATION
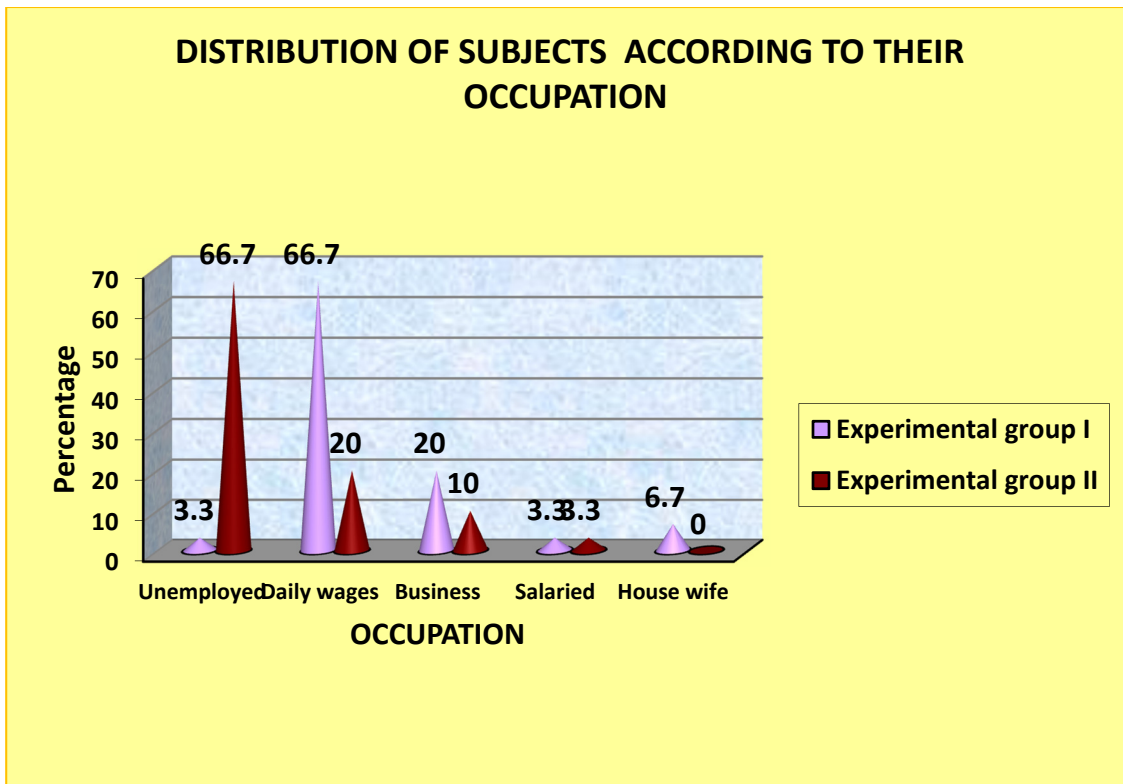
FIGURE.5. PERCENTAGE WISE DISTRIBUTION OF PARTICIPANTS ACCORDING TO THEIR OCCUPATION

The above clustered cone diagram shows that Most of the participants,20 (66.7%) in experimental group I were daily wages and 20 (66.7%) participants in experimental group II were unemployed and only 1 (3.3%) in experimental group I were unemployed and 1 (3.3%) participants in experimental group II and were salaried.

DISTRIBUTION OF SUBJECTS ACCORDING TO THEIR MONTHLY INCOME
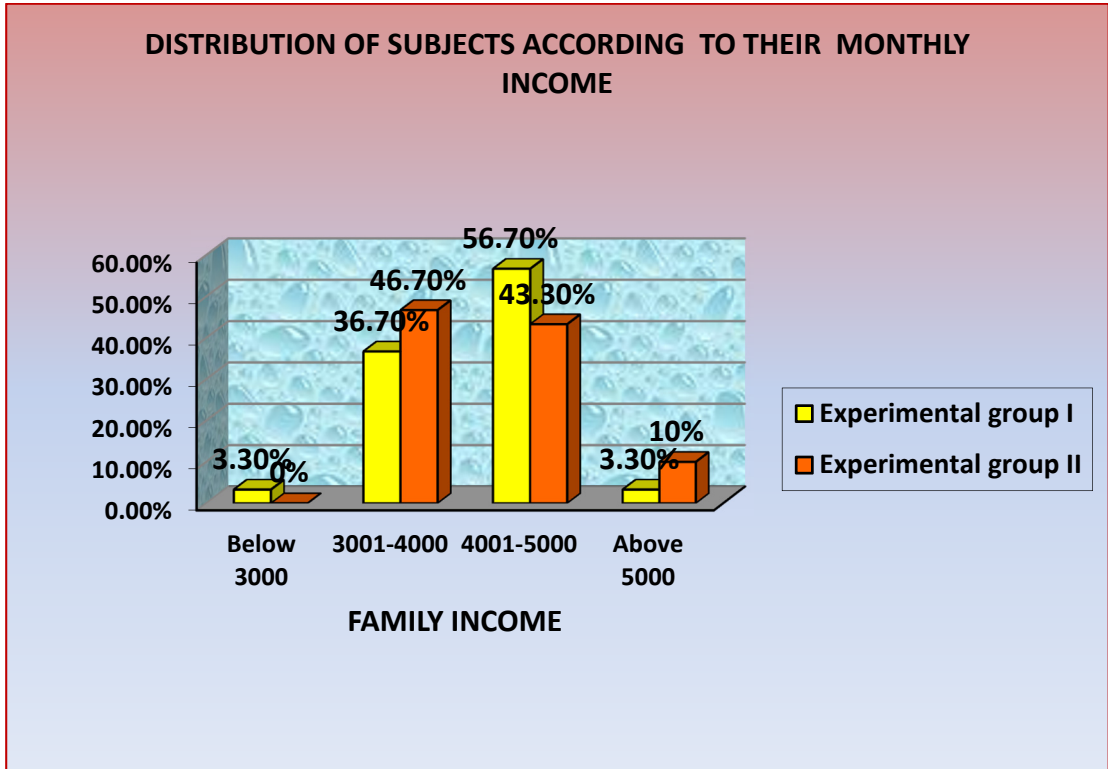
FIGURE.6. PERCENTAGE WISE DISTRIBUTION OF PARTICIPANTS ACCORDING TO THEIR MONTHLY INCOME

The above 3-D clustered column diagram shows that majority of the participants, 17 (5.7%) and 14 (4.7%) in experimental group I and experimental group II were having the family income between Rs4001-5000 and only 1 (3.3%) in experimental group I and no participants in experimental group II had family income of below Rs 3000.

Table– 2

DISTRIBUTION OF SUBJECTS ACCORDING TO THEIR CLINICAL VARIABLES.

n=30+30

S.NO	CLINICAL VARIABLES	GROUP I		GROUP II	
		NORMAL SALINE MOUTH WASH		SODIUM BICARBONATE MOUTH WASH	
		f	%	f	%
8.	**Duration of Cancer:**				
	a. 0-1 years	23	76.7	22	73.3
	b. 2-3 years	6	20	8	26.7
	c. 4-5 years	1	3.3	0	0
	d. Above 5 years	0	0	0	0
9.	**Stage of cancer :**				
	a. Stage I	10	33.3	4	13.3
	b. Stage II	19	63.4	26	86.7
	c. Stage III	1	3.3	0	0
	d. Stage IV	0	0	0	0
10.	**Nutritional status:**				
	a. Adequately nourished	11	36.7	3	10
	b. Mild malnutrition	14	46.7	25	83.3
	c. Moderate malnutrition	4	13.3	2	6.7
	d. Severe malnutrition	1	3.3	0	0
11.	**History of co-morbid condition:**				
	a. Diabetes mellitus	0	0	0	0
	b. Immunosuppressive disease	0	0	0	0
	c. Vitamin deficiencies	1	3.3	0	0
	d. None of the above	29	96.7	30	100
12.	**Frequency of taking oral hygiene:**				
	a. Once In a day	1	3.3	5	16.7
	b. Twice in a day	15	50	11	36.7
	c. Before and after each meals	14	46.7	14	46.6
13.	**Past history chemo/radiation therapy:**				
	a. Chemo and radiation	0	0	5	16.7
	b. Chemotherapy alone	19	63.3	20	66.7
	c. Radiationtherapy alone	5	16.7	1	3.3

S.NO	CLINICAL VARIABLES	GROUP I		GROUP II	
		NORMAL SALINE MOUTH WASH		SODIUM BICARBONATE MOUTH WASH	
		f	**%**	**f**	**%**
	d. None of the above	6	20	4	13.3
14.	**Life style habits:** a.Smoker and chewing tobacco product b. Smoker only c. Chewing tobacco product only d. No habits	11 11 7 1	36.7 36.7 23.3 3.3	15 6 7 2	50 20 23.3 6.7
15.	**Fractionated dosage of radiotherapy per day:** a. Less than 200 cGy b. More than 200 cGy	12 18	40 60	16 14	53.3 46.7
16.	**History of using any Dentures:** a. Using **b.** Not using	0 30	0 100	0 30	0 100

In the aspect of duration of illness, majority of the participants, 23 (76.7%) and 22 (73.3%) were having cancer for the duration of 0-1 year in experimental group I and experimental group II, 6 (20%) and 8 (26.7%) were having the duration of 2-3 years, 1 (3.3%) and 0 (0%) were in the duration of 3-4 years in experimental group I and experimental group II and no one had the duration of more than 4 years in both experimental group I and Experimental group II respectively.

With regard to the stage of Cancer, most of the participants, 19 (63.4%) and 26 (86.7%) were in II stage of Cancer in experimental group I and experimental group II,10 (33.3%) and 4 (13.3%) were in stage I in experimental group I and

experimental group II, only 1 (3.3%) and 0 (0%) participant were in stage III and no one were in stage IV in experimental group I and experimental group II.

Regarding the nutritional status, majority of participants, 14 (46.7%) and 25 (83.3%) were in mild malnutrition in experimental group I and experimental group II respectively, 11 (36.7%) and 3 (10%) participants were adequately nourished , 4 (13.3%) and 2 (.7%) were in moderate malnutrition , 1 (3.3%) and 0 (0%) were in severe malnutrition in experimental group I and experimental group II respectively.

In the aspect of co-morbid conditions, all the participants 30 (100%) in experimental group II and majority,29 (96.7%) participant in experimental group I were not had any co-morbid conditions and only 1 (3.3%) participant in experimental group I had vitamin deficiencies and no one had Diabetes mellitus and Immunosuppressive disease in both the group.

With regard to the frequency of oral hygiene, majority of participants ,15 (50%) and 11 (36.7%) took oral hygiene twice in a day in experimental group I and experimental group II respectively,14 (46.6%) participants took oral hygiene before and after each meals in experimental group I and experimental group II,only 1 (3.3%) and 5 (16.7%) participants took oral hygiene, once in a day in experimental group I and experimental group respectively.

Most of the participants ,19 (63.3%) and 20 (66.7%) were undergone chemotherapy alone in the past in experimental group I and experimental group II,5 (16.7%) and 1 (3.3%) participants had the history of radiation therapy in experimental group I and experimental group II respectively , 0(0%) and 5 (1.7%) participants took chemo and radiation therapy in the past, 6(20) and 4 (13.3%) participants were not

undergone chemo or radiation therapy in the past in both experimental group I and experimental group II respectively.

Most of the participants, 11 (36.7%) were smoker in experimental group I and 15 (50%) were had the history of chewing tobacco products in experimental group II,11 (36.7%) and 6 (20%) were smoker only in experimental group I and experimental group II,7 (23.3%) participants had the history of chewing tobacco products in experimental group I and experimental group II, only 1 (3.3%) and 2 (6.7%) were not having the above habits in experimental group I and experimental group II.

In consistent with the fractionated daily dose of Radiation therapy, most of the participants,18 (60%) in experimental group I were having more than 200 cGy of fractionated dosage of radiatiotherapy per day and majority,16 (53.3%) participants in experimental group II were having less than 200cGy of fractionated dose of radiotherapy per day and 12 (40%) participants in experimental group I were having less than 200cGy of fractionated dose of radiotherapy per day and 14 (46.7%) participants were having more than 200cGy of fractionated dose of radiotherapy per day in experimental group II.

All the participants, 30 (100%) in each Experimental group I and Experimental group II were not using any dentures.

