EFFECTIVENESS OF POVIDONE- IODINE (2%) VS NORMAL SALINE (0.9%) MOUTH RINSING ON ORAL MUCOSITIS AMONG PATIENTS RECEIVING EXTERNAL RADIATION THERAPY FOR HEAD AND NECK MALIGNANCY

A DISSERTATION SUBMITTED TO THE TAMILNADU DR.M.G.R MEDICAL UNIVERSITY, CHENNAI, IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTER OF SCIENCE IN NURSING

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CERTIFICATE

This is the bonafide certificate of **Miss.Rajathi.R M.Sc. (N) II** Year student from Sacred Heart Nursing College, Ultra Trust, Madurai, submitted in partial fulfillment for the Degree of Master of Science in Nursing, under the Tamil Nadu Dr.M.G.R. Medical University, Chennai.

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"God is our refuse and strength, an ever present help in trouble"
Psalm :46.1

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ABSTRACT

" A study to assess the effectiveness of povidone –iodine (2%) vs normal saline (0.9%) mouth rinsing on oral mucositis among patients receiving external radiation therapy for head and neck malignancy from Devaki Cancer and Research Centre at Madurai". The research design adopted for the study was quasi experimental pretest, post test two group design. The simple random sampling technique was used by lottery method to select the 30 samples for experimental group- I and 30 samples for experimental group- II, who fulfilled the inclusion and exclusion criteria. The experimental group- I was receiving 10 ml of povidone –iodine (2%) mouth rinsing for two times for continuous 14 days. The experimental group- II was treated with 20 ml of normal saline (0.9%) mouth rinsing two times a day for continuous 14 days after receiving routine mouth care . The oral mucositis status was assessed by using oral mucositis assessment scale (OMAS) for experimental group- I and experimental group- II on 7^{th} and 14^{th} day. Collected data were analyzed in terms of both descriptive and inferential statistics. A probability of < 0.05 was considered to be significant. Findings of the study was evidenced that the mean post test oral mucositis score of experimental group- I (4.03) after povidone-iodine mouth rinse significantly lower than the experimental group II (4.8) who have received normal saline mouth rinse. The mean post test erythema score of experimental group- I (1.33) was significantly higher than the experimental group-II (1.3). There was a significant association between the pre test oral mucositis score of experimental group- II with age (χ^2 =86.8, P> 0.05%). There was no association between the pre test oral mucositis score of experimental group I with demographic variables such as age, sex, education, occupation, marital status, history of smoking, betel nut chewing and pan or kutka chewing. Both mouth rinses which were used in this study were found to be effective. Among this povidone- iodine (2%) is found to be superior in reducing oral mucositis in subjects who has received radiation therapy when compared to normal saline mouth rinse.

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CHAPTER -1

INTRODUCTION

BACKGROUND OF THE STUDY:

"Time is shortening but every day that I challenge this cancer and survive is a victory for me"

-Ingird Bergman

Cancer is a generic term for a large group of disease that can affect any part of the body. Other terms used are malignant tumors and neoplasm's. One defining feature of cancer is the rapid creation of abnormal cells that grow beyond their usual boundaries and which can then invade adjoining parts of the body and spread to either organs of the body and spread to the other organs this process is referred to as metastasis. (Who.int/cancer)

Tatiana macfarlane and Sudhir nair (2012) defined head and neck cancer that arises in the head and neck region (in the nasal cavity sinuses, lips, mouth, salivary glands, throat or larynx , primary tumor) most head and neck cancers are squamous cell carcinomas. world wide the head and neck cancer. It is the most common cancer of males in India and the fifth most common in females . In India the age adjusted rates among females is the highest .

Poonam joshi and Pankaj chaturvedi *(2014)* stated that head and neck cancer are the most common cancers in developing countries, especially in southeast Asia. Head and neck cancers are more common in males compared to females this is mainly attributed to tobacco nut chewing, alcohol etc.oral

cancers are most common amongst all head and neck squamous cell carcinoma.

Mountzios (2015) described that head and neck cancer (HNC) represents the sixth most common malignancy and accounts for approximately 6% of new cancer cases annually worldwide. As life expectancy constantly increases, the onset of HNC in patients older than 65 years of age at diagnosis is not rare and up to one fourth of cases occurs in patients older that 70 years at age. The frailty of elderly patients with HNC is attributed to the high incidence of smoking and alcohol abuse in this malignancy and the presence of substantial cardiovascular, respiratory or metabolic co morbidities.

Staffurth et al.,(2010)explained that treatment of H&N cancer can consist of surgery, radiotherapy or chemotherapy and various combinations of the three in different temporal sequences or concurrently. Over the last 20 years, a range of innovative radiotherapies have been appraised. These include altered fractionation schedules; use of new radio therapeutic technologies, use of metallic compensators, and combinations with different chemotherapy and drug combinations.

Christiane Miaskowski and Aishan shih (2013) Stated that Radiation therapy remains the primary methods of treatment for patients with head and neck cancer. The tissue destruction and functional alterations in the oral cavity lead to the development of oral mucositis.

David, Rosenthal and Andrea Trotti (2009) revealed that Radiation-induced mucositis is a common toxicity for head and neck cancer 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 sub site exposed, treatment intensity, and

individual patient predisposition. The consequences of mucositis include pain, dysphagia including feeding tube dependency, dehydration, micronutrient deficiencies, weight loss, and potentially life-threatening aspiration.

Oien and Truelove (2012) stated that Oral mucositis is a complication affecting many patients receiving chemotherapy, head and neck radiation and those undergoing bone marrow transplant therapies. Caterina da Mota (2012) defined Oral mucositis is