DISTRIBUTION OF SUBJECTS ACCORDING TO THE STAGE OF CANCER
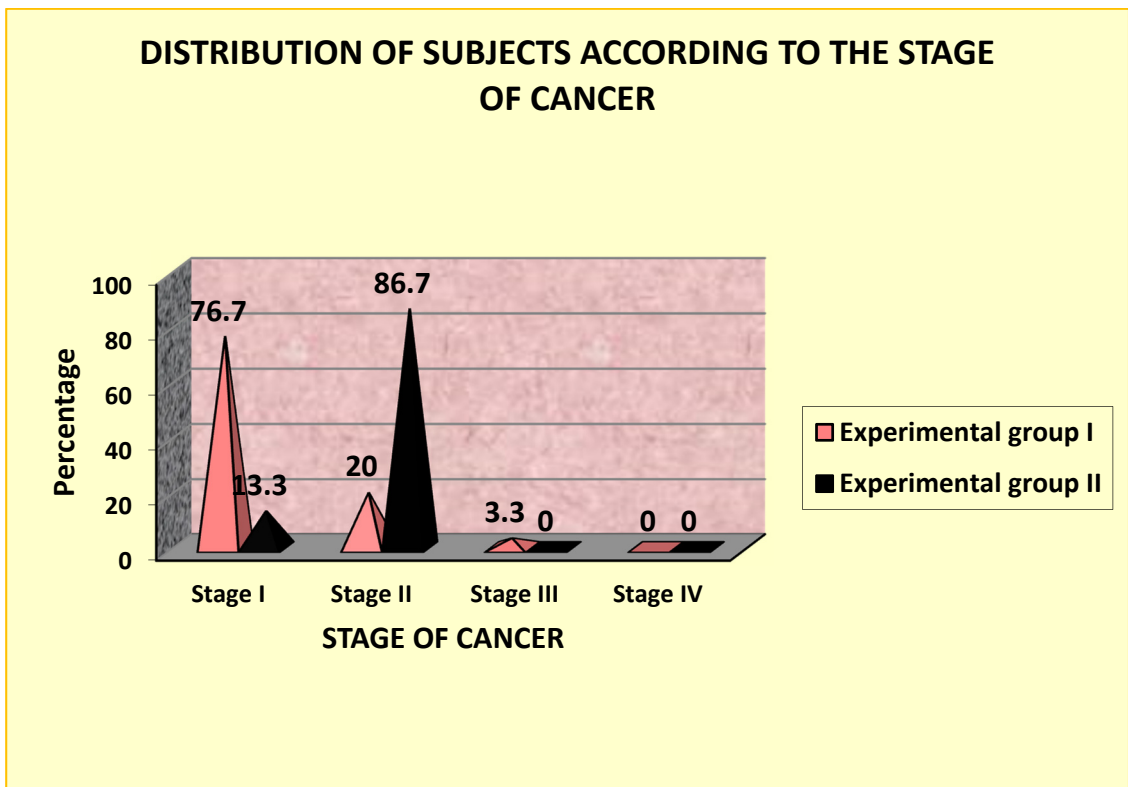
FIGURE.7. PERCENTAGE WISE DISTRIBUTION OF PARTICIPANTS ACCORDING TO THEIR STAGE OF CANCER

The above clustered pyramid diagram shows that most of the participants, 19 (63.4%) and 26 (86.7%) were in II stage of Cancer in experimental group I and experimental group II, and only 1 (3.3%) and 0 (0%) participants were in stage III and no one were in stage IV in experimental group I and experimental group II.

PERCENTAGE DISTRIBUTION OF SUBJECTS ACCORDING TO THEIR NUTRITIONAL STATUS
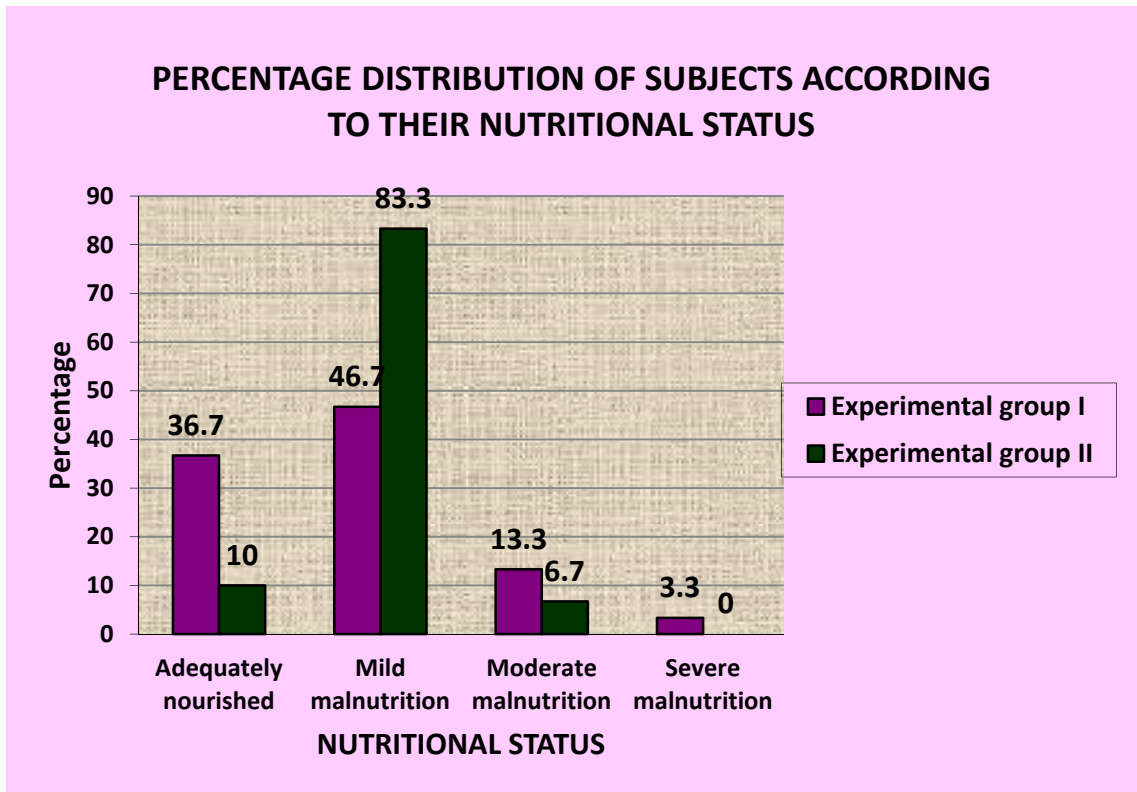
FIGURE.8. PERCENTAGE DISTRIBUTION OF SUBJECTS ACCORDING TO THEIR NUTRITIONAL STATUS

The above Clustered diagram shows that majority of participants, 14 (46.7%) and 25 (83.3%) were in mild malnutrition in experimental group I and experimental group II , 11 (36.7%) and 3 (10%) participants were adequately nourished , 4 (13.3%) and 2 (.7%) were in moderate malnutrition , 1 (3.3%) and 0 (0%) were in severe malnutrition in experimental group I and experimental group II respectively.

DISTRIBUTION OF SUBJECTS ACCORDING TO THE HISTORY OF CO-MORBID CONDITIONS
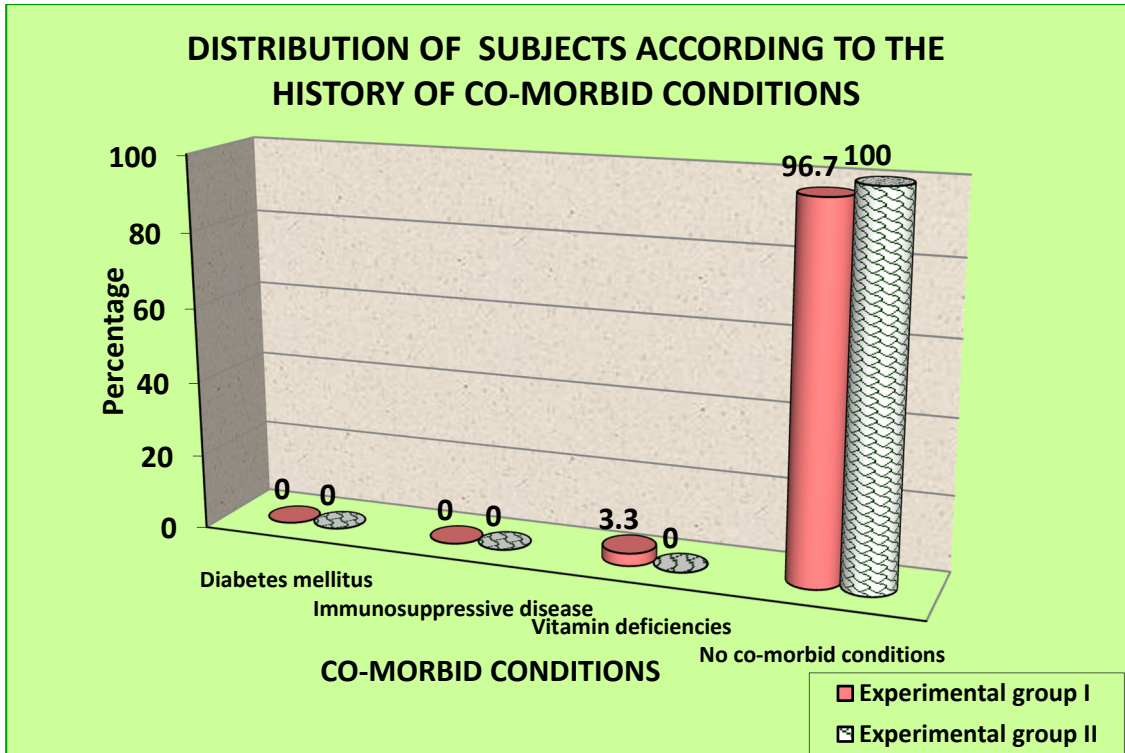
FIGURE.9.PERCENTAGE WISE DISTRIBUTION OF SUBJECTS ACCORDING TO THEIR CO-MORBID CONDITIONS

The above Stacked column diagram shows that all the participants, 30 (100%) in experimental group II and majority, 29 (96.7%) participant in experimental group I were not had any co-morbid conditions and only 1 (3.3%) participant in experimental group I had vitamin deficiencies and no one had Diabetes mellitus and Immunosuppressive disease in both the groups.

DISTRIBUTION OF SUBJECTS ACCORDING TO THE FREQUENCY OF TAKING ORAL HYGIENE
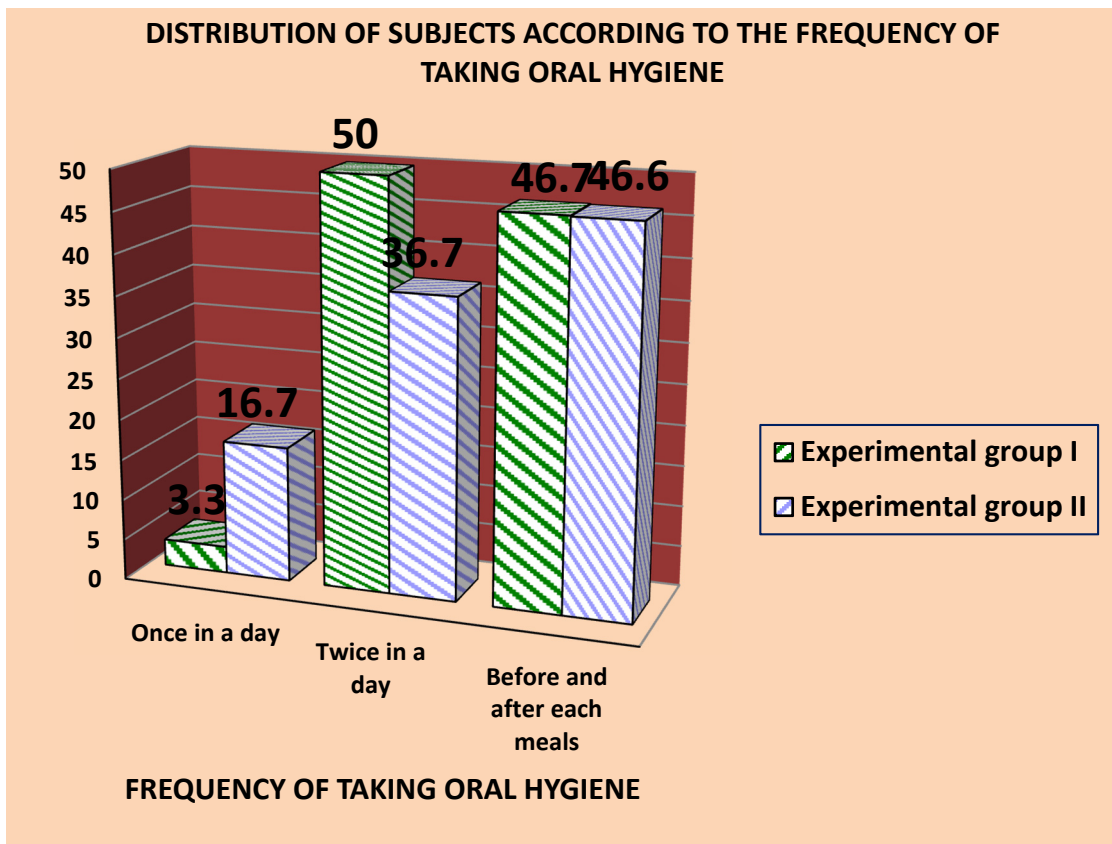
FIGURE.10.PERCENTAGE WISE DISTRIBUTION OF SUBJECTS ACCORDING TO THEIR FREQUENCY OF TAKING ORAL HYGIENE

The above clustered column diagram shows that majority of participants ,15 (50%) and 11 (36.7%) took oral hygiene twice in a day in experimental group I and experimental group II,only 1 (3.3%) and 5 (16.7%) participants took oral hygiene once in a day in experimental group I and experimental group respectively.

DISTRIBUTION OF SUBJECTS ACCORDING TO THEIR
FRACTIONATED DOSAGE OF RADIATION PER DAY
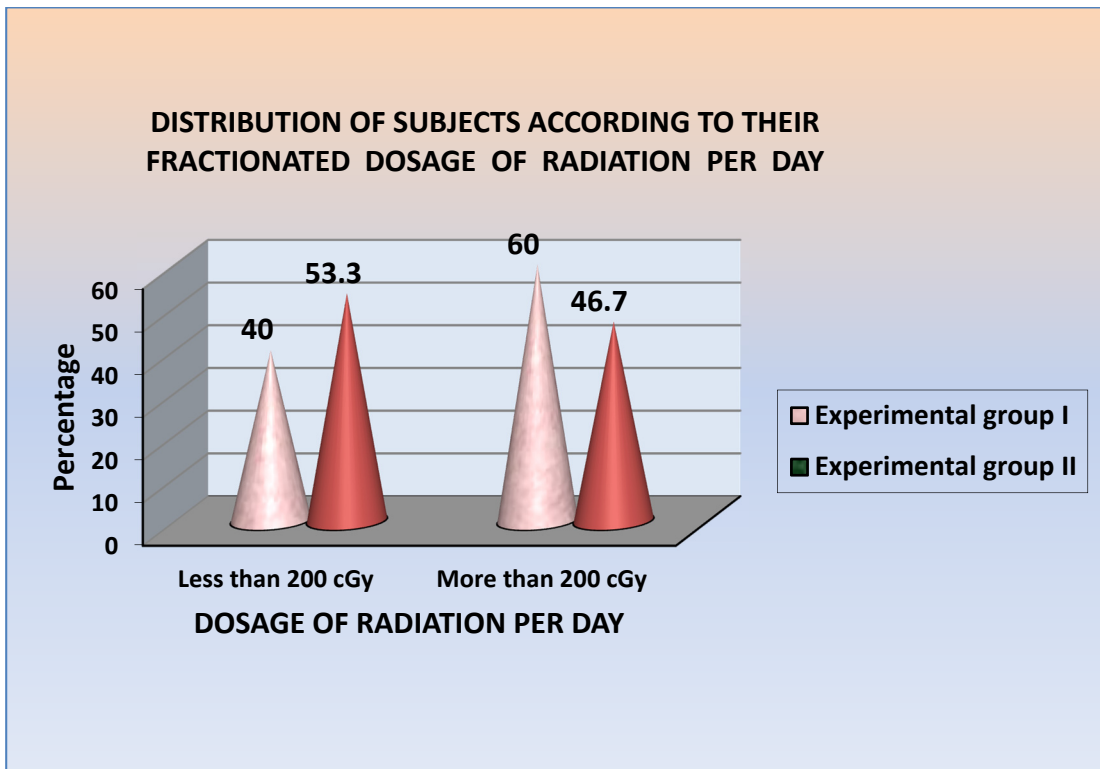
FIGURE. 11 .PERCENTAGE WISE DISTRIBUTION OF PARTICIPANTS ACCORDING TO THEIR FRACTIONATED DOSAGE OF RADIOTHERAPY PER DAY

The above clustered cone diagram shows that most of the participants,18 (60%) in experimental group I were having more than 200 cGy of fractionated dosage of radiatiotherapy per day and majority,16 (53.3%) participants in experimental group II were having less than 200cGy of fractionated dose of radiotherapy per day and 12 (40%) participants in experimental group I were having less than 200cGy of fractionated dose of radiotherapy per day and 14 (46.7%) participants were having more than 200cGy of fractionated dose of radiotherapy per day in experimental group II.

DISTRIBUTION OF SUBJECTS CCORDING TO THEIR HISTORY OF USING ANY DENTURES
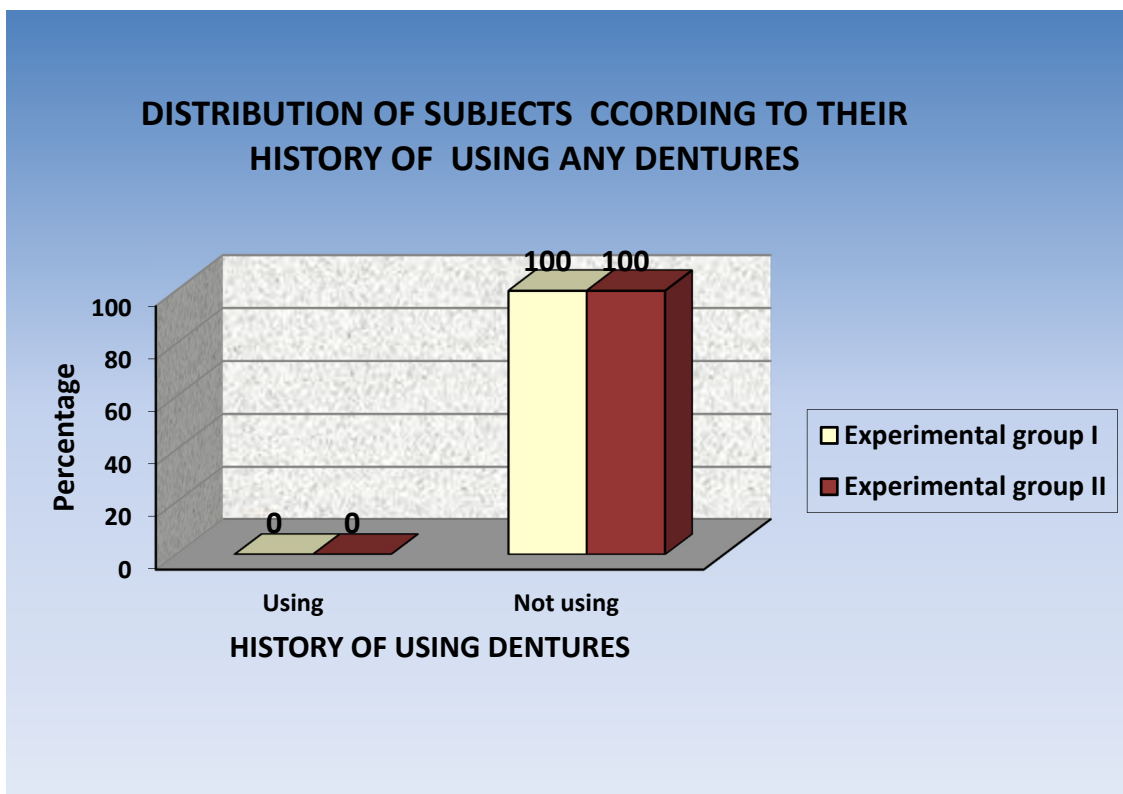
FIGURE. 12.PERCENTAGE WISE DISTRIBUTION OF PARTICIPANTS ACCORDING TO THEIR HISTORY OF USING DENTURES

The above clustered column diagram shows that no one in Experimental group I and Experimental group II were using any dentures.

Table 3.

PRE TEST LEVEL OF ORAL MUCOSITIS AMONG PATIENTS UNDERGOING RADIATION THERAPY FOR HEAD AND NECK CANCER

n=60

LEVEL OF ORAL MUCOSITIS	EXPERIMENTAL GROUP I (NORMAL SALINE MOUTH WASH)		EXPERIMENTAL GROUP II (SODIUM BICARBONATE MOUTH WASH)	
	Pre test		Pre test	
	f	%	f	%
Nil	-	-	-	-
Mild	-	-	-	-
Moderate	8	26.7	8	26.7
Severe	22	73.3	22	73.3
Life threatening	-	-	-	-

The above table shows the frequency and percentage distribution of level of oral mucositis amongsubjects undergoing Radiation therapy for Head and neck Cancer.

Majority of the participants, 22(73.3%) were in severe Oral mucositis and 8 (2.7%) participants were in moderate level of oral mucositis and there is no mild or life threatening illness among the subjects with Oral mucositis.

PRE TEST LEVEL OF ORAL MUCOSITIS IN EXPERIMENTAL GROUP I AND II
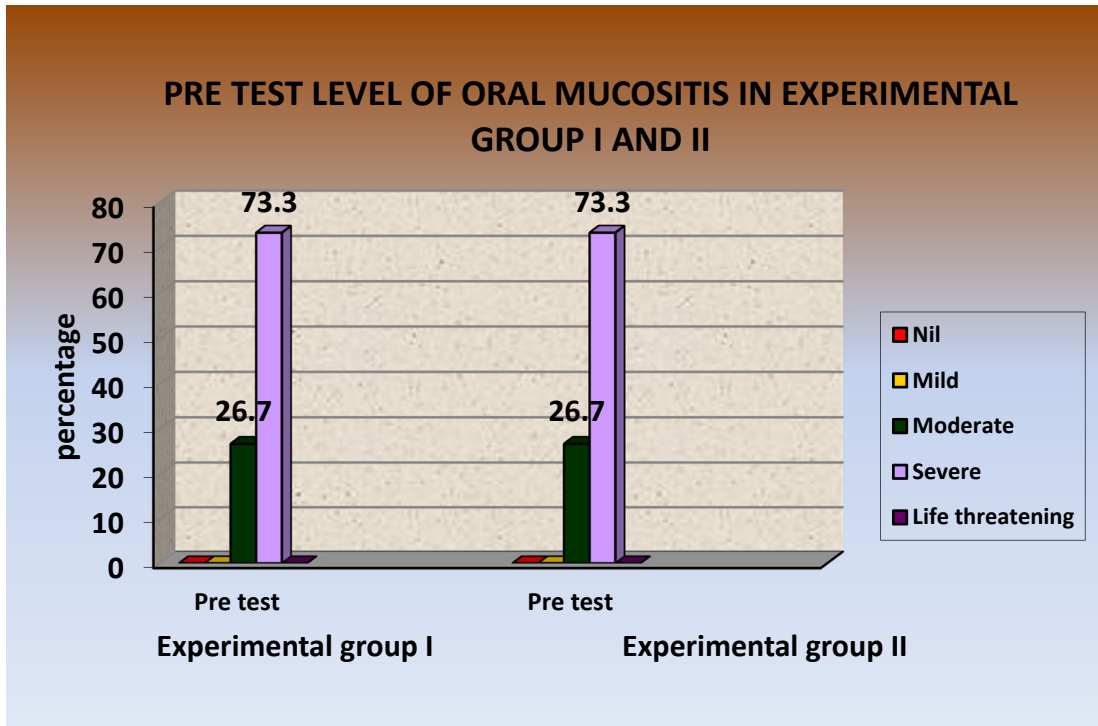
FIGURE.13. PRE TEST LEVEL OF ORAL MUCOSITIS IN EXPERIMENTAL GROUP I AND EXPERIMENTAL GROUP II

The above 3-D clustered diagram shows that majority of the participants, 22(73.3%) were in severe grade of mucositis and 8 (2.7%) participants were in moderate level of oral mucositis in each experimental group I and experimental group II. There is no mild or life threatening illness in both experimental group I and experimental group II respectively.

Table.4.

EFFECTIVENESS OF NORMAL SALINE MOUTH WASH ON ORAL MUCOSITIS AMONG SUBJECTS UNDERGOING RADIATION THERAPY IN EXPERIMENTAL GROUP I

n=30

VARIABLE	PRE TEST		POST TEST		MEDIAN DIFFERENCE	'Z'-VALUE	P-VALUE
	Median	IQR (Q3-Q1)	Median	IQR (Q3-Q1)			
Experimental group I (Normal saline mouth wash)	3	2-3	0	0-1	3	5.035	**0.000*****

(* P<0.001 highly significant)**

The above table shows the comparison of level of Oral mucositis, before and after the interventions in Experimental group I by using wilcoxon signed rank test. The median value of pre test is 3 and post test value is 0 and the median difference (3) is very high, the obtained z value 5.035 at p-value 0.000 level of significance. Hence, it revealed that Normal saline mouth wash is very effective for reducing the level of Oral mucositis.

Table.5

EFFECTIVENESS OF SODIUM BICARBONATE MOUTH WASH ON ORAL MUCOSITIS AMONG SUBJECTS UNDERGOING RADIATION THERAPY IN EXPERIMENTAL GROUP II

n=30

VARIABLE	PRE TEST		POST TEST		MEDIAN DIFFERENCE	'Z'-VALUE	P-VALUE
	Median	IQR (Q3-Q1)	Median	IQR (Q3-Q1)			
Experimental group II (Sodium bicarbonate mouth wash)	3	2-3	2	1-2	1	4.465	**0.000*****

(*** P<0.001 highly significant)

The above table shows the comparison of level of Oral mucositis, before and after the interventions in Experimental group II by using wilcoxon signed rank test. The median value of pre test is 3 and post test value is 2 and the median difference is 1. The obtained z value 4.465 at p-value 0.000 level of significance. Hence it reveals that Sodium bicarbonate mouth wash is also effective for reducing the level of Oral mucositis.

Table.6

COMPARISON OF THE INTERVENTIONS BETWEEN EXPERIMENTAL GROUP I AND EXPERIMENTAL GROUP II

n = 30+30

AREA	NORMAL SALINE		SODIUM BICARBONATE		MEDIAN DIFFERENCE	'Z'-VALUE	P-VALUE
	MEDIAN	IQR (Q3-Q1)	MEDIAN	IQR (Q3-Q1)			
Pre test	3	2-3	3	2-3	0	0	1
Post test	0	0-1	2	1-2	2	4.445	0.000***

(* P<0.001 highly significant)**

The data presented in the above table   depicts the comparison between both Interventions in Experimental group I and II. In Experimental GroupI (Normal saline mouth wash), the Post test score of Oral mucositis effectively reduced from 3 to 0 and in Experimental Group II(Sodium bicarbonate mouth wash), the Post test score of Oral mucositis considerably reduced from 3 to 2. By using Mann Whitney "u" test, the median difference between the post test score is 2. The obtained "Z" value is 4.445 at p-value 0.000 level of significance. Hence the above findings statistically proved that Normal saline mouth wash is more effective than Sodium bicarbonate mouth wash on reducing the level of Oral mucositis.

Table.7

ASSOCIATION BETWEEN THE LEVEL OF ORAL MUCOSITIS IN EXPERIMENTAL GROUP I WITH THEIR SELECTED DEMOGRAPHIC AND CLINICAL VARIABLES

n=30

S. NO	DEMOGRAPHIC VARIABLES	NO		MILD		X^2-VALUE	P-VALUE
		f	%	f	%		
1.	Age (in years): a. 21-30 b. 31-40 c. 41-50 d. 51-60	1 0 3 12	3.3 0 10 40	1 0 3 10	3.3 0 10 33.3	0.048 (df=2)	0.976
2.	Gender : a. Male b. Female	13 3	43.3 10	14 0	46.7 0	2.91 (df=1)	0.088
3.	Religion: a. Hindu b. Christian c. Muslim d. Others	16 0 0	53.3 0 0	14 0 0	46.7 0 0	0	1
4.	Marital status: a. Unmarried b. Married c. Widow d. Divorced e. Separated	4 7 0 0 0	13.3 23.3 0 0 0	3 16 0 0 0	10 53.3 0 0 0	1.65 (df=1)	0.199
5.	Education: a. No formal education b. Primary education c. Secondary education d. Higher secondary education e. Graduate and above	7 9 0 0	23.3 30 0 0	7 6 1 0	23.3 20 3.3 0	1.47 (df=2)	0.479
6.	Occupation: a. Unemployed b. Daily wages c. Business d. Salaried e. House wife	1 10 2 1 2	3.3 33.3 6.7 3.3 6.7	0 10 4 0 0	0 33.3 13.3 0 0	4.55 (df=4)	0.34

S. NO	DEMOGRAPHIC VARIABLES	NO		MILD		X²-VALUE	P-VALUE
		f	%	f	%		
7.	**Family monthly income:** a. Below 3000 b. 3001-4000 c. 4001-5000 d. Above 5000	1 6 9 0	3.3 20 30 0	0 5 8 1	0 16.7 26.7 3.3	2.02 (df=3)	0.567
8.	**Duration of Cancer:** a. 0-1 years b. 2-3 years c. 4-5 years d. Above 5 years	11 4 1 0	36.7 13.3 3.3 0	12 2 0 0	40 6.7 0 0	1.58 (df=2)	0.453
9.	**Stage of cancer :** a. Stage I b. Stage II c. Stage III d. Stage IV	4 11 1 0	13.3 36.7 3.3 0	6 8 0 0	20 26.7 0 0	1.75 (df=2)	0.417
10.	**Nutritional status:** a. Adequately nourished b. Mild malnutrition c. Moderate malnutrition d. Severe malnutrition	4 9 3 0	13.3 30 10 0	7 5 1 1	23.3 16.7 3.3 3.3	3.84 (df=3)	0.279
11.	**History of co-morbid condition:** a. Diabetes mellitus b. Immunosuppressive disease c. Vitamin deficiencies d. None of the above	0 0 1 15	0 0 3.3 50	0 0 0 14	0 0 0 46.7	0.91 (df=1)	0.341
12.	**Frequency of taking oral hygiene:** a. Once In a day b. Twice in an day c. Before and after each meals	1 9 6	3.3 30 20	0 6 8	0 20 26.7	1.76 (df=2)	0.415
13.	**Past history chemo/radiation therapy:** a.Chemo and radiation b. Chemotherapy alone c. Radiation therapy d. None of the above	0 11 3 2	0 36.7 10 6.7	0 8 2 4	0 26.7 6.7 13.3	1.21 (df=2)	0.545
14.	**Life style habits:** a. Smoker and chewing tobacco product b. Smoker only	4 5 6	13.3 16.7 20	7 6 1	23.3 20 3.3	5.37 (df=3)	0.147

S. NO	DEMOGRAPHIC VARIABLES	NO		MILD		X²-VALUE	P-VALUE
		f	%	f	%		
	c. Chewing tobacco product only d. No habits	1 0	3.3 0	0 0	0 0		
15.	**Fractionated dosage of radiotherapy per day:** a. Less than 200 cGy b. More than 200 cGy	5 11	16.7 36.7	7 7	23.3 23.3	1.09 (df=1)	0.296
16.	**History of using any Dentures:** a. Using b. Not using	0 16	0 53.3	0 14	0 46.7	0	1

(*-P<0.05 ,significant and **-P<0.01 & ***-P<0.001 , Highly significant)

The above table reveals that there is no significant association between the posttest level of Oral mucositis with their demographic and clinical variables in Experimental Group I.

ASSOCIATION BETWEEN THE LEVEL OF ORAL MUCOSITIS IN EXPERIMENTAL GROUP II WITH SELECTED DEMOGRAPHIC AND CLINICAL VARIABLES

n=30

S. No	Demographic variables	No		Mild		Moderate		Severe		X^2-value	p-value
		f	%	f	%	f	%	f	%		
1.	**Age (in years):**										
	a. 21-30	0	0	1	3.3	0	0	0	0	17.52	0.041*
	b. 31-40	0	0	1	3.3	0	0	1	3.3	(df=6)	
	c. 41-50	4	13.3	4	13.3	4	13.3	1	3.3		
	d. 51-60	1	3.3	2	6.7	11	33.3	0	0		
2.	**Gender :**										
	a. Male	5	16.7	7	23.3	14	46.7	0	0	14.35	0.002
	b. Female	0	0	1	3.3	1	3.3	2	6.7	(df=3)	
3.	**Religion:**										
	a. Hindu	5	16.7	8	26.7	15	50	1	3.3		
	b. Christian	0	0	0	0	0	0	1	3.3	14.48	0.002
	c. Muslim	0	0	0	0	0	0	0	0	(df=3)	
	d. Others	0	0	0	0	0	0	0	0		
4.	**Marital status:**										
	a. Unmarried	0	0	2	6.7	-	-	-	-		
	b. Married	5	13.3	23	76.6	-	-	-	-	0.43	
	c. Widow	0	0	0	0	-	-	-	-	(df=1)	0.513
	d. Divorced	0	0	0	0	-	-	-	-		
	e. Separated	0	0	0	0	-	-	-	-		
5.	**Education:**										
	a. No formal education	3	10	4	13.3	9	30	1	3.3		
	b. Primary education	2	6.7	2	6.7	6	20	0	0	11.34	0.253
	c. Secondary education	0	0	1	3.3	0	0	1	3.3	(df=9)	
	d. Higher secondary education	0	0	1	3.3	0	0	0	0		
	e. Graduate and above	0	0	0	0	0	0	0	0		
6.	**Occupation:**										
	a. Unemployed	0	0	0	0	0	0	0	0		
	b. Daily wages	5	16.7	3	10	12	40	0	0		
	c. Business	0	0	4	13.3	2	6.7	2	6.7	28.17	0.001**
	d. Salaried	0	0	1	3.3	0	0	0	0	(df=9)	
	e. House wife	0	0	0	0	1	3.3	0	0		

S. No	Demographic variables	No		Mild		Moderate		Severe		X²-value	p-value
		f	%	f	%	f	%	f	%		
7.	**Family monthly income:**										
	a. Below 3000	0	0	0	0	0	0	0	0	13.08	0.042**
	b. 3001-4000	1	3.3	2	6.7	10	33.3	1	3.3	(df=6)	
	c. 4001-5000	4	13.3	3	10	5	16.7	1	3.3		
	d. Above 5000	0	0	3	10	0	0	0	0		
8.	**Duration of Cancer:**										
	a. 0-1 years	3	10	7	23.3	10	33.3	2	6.7	2.34	0.504
	b. 2-3 years	2	6.7	1	3.3	5	16.7	0	0	(df=3)	
	c. 4-5 years	0	0	0	0	0	0	0	0		
	d. Above 5 years	0	0	0	0	0	0	0	0		
9.	**Stage of cancer :**										
	a. Stage I	0	0	2	6.7	2	6.7	0	0	2.02	0.568
	b. Stage II	5	16.7	6	20	13	43.3	2	6.7	(df=3)	
	c. Stage III	0	0	0	0	0	0	0	0		
	b. Stage IV	0	0	0	0	0	0	0	0		
10.	**Nutritional status:**										
	a. Adequately nourished	1	3.3	1	3.3	1	3.3	0	0	1.95	0.924
	b. Mild malnutrition	4	13.3	6	20	13	43.3	2	6.7	(df=6)	
	c. Moderate malnutrition	0	0	1	3.3	1	3.3	0	0		
	d. Severe malnutrition	0	0	0	0	0	0	0	0		
11.	**History of co-morbid condition:**										
	a. Diabetes mellitus	0	0	0	0	0	0	0	0	0	1
	b. Immunosuppressive disease	0	0	0	0	0	0	0	0		
	c. Vitamin deficiencies	0	0	0	0	0	0	0	0		
	d. None of the above	5	16.7	8	26.7	15	50	2	6.7		
12.	**Frequency of taking oral hygiene:**										
	a. Once In a day	0	0	1	3.3	3	10	1	3.3	7.81	0.253
	b. Twice in an day	1	3.3	2	6.7	8	26.7	0	0	(df=6)	
	c. Before and after each meals	4	13.3	5	16.7	4	13.3	1	3.3		
13.	**Past history chemo/radiation therapy:**										
	a. Chemo and radiation	2	6.7	0	0	3	10	0	0	11.32	0.254
	b. Chemotherapy alone	2	6.7	7	23.3	9	30	2	6.7	(df=9)	
	c. Radiation therapy	1	3.3	0	0	0	0	0	0		

S. No	Demographic variables	No		Mild		Moderate		Severe		X²-value	p-value
		f	%	f	%	f	%	f	%		
	d. None of the above	0	0	1	3.3	3	10	0	0		
14.	**Life style habits:** a. Smoker and chewing tobacco product b. Smoker only c. Chewing tobacco product d. No habits	5 0 0 0	13.3 0 0 0	4 1 3 0	13.3 3.3 10 0	6 4 4 1	20 13.3 13.3 3.3	0 1 0 1	0 3.3 0 3.3	15.15 (df=9)	0.087
15.	**Fractionated dosage of radiotherapy per day:** a. Less than 200 cGy b. More than 200 cGy	4 1	13.3 3.3	4 4	13.3 13.3	8 7	26.7 23.3	0 2	0 6.7	3.75 (df=3)	0.290
16.	**History of using any Dentures:** a. Using b. Not using	0 5	0 16.7	0 8	0 26.7	0 15	0 50	0 2	0 6.7	0	1

(*-P<0.05 ,significant and **-P<0.01 & ***-P<0.001 , Highly significant)

The above table reveals that there is a significant association between the posttest level of Oral mucositis among the subjects undergoing Radiation therapy with their selected demographic variables such as age, occupational status and monthly family income, and there is no significant association between the post test level of Oral mucositis and other demographic variables such gender, religion, education, duration of illness, stage of Cancer, nutritional status, history of co-morbidity, frequency of taking oral hygiene, past history of chemo/radiation therapy, life style habits, fractionated daily dose of Radiation and history of using any dentures.

Discussion

CHAPTER V
DISCUSSION

Based on the objectives of the study and hypothesis, this chapter deals with the detailed discussion of the results of the data interpreted from the statistical analysis. The purpose of the study was to compare the effectiveness of Normal saline mouth wash versus Sodium bicarbonate mouth wash on Oral mucositis among patients undergoing Radiation therapy in Oncology ward at Government Rajaji Hospital Madurai.

Oral mucositis is a frequent complication of radiation therapy for head and neck carcinoma,and its severity is directly related to the type of radiationand to the total dosage, fractionation, and durationof treatment.Oral mucositis can occur withcumulative radiation therapy doses as low as 1000–2000 centigrays(cGy) with therapy administered at a rate of 200 cGyper day.In greater than half of patients with mucositis,the condition is of such severity as to requireparenteral analgesia, interruption of radiation therapy and/or hospitalization,and the need for parenteral or tube feeding,all of which increase the cost of cancer therapy andhave a negative impact on quality of life.

Mucositis associated morbidity can lead to interruption in radiation therapy and/or prevent delivery of the total planned dose, both of which likely have a negativeimpact on survival rates.

Current management of oral mucositisconsists of the use of topical anesthetics and/oranti-inflammatory drugs (e.g., lidocaine, diphenhydramine)and agents such as colloidal silver solutions,salt and soda rinses, or hydrogen peroxide rinses.Normal

Saline solution is thought to aid in the formation of granulation tissue and to promote healing. Sodium bicarbonate has also been used as a cleansing agent because of its ability to dissolve mucus and loosen debris.Thus the severity of oral mucositis will be reduced and it promotes the healing process.

This study is consistent with Rahn *et al.*(2011) conducted a study on the prevalence of Oral mucositis among patients undergoing Radiation therapy for Head and neck cancer.The findings of the study concluded that among 76 patients,frequency of mucositis is high in patients treated with radiotherapy, affecting 100% of patients overall.The onset, intensity, and duration of mucositis varies with the individual but most often starts in the second week of therapy or after a dose of about 2000 cGy.More than 50% of the patients (40 patients) in the present trial developed mucositis in the first week after radiotherapy, while remaining 36 developed mucositis after 2 weeks of therapy.

This study is also consistent with Shanthi Appavu(2012)conducted a study on Nurses roles in the management and prevention of oral complications related to cancer treatment. Descriptive design was adopted and convenience sampling was used in International cancer centre, Neyyoor. 118 patients admitted in oncology ward, medical ward and surgical ward of the hospital were interviewed including 40 staff nurses caring them on various aspects including management and prevention of oral complications related to cancer treatment. The results shows, out of 118 patients 9 had developed complications. The over all prevalence rate was found to be higher in oncology ward (13.6%) as compared to medical ward (4.2%). The findings revealed that the majority of staff (67.5%) reported, they give more important to oral mucositis. More than one third of the nurses had also

reported that they inspect for local infection (37.5%), Xerostomia (37.55), functional disabilities (15.0%), taste alteration (20.0%) and abnormal dental development (10.0%). As a conclusion there is a great need to educate not only nurses but relatives and the patients to adopt certain preventive strategies to reduce the prevalence of oral complications related to cancer treatment.

This study is also consistent with Parulekar et al; (2011) have estimated that chemotherapy-induced mucositis varies from 40 to 76% in patients treated respectively with standard and high-dosechemotherapy.Nearly all (90% to 97%) patients receiving radiotherapy in the head and neck will develop some degree of mucositis.Of these patients treated with radiotherapy with or without chemotherapy, 34% to 43% will present severe mucositis.

The aim of the study was to compare the effectiveness of Normal saline mouth wash versus Sodium bicarbonate mouth wash on Oral mucositis among patients undergoing Radiation therapy in Oncology ward at Government Rajaji Hospital Madurai. True experimental- comparative design was adopted for doing this study. A total number of 60 samples were selected by using a Simple random sampling technique- lottery method , samples are equally distributed into both the groups, among that 30 samples were treated with Normal saline mouth wash and remaining 30 samples were treated with Sodium bicarbonate mouth wash.

BASELINE VRIABLES OF SUBJECTS WITH ORAL MUCOSITIS IN EXPERIMENTAL GROUP I AND II

The present study showed that the higher frequency,22 (73.3%) in Experimental group I and 14 (4.7%) participants in Experimental group II belongs to 51-60 years of age group.

This statistics is supported by Journal on Head and Neck Cancer in New South Wales.The majority of new head and neck cancer cases were diagnosed in people aged 60 years and over: 63 per cent of males and 60 per cent of females.

This result is also supported by José-Luis Pico conducted a randomized clinical trial on patients with Oral mucositis. The morbidity of all mucositis can be profound and it is estimated that approximately 65% of patients treated with radical radiotherapy to the oral cavity and oral pharynx will require hospitalization for treatment-related complications.

Most of the participants,27 (90%) and 26(86.7%) were males in Experimental group I and Experimental group II respectively.

This data is supported by Head and Neck Cancer in New South Wales.After allowing for differences in age, males were three times more likely than females to be diagnosed with head and neck cancer.Head and neck cancer incidence was considerably higher in males than females across all age categories.

All the participants,30 (100%) in Experimental group I and most of them 29(9.7%) from Experimental group II belongs to Hindu by religion.

Most of the participants, 15(50%) in Experimental group I were educated upto primary education but in Experimental group II, most of the participants, 17 (5.7%) were not having any formal education.

Majority of the participants, 20 (66.7%) in Experimental group I were daily wages and Experimental group II were unemployed.

Most of the participants, 17 (56.7%) family monthly income were Rs 4001-5000 in Experimental group I and in Experimental group II, majority 14 (46.7%) were having Rs 3001-4000.

With regard to the duration of illness,majority of participants, 23 (76.7%) and 22 (73.3%) were having Cancer for the period of 0-1 year in Experimental group I and Experimental group II respectively.

Most of the participants, 19 (20%) and 26 (8.7%) were in II stage of Cancer in Experimental group I and Experimental group II. Majority of the participants,14 (46.7%) and 25 (83.3%) in Experimental group I and Experimental group II were with mild malnutrition.

All the participants, 30 (100%) in Experimental group I and majority,29 (9.7%) from Experimental group II were not having any co-morbid conditions.

Most of the participants,14 (46.7%) in each Experimental group I and Experimental group II were taken oral hygiene before and after each meals.

This statistics is consistent with Satheesh Kumar PS, Anita Balan, et al; (2009) conducted a study on oral mucositis.Significant reduction in oral mucositis can be attained by proper oral hygiene measures. It was noted that proper oral care also reduced oral toxicity of radiation therapy. Furthermore, oral decontamination can reduce infection of the oral cavity by opportunistic pathogens.Therefore, a second function of oral decontamination can be to reduce the risk of systemic sepsis from resident oral and/or opportunistic pathogens.

Majority of the participants, 19 (3.3%) and 20 (66.7%) were having the past history of using chemotherapy in Experimental group I and Experimental group II respevtively.

This study is supported by Adamietz et al ; have reported that mucositis may be seen in nearly every patient when chemotherapy and radiotherapy are used simultaneously.

Most of the participants, 11(3.7%) and 15(50%) were smoker and having the history of chewing tobacco products in Experimental group I and Experimental group II respectively.

This statistics is supported by Dr.C.Ramesh, conducted a study at KIDWAI MEMORIAL INSTITUTE OF ONCOLOGY. The estimated number of new cancers in India per year is about 7 lakhs and over 3.5 lakhs people die of cancer each year. Out of these 7 lakhs new cancers about 2.3 lakhs (33%) cancers are tobacco related.

This statistics is also supported by the study conducted at National cancer Institute that Using tobacco or alcohol increases the risk of Head and neck cancer. In fact, 85 percent of head and neck cancers are linked to tobacco use, including smoking and smokeless tobacco.

Majority of the participants, 18 (60%) were taking more than 200c Gy of fractionated dose of radiotherapy per day in Experimental group I and majority,16 (53.3%) participants in Experimental group II were taking less than 200c Gy of fractionated dose of radiotherapy per day.

This result is consistent with Balan.A , Shankar.A et al; conducted a study on patients receiving Radiotherapy or Chemotherapy will receive some degree of Oral mucositis and the incidence of Oral mucositis was especially high in patients : (i) With primary tumors in the oral cavity, oropharynx, or nasopharynx; (ii) who also received concomitant chemotherapy; (iii) who received a total dose over 5,000 cGy; and (iv) who were treated with altered fractionation radiation schedules.

Trotti performed a systematic review of the literature to determine the frequency of mucositis in patients undergoing radiation to the head and neck. Thirty-three studies analyzing over 6100 patients were included. The incidence of mucositis in patients undergoing radiation was greater than 90% and was 100% in patients given altered fractionation. The overall incidence of grade 3 and 4 mucositis was 39%, with an incidence of 57% in patients treated with altered fractionation.

No one in Experimental group I and Experimental group II were using any dentures.

FINDINGS BASED ON THE OBJECTIVES

The first objective of the study was to assess the level of Oral mucositis on patients undergoing Radiation therapy for Head and neck cancer.

In this study the level of Oral mucositis among patients undergoing Radiation therapy for Head and Neck cancer were measured by NCI-CTC-Radiation induced oral mucositis grading scale.

The present study reveals that pre test score of NCI-CTC-Radiation induced oral mucositis grading scale on Oral mucositis were 22(73.3%) participants were in

severe Oral mucositis and remaining 8 (2.7%) participants were in moderate level of Oral mucositis in each experimental group I and experimental group II.There is no mild or life threatening illness in both experimental group I and experimental group II.

This study is supported by Sheetal Udaykar1, Nootan Mali2, Mahadeo Shinde Assistant Professor G. S. Mandal Mit College of Nursing, Aurangabad. The current head and neck radiotherapy protocols have a mucositis incidence of 85-100%. For altered fractionated radiation, the incidence is 100%, for chemo radiation 89%,and for conventional radiation 97%. The incidence of mucositis can approach 90-100% in patients receiving aggressive myelo-ablative chemotherapy. The severity of mucositis depends on different factors—e.g., anti-cancer treatment protocol, age and diagnosis of the patient, level oforal hygiene during therapy, and genetic factors.

This study is also supported by *Luiz Evaristo Ricci Volpato ,et al; (2013) conducted a study on Oral mucositis.* Nearly all (90% to 97%) patients receiving radiotherapy in the head and neck will develop some degree of mucositis. Of these patients treated with radiotherapy with or without chemotherapy, 34% to 43% will present severe mucositis. As a result, the patient's quality of life is affected, hospital admittance rates are higher, the use of total parenteral nutrition is increased and interruption of treatment is more frequent, all of which compromise tumor control. Mucositis causes 9% to 19% of chemotherapy and radiotherapy interruption.

This study is also consistent with Trotti A, Bellm L A,et al; (2013) conducted study to determine the frequency of mucositis and associated outcomes in patients receiving radiotherapy (RT) for head and neck cancer through a systematic review. According to the study protocol, databases were searched for randomized clinical

trials(English only, 1996-1999) of patients with head and neck cancer receiving RT with or without chemotherapy that reported one or more outcomes of interest. Thirty-three studies (n=6181 patients) met inclusion criteria. Mucositis was defined using a variety of scoring systems. The mean incidence was 80%. Over one-half of patients (56%) who received altered fractionation RT (RT-AF) experienced severe mucositis (grades 3-4) compared to 34% of patients who received conventional RT. Rates of hospitalization due to mucositis, reported in three studies (n=700), were 16% overall and 32% for RT-AF patients. Eleven percent of patients had RT regimens interrupted or modified because of mucositis in five studies (n=1267) reporting this outcome.

The second objective of the study was to evaluate the effectiveness of   Normal saline mouth wash in Experimental group I and Sodium bicarbonate mouth wash in Experimental Group II

The findings of the study reveal that when the participants in the Experimental group I was administered with Normal saline mouth wash, he / she showed a marked improvement in the healing process of Oral mucositis. Saline solution can enhance oral lubrication directly as well as by stimulating salivary glands to increase salivary flow. Normal saline (.9%) is a not irritant and is believed to help in formation of granulation tissue and to promote healing. Its safe, economical and readily available mouthwash the use of which can be promoted.

This study finding was consistent with the study conducted by Gesa meyer Hamme (2013) .A gargle solution composed by 5 herbs as well as saline gargle solution was administered in a randomised, controlled, two-armed clinical trial (treatment: control:) to chemotherapy patients, compared to Borax solution gargling alone. All patients received basic treatment with antibiotics and vitamin supplements

not further described. Improvement on mucositis symptoms was seen in 96.2% of the treatment group and 76.1% of the control group, judged by subjective clinical scales.

The mean post test score of NCI-CTC-Radiation induced oral mucositis was 0.47 among patients with varying grade of Radiation induced oral mucositis in Experimentl group I.After administering Normal saline mouth washits level was significantly lower than their mean pre test score of NCI-CTC-Radiation induced oral mucositis,2.73.The difference in mean percentage is 56.This difference is very high and it is statistically significant.This findings reveals that Normal saline mouth wash is very effective in the healing of Radiation induced oral mucositis.

The findings of the study also reveals that when the participants in the Experimental group II was administered with Sodium bicarbonate mouth wash, he / she showed a marked improvement in the healing process of Oral mucositis. Sodium bicarbonate solution acts as a mechanical cleanser on the teeth and gums, neutralizes the production of acid in the mouth and also acts as an antiseptic to help prevent infections.

In the Experimental group II, the mean post test score of oral mucositis has considerably reduced from 2.73 to 1.47 and the difference in mean percentage is 31. This difference is also high and it is statistically significant.This findings reveals that Sodium bicarbonate is alsoeffective in the healing of oral mucositis.

This finding is consistent with Elsivier (2011) conducted a Randomized clinical trial.In this study comparison made between patient preference for a new supersaturated calcium phosphate oral rinse, NeutraSal to our historical rates for patients using standard salt and soda rinses.35 patients were evaluated all receiving

radiation therapy, 12 of them received both chemotherapy and radiation therapy concurently, for confirmed squamous cell or adenocarcinoma cancer. They were evaluated utilizing NeutraSal® against the standard of care salt and soda rinses. Historical degrees of the side effects using the standard of care option and the NeutraSal®. Patients were evaluated weekly during treatment and approximately 4-6 weeks for the acute toxicities and subquent follow up every 4-8 week for 9 months post treatment.Among the 35 patients evaluated, it was found that the oral toxicities was found that the oral toxicities associated with radiation therapy were significantly lower than NeutraSal® rinses was utilized. The findings of this study revealed thatroutine use of standard salt and soda oral rinse by patients undergoing head and neck radiation significantly reduced the severity of acute mucosal toxicity and compares favorably to outcomes with and soda rinses.

- **Thus, H_1:**There is a significant difference between the pre and post test level of Oral mucositis among patients undergoing Radiation therapy for Head and neck cancer in Experimental group I and II was accepted.

- **The third objective of the study was to compare the effectiveness between Normal saline mouth wash and Sodium bicarbonate mouth wash in Experimental group I and II**

In Experimental group I, the median value of pre test is 3 and the median value of post test is effectively reduced to 0 and the median difference (3) is very high, the obtained z value 5.035 at p-value 0.000 level of significance by using Mann Whitney 'u' test.

In Experimental group II, the median value of pre test is 3 and the median value of post test is considerably reduced to 2 and the median difference is 1, the

obtained z value 4.465 at p-value 0.000 level of significanceby using, Mann Whitney 'u' test .

This findings depicts that, Normal saline mouth wash is more effective than Sodium bicarbonate mouth wash on Oral mucositis.

The mainstay of an effective oral care regimen is mouth rinses, and just plain salt water is one of the best and most cost effective mouth rinses available. It aids in removing debris and keeping the oral tissue moist and clean.Frequently rinsing the mouth with saline, may help prevent mouth sores and it can soothe the pain and keep food particles clear so as to prevent infection.Normal saline (0.9%) is not irritant and is believed to help in formation of granulation tissue and to promote healing. Its safe, economical and readily available mouthwash, the use of which can be promoted.

This findings were consistent with a study conducted by Sonis (2011), the effects of povidone-iodine and normal saline mouthwashes on oral mucositis was compared in patients after high dose chemotherapy. In the study, 132 patients were randomized to use normal saline (n=65) or povidone-iodine diluted 1:100 (n=67) mouthwashes for oral mucositis prophylaxis and treatment after high-dose chemotherapy followed by autologous peripheral stem cell transplantation. The study groups were well balanced in respect of age, sex, chemotherapy and the number of CD34+ cells in the graft. No significant difference was found between the groups in respect of oral mucositis characteristics, fever of unknown origin and other infections. The antimicrobial solution was less tolerable for patients. Oral mucositis occurred significantly more often in females than in males (86% vs 60%, P=0.0016) and was worse and of longer duration.It concluded that frequent mechanical cleansing of the

mouth by a simple saline solution is more effective compared to more sophisticated mouthwashes which can be harmful.

This result is also consistent with an interventional study conducted by Renata Lazari Sandoval. In this study immediate pain relief was achieved in 66.6% of the patients after the administration of Normal saline mouth wash . Based on the functional scale, mucositis grade III (not capable to eat solids) was reduced in 42.85% of the cases. According to the scale based on the clinical features, mucositis grade IV (ulcerative lesions) was reduced in 75% of the patients that presented this grade of mucositis at the beginning of Radiation Therapy.

Thus, H₂: There is a significant difference between the post test level of Oral mucositis between Experimental group I and II was accepted.

The fourth objective was to associate the level of Oral mucositis among patients undergoing Radiation therapy with selected demographic and clinical variables.

In the association of post test level of Radiation induced oral mucositiswith selected demographic variables in Experimental group I, the study result shows that there was no significant association between post test level of Oral mucositis with their selected demographic and clinical variables such as age,gender,religion, marital status, educational qualification,occupation, monthly family income,duration of illness, stage of Cancer,nutritional status, history of pre-morbid conditions,frequency of taking oral hygiene, past history of chemo/ radiation, life style habits, fractionated dose of radiotherapy per day and history of using any dentures.

This study is consistent with the studywhich was conducted in the School of nursing, University of California, San Francisco on Review of the current treatments

for Radiation Induced Oral Mucositis in Patients with head and neck cancer with the purpose to review the research studies on current treatment for radiation therapy-(RT-) induced mucositis in patients with head and neck cancer. Four types of agents have been evaluated for the management of RT-induced oral mucositis in patients with head and neck cancer and it was concluded that oral mucositis remains the most common complication among patients with head and neck cancer. The most effective measure to treat RT-induced mucositis in patients with head and neck cancer is frequent oral rinsing with a bland mouthwash, such as saline rinse, to reduce the amount of oral microbial flora. Pearson's chi-square analysis showed that mucositis was not significantly associated with the selected demographic variables such as age, gender,education, occupation, lower baseline neutrophil counts,dosage of radiation therapy etc.

In the association of post test level of Radiation induced oral mucositis with selected demographic variables among Experimental group II, the study result shows that there was an association between post test level of Radiation induced oral mucositis with age, occupation and family income.

This study is supported by Dodd MJ, Dibble SL, et al; (2011, conducted a Randomized clinical trial of the effectiveness of 3 commonly used mouthwashes to treat chemotherapy-induced mucositis)at San Francisco.The mouthwashes were soda, chlorhexidine, and "magic" mouthwash (lidocaine, Benadryl, and Maalox).Study Design: A randomized, double-blind clinical trial was implemented in 23 outpatient and office settings. Participants were monitored from the time they developed mucositis until cessation of the signs and symptoms of mucositis, or until they finished their 12-day supply of mouthwash. All participants followed a prescribed oral

Summary, Conclusion, Implications, Recommendations & Limitations

CHAPTER - VI

SUMMARY, CONCLUSION, IMPLICATIONS, RECOMMENDATIONS AND LIMITATIONS

This chapter narrates the summary of the study and conclusion drawn. It also clarifies the limitations of the study and the implications for different areas like nursing education, nursing practice, nursing administration and nursing research. It provides the recommendations made based on the study.

6.1 SUMMARY

The present study was undertaken to compare the effectiveness of Normal saline mouth wash versus sodium bicarbonate mouth wash on Oral mucositis among patients undergoing Radiation therapy for Head and neck cancer in Oncology ward at Government Rajaji Hospital, Madurai-20.

This study was carried out with the following objectives;

- To assess the level of Oral mucositis on patients undergoing Radiation therapy for Head and neck cancer.
- To evaluate the effectiveness of Normal saline mouth wash in Experimental group I and Sodium bicarbonate mouth wash in Experimental Group II
- To compare the effectiveness between Normal saline mouth wash and Sodium bicarbonate mouth wash on Oral mucositis among patients undergoing Radiation therapy in Experimental group I and II
- To associate the level of Radiation induced Oral mucositis among patients undergoing Radiation therapy with selected demographic and clinical variables.

The study was conducted based on the assumption that;

1. 1.The patients receiving radiation therapy for Head and Neck Cancer develops varying level of Oral mucositis

2. 2.Oral mucositis patients will cooperate for the Normal saline and Sodium bicarbonate mouth wash.

3. 3.Normal saline and sodium bicarbonate mouth wash has no side effects and it helps to heal Oral mucositis.

The following research hypothesis were formulated for the study;

- **H$_1$:**There is a significant difference between the pre and post test level of Oral mucositis among patients undergoing Radiation therapy for Head and neck cancer in Experimental group I and II

- **H$_2$:**There is a significant difference between the post test level of Oral mucositis between Experimental group I and II.

- **H$_3$:**There is a significant association between the level of Oral mucositis with selected demographic and clinical variables.

The study was conducted among selected patients with Oral mucositis, admitted in Oncology ward at Government Rajaji Hospital, Madurai-20.The True experimental – comparative design was used in this study. The Population for the study were patients with oral mucositis, admitted in Radiation oncology ward and who met the inclusion criteria. The duration of the data collection period was five weeks.

In this study, 60 Radiation induced oral mucositis patients were included. National-Cancer –Institute Common toxicity criteria-Oral mucositis grading scale was used in this study to assess the level of Oral mucositis among patients undergoing

Radiation therapy for Head and neck cancer, before and after Normal saline and Sodium bicarbonate mouth wash in Experimental group I and Experimental group II.Post test level of Oral mucositis was assessed 2 weeks after intervention. Data were analyzed using descriptive and inferential statistics.

6.2 MAJOR FINDINGS OF THE STUDY

Demographic and clinical variables shows the following findings;

With regard to the age, majority of the participants 22 (73.3%) and 14 (46.7%) were between the age group of 51-60 years in experimental group I and experimental group II respectively.

In the aspect of gender, most of the participants,27 (90%) in Experimental group I and 26 (86.7%) in Experimental group II were males.

Regarding the religion, all the participants, 30 (100%) in experimental group I and most of the participants in experimental group II, 29 (96.7%) were Hindus.

In the aspect of marital status, majority of the participants,23 (76.7%) and 28 (93.3%) were marriedin experimental group I and experimental group II respectively.

With regard to the educational status, most of the participants, 14 (46.7%) and 17 (5.7%) in experimental group I and experimental group II were not having any formal education respectively.

In the aspect of occupational status, most of the participants,20 (66.7%) in experimental group I were daily wages and 20 (66.7%) were unemployed in experimental group II.

With regard to the family income, majority of the participants, 17 (5.7%) in experimental group I were having the family income between Rs. 4001-5000 and 14 (4.7%) in experimental group II were hving the family income between Rs. 3001-4000.

In the aspect of duration of illness, majority of the participants, 23 (76.7%) and 22 (73.3%) were having cancer for the duration of 0-1 year in experimental group I and experimental group II respectively.

With regard to the stage of Cancer, most of the participants, 19 (63.4%) and 26 (86.7%) were in II stage of Cancer in experimental group I and experimental group II respectively.

Regarding the nutritional status, majority of participants, 14 (46.7%) and 25 (83.3%) were in mild malnutrition in experimental group I and experimental group II respectively.

In the aspect of co-morbid conditions, all the participants 30 (100%) in experimental group II and majority,29 (96.7%) participants in experimental group I were not had any co-morbid conditions.

With regard to the frequency of taking oral hygiene, majority of participants,15 (50%) and 11 (36.7%) took oral hygiene twice in a day in experimental group I and experimental group II respectively.

Most of the participants,19 (63.3%) and 20 (66.7%) were undergone chemotherapy alone in the past in experimental group I and experimental group II respectively.

Most of the participants, 11 (36.7%) were smoker in experimental group I and 15 (50%) were having the history of chewing tobacco products experimental group II .

In consistent with the fractionated daily dose of Radiation therapy, most of the participants,18 (60%) in experimental group I were having more than 200 cGy of fractionated dosage of radiatiotherapy per day and majority,16 (53.3%) participants in experimental group II were having less than 200cGy of fractionated dose of radiotherapy per day.

No participants in both the groups are using any dentures.

In the pre test, majority of the participants, 22(73.3%) were in severe level of oral mucositis and 8 (2.7%) participants were in moderate grade of oral mucositis in each experimental group I and experimental group II.There is no mild or life threatening illness in both experimental group I and experimental group II.

In the post test, majority,16(53.3%) participants were in no oral mucositis and 14 (46.7%) were in mild grade of oral mucositis and no moderate and severe grade of oral mucositis in the Experimental group I and in Experimental group II, majority, 15 (50%) were in moderate level, 8 (2.7%) were in mild level , 2 (6.7%) were in severe level and only 5 (16.7%) were in no Oral mucositis.

The post test score of mean (0.47) is lesser than the pre test score(2.73) in experimental group I.The difference in mean percentage is 56.This difference is very high and it is statistically significant.Similarly in experimental group II, the post test score of mean (1.47) is lesser than the pre test score(2.73).The difference in mean

percentage on oral mucositis is 31.This difference is also high and it is statistically significant.

The association between selected demographic variables and post test score of level oral mucositis were calculated by $\chi 2$at 0.05 level of significance. It described the relationship of individual demographic variable with level of oral mucositis after the intervention. The post test score level of Oral mucositis among the participants in Experimental group I were not significantly associated with their demographic variables.Whereas in the Experimental group II,the post test score of Radiation induced oral mucositis were significantly associated with their age, occupation and family income.All the other variables are not significantly associated with the post test level of oral mucositis.

6.3 CONCLUSION

The present study statistically proved that Normal saline mouth wash is very effective than Sodium bicarbonate mouth wash for reducing the severity of Oral mucositis.

6.4 IMPLICATIONS OF THE STUDY

This study has its implications in various areas such as

- Nursing Education
- Nursing Practice
- Nursing Administration
- Nursing Research

Nursing Education:

1. This study enhances the nursing students to acquire knowledge in complications and management of Radiation induced oral mucositis

2. As the Normal saline and sodium bicarbonate mouth wash has no adverse effects, the nurse can apply it without doctors orders, if needed.

3. This study enhances the student to think comprehensively in planning her/his intervention in managing the client with Radiation induced oral mucositis

4. This study provokes critical thinking to the student.

5. This study enables the student to compare the other possible ways of managing patients with Oral mucositis

6. This study arouses motivation to the students and to intellectually care for the client with Oral mucositis.

7. Normal saline and sodium bicarbonate mouth wash are easy to prepare, affordable and well acceptedby patients making it useful for improving the quality of life.

Nursing Practice

1. Nurses have responsibility to improve the quality of life among the patients with Oral mucositis

2. Normal saline and Sodium bicarbonate mouth wash helps to heal Oral mucositis

3. Present study motivates the nursing personnel about the importance of Normal saline and Sodium bicarbonate mouth wash

4. Normal saline and Sodium bicarbonate mouth wash are cost effective.

5. The incidence of oral mucositis was especially high in patients receiving radiation therapy for head and neckcancer. In addition, they also contribute to economic ramifications of the affected patient.

Nursing Administration

1. Nursing educators should provide adequate training to nursing students regarding Normal saline and sodium bicarbonate mouth wash.

2. Continuing nursing education and in-service education can be planned by nurse administrators also aid in formulating policies and protocols.

3. Appropriate and feasible organizational intervention like health education, domiciliary care services and health promotion activities will provide greater outcome

4. The nurse administrator should organize activities toexplain and train the nurses about their role in decreasing the severity of Oral mucositis and itscomplications.

5. The nurse administrator should take interest in dissemination of theinformation through instructional material.

6. Inclusion of new procedures in the Nursing service department can be facilitated by the data obtained from the study.

Nursing Research

1. The study motivates for further studies related to this field

2. This study calls for further studies on the comfort aspect of the client on Oral mucositis.

3. In-service education programme can be conducted to aid the clinical nurses in updating the knowledge in Normal saline and sodium bicarbonate mouth wash

4. This study can be a base line for further studies.

5. This may increase the awareness ofthe nurses, and may also highlight the important role thatnurses can play in decreasing the complications due to Oral mucositis in radiotherapy patients.

6.5 RECOMMENDATIONS:

1. A similar study can be replicated with larger sample.

2. A similar study can be conducted in various settings like Medical oncology ward, and pediatric ward.

3. A study can be done to find out the prevalence of Radiation induced oral mucositis in patients undergoing Radiation therapy.

4. Similar study can be conducted as a comparative study between Radiation induced oral mucositis and Chemotherapy induced oral mucositis

7. Similar study can be conducted as a comparative study between male clients and female clients.

8. Similar study can be conducted as a long term study

9. This study can be conducted to evaluate the knowledge and attitude of nurses regarding prevention of Oral mucositis.

6.6 LIMITATIONS

Some of the Clinical procedures such as Radiation therapy and specimen collection etc were disturbed the Researcher while giving mouth wash in the morning session.Hence those procedures were planned ahead to the intervention.

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Appendices

APPENDIX – I

LETTER SEEKING PERMISSION TO CONDUCT STUDY

From

      Mrs.Sunitha.G,
      M.Sc (N) I year student,
      College of Nursing,
      Madurai Medical College,
      Madurai-20.

To

      The professor and Head of the Department,
      Department of Radiation oncology,
      Government Rajaji Hospital,
      Madurai-20.

Through the proper channel,

Respected Madam,

Sub: College of Nursing, Madurai Medical college, Madurai-M.Sc.,(N) I year – Medical Surgical Nursing student-Permission letter for conducting study in Radiation oncology ward, Government Rajaji Hospital, Madurai- requested –regarding;

As per the curriculum recommended by the Tamilnadu Dr.MGR Medical University, I year M.Sc (N) students are required to conduct a dissertation study.I have selected the study topic **"A study to compare the effectiveness of Normal saline mouth wash versus Sodium bicarbonate mouth wash on Oral mucositis among patients undergoing Radiation therapy in Oncology ward at Government Rajaji Hospital, Madurai"** for the partial fulfilment of the course. I assure that I will not interfere with the routine activity of the department.

Kindly consider my request and permit me to conduct the study.

Thanking you,

Place: Madurai
Date: 24.07.2014

yours faithfully,

(SUNITHA.G)

Dr.S. VASANTHAMALAI
BSc. M.D DMRT
PROFESSOR OF RADIOTHERAPY
MADURAI MEDICAL COLLEGE
MADURAI.

APPENDIX – II

ETHICAL COMMITTEE APPROVAL LETTER

Ref. No. 68/E4/2/2014   Govt. Rajaji Hospital,
Madurai.20. Dated: 02.2014

Institutional Review Board / Independent Ethics Committee.
Captian. Dr. B. Santhakumar, M.D., (F.M.,)
Dean, Madurai Medical College &
Govt Rajaji Hospital, Madurai 625020. **Convenor**

         Sub: Establishment-Govt. Rajaji Hospital, Madurai-20-
              Ethics committee-Meeting Minutes- for January 2014
              Approved list -regarding.

     The Ethics Committee meeting of the Govt. Rajaji Hospital, Madurai was held on 20.1.2014, Monday at 10.00 am to 12.00.noon at the Anaesthesia Seminar Hall, Govt. Rajaji Hospital, Madurai. The following members of the committee have attended the meeting.

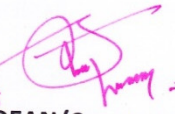|		
1.Dr. V. Nagarajan, M.D., D.M (Neuro) Ph: 0452-2629629 Cell.No 9843052029	Professor of Neurology (Retired) D.No.72, Vakkil New Street, Simmakkal, Madurai -1	Chairman
2. Dr.Mohan Prasad , M.S M.Ch Cell.No.9843050822 (Oncology)	Professor & H.O.D of Surgical Oncology(Retired) D.No.72, West Avani Moola Street, Madurai -1	Member Secretary
3. Dr. Parameswari M.D (Pharmacology) Cell.No.9994026056	Director of Pharmacology Madurai Medical College	Member
4. Dr.S. Vadivel Murugan, MD., (Gen.Medicine) Cell.No 9566543048	Professor of Medicine Madurai Medical College	Member
5. Dr.S. Meenakshi Sundaram, MS (Gen.Surgery) Cell.No 9842138031	Professor & H.O.D of Surgery Madurai Medical College	Member
6. Mrs. Mercy Immaculate Rubalatha, M.A., Med., Cell. No. 9367792650	50/5, Corporation Officer's quarters, Gandhi Museum Road, Thamukam, Madurai-20	Member
7. Thiru.Pala. Ramasamy , BA.,B.L., Cell.No 9842165127	Advocate, D.No.72.Palam Station Road, Sellur, Madurai -2	Member
8. Thiru. P.K.M. Chelliah ,B.A Cell.No 9894349599	Businessman, 21 Jawahar Street, Gandhi Nagar, Madurai-20	Member

The following Project was approved by the committee

| Name of P.G.	Course	Name of the Project	Remarks
G. Sunitha	M.Sc. Nursing, College of Nursing, Madurai Medical College, Madurai	A Study to compare the effectiveness of normal saline versus sodium Bicarbonate mouth wash on radiation induced mucositis among patients undergoing radiation therapy at Oncology department, Government Rajaji Hospital, Madurai.	Approved

Please note that the investigator should adhere the following: She/He should get a detailed informed consent from the patients/participants and maintain it Confidentially.

1. She/He should carry out the work without detrimental to regular activities as well as without extra expenditure to the institution or to Government.
2. She/He should inform the institution Ethical Committee, in case of any change of study procedure, site and investigation or guide.
3. She/He should not deviate the area of the work for which applied for Ethical clearance. She/He should inform the IEC immediately, in case of any adverse events or Serious adverse reactions.
4. She/He should abide to the rules and regulations of the institution.
5. She/He should complete the work within the specific period and if any Extension of time is required He/She should apply for permission again and do the work.
6. She/He should submit the summary of the work to the Ethical Committee on Completion of the work.
7. She/He should not claim any funds from the institution while doing the work or on completion.
8. She/He should understand that the members of IEC have the right to monitor the work with prior intimation.

Member Secretary   **Chairman**
Ethical Committee

26.2.14   **DEAN/Convenor**
Govt. Rajaji Hospital,
Madurai- 20.

7/2/14

To

APPENDIX – III

CONTENT VALIDITY CERTIFICATE

CERTIFICATE OF VALIDATION

This is to certify that the tool

SECTION A - Demographic Data

SECTION B -National CancerInstitute - CommonToxicity criteria
oral mucositis grading scale

Prepared for data collection by, Mrs.SUNITHA.G, II year M.Sc (N) student, College of Nursing, Madurai Medical College, Madurai, Who has undertaken the study field on thesis entitled "A study to compare the effectiveness of Normal saline mouth wash versus Sodium bicarbonate mouth wash on oral mucositis among patients undergoing Radiation therapy in Oncology ward at Government Rajaji Hospital Madurai."

SIGNATURE OF THE EXPERT

NAME: Dr.S. VASANTHAMALAI
        BSc. M.D DMRT

DESIGNATION: PROFESSOR OF RADIOTHERAPY
              MADURAI MEDICAL COLLEGE
              MADURAI.

DATE: 2/8/14.

CERTIFICATE OF VALIDATION

This is to certify that the tool

SECTION A - Demographic Data

SECTION B -National CancerInstitute - Common Toxicity criteria
oral mucositis grading scale

Prepared for data collection by, Mrs.SUNITHA.G, II year M.Sc (N) student, College of Nursing, Madurai Medical College, Madurai, Who has undertaken the study field on thesis entitled "A study to compare the effectiveness of Normal saline mouth wash versus Sodium bicarbonate mouth wash on oral mucositis among patients undergoing Radiation therapy in Oncology ward at Government Rajaji Hospital Madurai."

SIGNATURE OF THE EXPERT

NAME: G. Jaya Thanga Selvi

DESIGNATION: Prof Cum HOD - Med - Surg

DATE: 25/7/014

CERTIFICATE OF VALIDATION

This is to certify that the tool

SECTION A - Demographic Data

SECTION B -National CancerInstitute - Common Toxicity criteria

oral mucositis grading scale

Prepared for data collection by, Mrs.SUNITHA.G, II year M.Sc (N) student, College of Nursing, Madurai Medical College, Madurai, Who has undertaken the study field on thesis entitled "A study to compare the effectiveness of Normal saline mouth wash versus Sodium bicarbonate mouth wash on oral mucositis among patients undergoing Radiation therapy in Oncology ward at Government Rajaji Hospital Madurai."

SIGNATURE OF THE EXPERT

Head of the Department
Medical Surgical Nursing
Dhanalakshmi Srinivasan College of Nursing
Perambalur - 621 212.

NAME:

DESIGNATION: Associate Professor

DATE: 07/08/14

CERTIFICATE OF VALIDATION

This is to certify that the tool

SECTION A - Demographic Data

SECTION B -National CancerInstitute - Common Toxicity criteria
oral mucositis grading scale

Prepared for data collection by, Mrs.SUNITHA.G, II year M.Sc (N) student, College of Nursing, Madurai Medical College, Madurai, Who has undertaken the study field on thesis entitled "A study to compare the effectiveness of Normal saline mouth wash versus Sodium bicarbonate mouth wash on oral mucositis among patients undergoing Radiation therapy at Oncology ward, Government Rajaji Hospital Madurai."

SIGNATURE OF THE EXPERT

NAME: Dr. (mm) B.SARA)

DESIGNATION: Reader in Nursing

DATE: 27/08/14

CERTIFICATE OF VALIDATION

This is to certify that the tool

SECTION A - Demographic Data

SECTION B -National CancerInstitute - Common Toxicity criteria
oral mucositis grading scale

Prepared for data collection by, Mrs.SUNITHA.G, II year M.Sc (N) student, College of Nursing, Madurai Medical College, Madurai, Who has undertaken the study field on thesis entitled "A study to compare the effectiveness of Normal saline mouth wash versus Sodium bicarbonate mouth wash on oral mucositis among patients undergoing Radiation therapy in Oncology ward at Government Rajaji Hospital Madurai."

L. Anand

SIGNATURE OF THE EXPERT

NAME: L.ANAND

DESIGNATION:LECTURER,
College of Nursing,
NEIGRIHMS,
Shillong

DATE: 08.08.14

APPENDIX-IV

INFORMED CONSENT FORM

ஒப்புதல் அறிக்கை

பெயர்:   **நாள்:**

எனக்கு இந்த செவிலிய ஆய்வினைப் பற்றிய முழு விவரம் விளக்கமாக எடுத்துரைக்கப்பட்டது. இந்தஆய்வில் பங்கு கொள்வதில் உள்ளநன்மைகள் மற்றும் தீமைகள் பற்றிமுழுமையாக புரிந்துகொண்டேன். இந்த ஆய்வில் தானாக முன்வந்து பங்குபெறுகிறேன். மேலும் எனக்கு இந்த ஆய்விலிருந்து எந்த சமயத்திலும் விலகிக கொள்ள முழு அனுமதி வழங்கப்பட்டுள்ளது. என்னுடைய பெயர் மற்றும் அடையாளங்கள் ரகசியமாக வைத்துக்கொள்ளப்படும் என்றும் எனக்கு உறுதியளிக்கப்பட்டுள்ளது.

கையொப்பம்

APPENDIX V
SEMI STRUCTURE INTERVIEW SCHEDULE

SECTION- A

Sample No :

DEMOGRAPHIC DATA

1. AGE
        a) 20yrs to 30 yrs
        b) 31 yrs to 40 yrs
        c) 41 yrs to 50 yrs
        d) 51yrs to 60 yrs

2.GENDER
        a)Male
        b)Female

3. RELIGION
        a) Hindu
        b) Christian
        c) Muslim
        d) Others

4. MARITAL STATUS
        a) Unmarried
        b) Married
        c) Widow/Widower
        d) Divorced
        e) Separated

5.EDUCATION
        a) No formal education
        b) Primary education
        c) Secondary education
        d) Higher secondary education
        e) Graduate and above

6.OCCUPATION
        a) Unemployed
        b) Daily wages
        c) Business
        c) Salaried
        d) Housewife

7. FAMILY MONTHLY INCOME IN RUPEES
     a) Below 3000
     b) 3001-4000
     c) 4001-5000
     d) Above 5000

8. DURATION OF ILLNESS
     a) 0-1 year
     b) 2-3 years
     c) 4-5years
     d) Above 5years

9. STAGE OF CANCER
     a) Stage I
     b) Stage II
     c) Stage III
     d) Stage IV

10. NUTRITIONAL STATUS
     a) Adequately nourished
     b) Mild malnutrition
     c) Moderate malnutrition
     d) Severe malnutrition

11. HISTORY OF CO-MORBID CONDITIONS
     a) Diabetes mellitus
     b) Immunosuppressive diseases
     c) Vitamin deficiencies
     d) None of the above

12. FREQUENCY OF TAKING ORAL HYGIENE
     a) Oncein a day
     b) Twice a day
     c) Before and after each meals

13. PAST HISTORY OF CHEMO/RADIATION THERAPY
     a) Chemo and Radiation therapy
     b) Cemotherapy alone
     c) Radiation therapy alone
     d) None of the above

14.LIFE STYLE HABITS
    a) Smoker and chewing tobacco products
    b) Smoker only
    c) Chewing tobacco products only
    d) No habits

15.FRACTIONATED DOSAGE OF RADIOTHERPY PER DAY
    a) Less than 200 cGy
    b) More than 200 cGy

16.HISTORY OF USING ANY DENTURES
    a) Using
    b) Not using

ஆராய்ச்சியாளரின் வடிவமைக்கப்பட்ட நேர்காணல் படிவம்

பகுதி–அ
<u>தன்னிலைவிபரக் குறிப்பு</u>

நேர்காணல் படிவம் எண் : 1

1. வயது

    அ. 20–30 வயது

    ஆ. 31–40 வயது

    இ. 41–50 வயது

    ஈ. 51–60 வயது

2. பாலினம்

    அ. ஆண்

    ஆ. பெண்

3. மதம்

    அ. இந்து

    ஆ. கிறிஸ்துவம்

    இ. இஸ்லாம்

    ஈ. மற்றவை

4. திருமணநிலை

    அ. திருமணமாகாதவர்

    ஆ. திருமணமானவர்

    இ. கணவர் /மனைவியை இழந்தவர்

    ஈ. விவாகரத்தானவர்

    உ. பிரிந்துவாழ்பவர்

5. கல்வித் தகுதி

    அ. படிப்பறிவின்மை

    ஆ. ஆரம்பக் கல்வி

    இ. உயர்நிலைக்கல்வி

    ஈ. மேல்நிலைக் கல்வி

    உ. பட்டப்படிப்புமற்றும் அதற்குமேல்

6. வேலை

    அ. வேலை இல்லை

    ஆ. தினக்கூலி

    இ. சொந்தத் தொழில்

    ஈ. நிறுவனத்தில் வேலை

    உ. இல்லத்தரசி

7. குடும்பவருமானம்

    அ. 3000-க்கும் குறைவு

    ஆ. 3001 - 4000

    இ. 4001 - 5000

    ஈ. 5000-க்குமேல்

8. நோய் தாக்கம் உள்ளகாலம்

    அ. 0-1 வருடம்

    ஆ. 2 – 3 வருடம்

    இ. 4 – 5 வருடம்

    ஈ. 5 வருடத்திற்குமேல்

9. புற்றுநோயின் பாகங்கள்

    அ. ஒன்று

    ஆ. இரண்டு

    இ. மூன்று

    ஈ. நான்கு

10. உணவுபழக்கத்தின் தன்மை

    அ. அளவானது

    ஆ. சுமாரானஊட்டச்சத்து

    இ. குறைவானஊட்டச்சத்து

    ஈ. மிகவும் குறைவானஊட்டச்சத்து

11. துணைநோய்கள்

    அ. நீரிழிவுநோய்

    ஆ. எதிர்ப்புசத்துகுறைவு

    இ. விட்டமின் C குறைவு

    ஈ. மேலேஉள்ளவையுமில்லை

12. பல் சுத்தத்திற்கான இடைவேளை

    அ. ஒருமுறைமட்டும்

    ஆ. இருமுறை

    இ. சாப்பிடுவதற்குமுன் மற்றும் சாப்பிட்டதற்குபின்

13. முன்னால் எடுத்துக்கொண்டபுற்றுநோய்க்கானமருந்துமற்றும் கதிர் சிகிச்சைமுறை

    அ. புற்றுநோய்க்கானமருந்துமற்றும் கதிர் சிகிச்சை

    ஆ. புற்றுநோய்க்கானமருந்துமட்டும்

    இ. புற்றுநோய்க்கானகதிர் சிகிச்சைமட்டும்

    ஈ. மேலேஉள்ளவையுமில்லை

14. வாழ்க்கைமுறையில் கடைப்பிடிக்கும் பழக்கவழக்கங்கள்

    அ. புகை பிடித்தல் மற்றும் புகையிலைபோடுதல்

    ஆ. புகை பிடித்தல் மட்டும்

    இ. புகையிலைபோடுதல் மட்டும்

    ஈ. மேலேஉள்ளவையுமில்லை

15. புற்றுநோய்க்கானகதிர் சிகிச்சையின் அளவீடு

    அ. 200 cGy-க்குகுறைவு

    ஆ. 200 cGy-க்குஅதிகம்

16. செயற்கையானபல் ஏதேனும் உபயோகித்தீர்களா?

    அ. ஆம்

    ஆ. இல்லை

SECTION B

NATIONAL CANCER INSTITUTE-COMMON TOXICITY CRITERIA-
ORAL MUCOSITIS GRADING SCALE

GRADE0	GRADE1 (MILD)	GRADE2 (MODERATE)	GRADE3 (SEVERE)	GRADE4 (LIFE THREATENING)
None	Erythema of the mucosa	Patchy pseudomembranous reaction (paces generally ≤1.5cm in diameter and noncontiguous)	Confluent pseudomembranous reaction (contiguous patches generally ≥1.5cm in diameter)	Necrosis or deep ulceration; may include bleeding not induced by minor trauma or abrasion

APPENDIX - VI

CERTIFICATE OF ENGLISH EDITING

TO WHOMSOEVER IT MAY CONCERN

This is to certify that the dissertation "A study to compare the effectiveness of Normal saline mouth wash versus Sodium bicarbonate mouth wash on oral mucositis among patients undergoing Radiation therapy in Oncology ward at Government Rajaji Hospital Madurai." done by Mrs.Sunitha.G, M.Sc Nursing II Year student, College of Nursing, Madurai Medical College, Madurai has been edited for English language appropriateness.

Name : G. SAKUNTHALADEVI M.A. B.Ed

Designation: P.G. ASST IN ENGLISH

Institution : Govt. Hr. Sec. School, P. Pudupatti - 626104

G. SAKUNTHALADEVI, M.A.,B.Ed.,
P.G. Asst. (English)
Govt. Hr. Sec. School
P. PUDUPATTI - 626 104,
Virudhunagar Dt.

APPENDIX - VII

CERTIFICATE OF TAMIL EDITING

TO WHOMSOEVER IT MAY CONCERN

This is to certify that the dissertation "A study to compare the effectiveness of Normal saline mouth wash versus Sodium bicarbonate mouth wash on oral mucositis among patients undergoing Radiation therapy in Oncology ward at Government Rajaji Hospital Madurai" done by Mrs.Sunitha.G, M.Sc Nursing II Year student, College of Nursing, Madurai Medical College Madurai has been edited for Tamil language appropriateness.

Name : *[handwritten]* ஏம்.ஏ (தமிழ்) ஏம்.எட்; ஏம்.பிள்

Signature *[handwritten]* 07.08.14

தலைமையாசிரியர்,
அரசு மேல் நிலைப்பள்ளி,
சாலைமறக்குளம் - 626 607.
விருதுநகர் மாவட்டம்.

Designation: *[handwritten]* தலைமை ஆசிரியை

Institution : *[handwritten]* அரசு மேல்நிலைப்பள்ளி,
சாலைமறக்குளம் - 626 607

APPENDIX - VIII

PROCEDURE OF NORMAL SALINE MOUTH WASH

DEFINITION

It refers to rinsing the oral cavity with Normal saline (one teaspoon of salt(6gms) in 250 ml of water which contains sodium 150mmol/litre and chloride 150mmol/litre) mouth wash solution.

EQUIPMENTS NEEDED

- Sodium chloride/ common salt in a bowl
- Tea spoon to measure the sodium chloride
- Measuring glass to measure the boiled cooled water
- Tumbler to take the prepared solution
- Towel to wipe

PURPOSES
- It enhance oral lubrication
- It stimulate the salivary glands to increase salivary flow
- It promotes wound healing
- To keep food debris out of healing wounds
- To prevent infection
- It encourage the draining of pus from dental abscesses

PROCEDURE TIPS

- Gargle the mouth wash for 1 minute and spit out
- Do not swallow the mouth wash
- Rinse every 2 to 6 hours if indicated

PLAN OF ACTION

ACTION	RATIONALE
Explain the procedure to the client	It helps to get co-operation from te client
Perform hand hygiene	Hand hygiene deter the spread of micro organisms
Wear apron and mask	It maintain an area free of micro organisms
Fill 250 ml of boiled cooled water in a measuring cup	For mixing the salt
Measure one teaspoon of salt(6gms) in a measuring spoon	For preparing the solution
Put the measured salt into the cup of water and stir the salt in the water until the salt dissolves.	Stirring helps to dissolve the salt completely
Take 40 ml of mouthwash from the measuring cup into the Tumbler and instruct the client to gargle the prepared solution for one minute and spit out.	Gargling the solution promotes the healing process

PROCEDURE OF SODIUM BICARBONATE MOUTH WASH

DEFINITION

It refers to rinsing the oral cavity with Sodium bicarbonate (one teaspoon of sodium bicarbonate(1.3gm) in 250 ml of water) mouth wash solution

PURPOSES
- It works as a mechanical cleanser on the teeth and gums
- It neutralizes the production of acid in the mouth
- It acts as an antiseptic to help prevent infections
- It helps to prevent tooth decay

EQUIPMENTS NEEDED
- Sodium bicarbonate/ Baking soda in a bowl
- Tea spoon to measure the sodium bicarbonate
- Measuring glass to measure the boiled cooled water
- Tumbler to take the prepared solution
- Towel to wipe the mouth

PROCEDURE TIPS
- Gargle the mouth wash for 1 minute and spit out
- Do not swallow the mouth wash
- Rinse every 2 to 6 hours if indicated
- Keep away from small children to avoid accidental ingestion

PLAN OF ACTION

ACTION	RATIONALE
Explain the procedure to the client	It helps to get co-operation from te client
Perform hand hygiene	Hand hygiene deter the spread of micro organisms
Wear apron and mask	It maintain an area free of micro organisms
Fill 250 ml of boiled cooled water in a measuring cup	For mixing the salt
Measure one teaspoon of sodium bicarbonate(1.3gm) in a measuring spoon	For preparing the solution
Put the measured sodium bicarbonate into the cup of water and stir it in the water until the sodium bicarbonate dissolves.	Stirring helps to dissolve the salt completely
Take 40 ml of mouthwash from the measuring cup into the Tumbler and instruct the client to gargle the prepared solution for one minute and spit out.	Gargling the solution promotes the healing process

APPENDIX – IX

SNAP SHOT OF THE PROEJCT

Researcher collecting information from the subjects

Researcher providing intervention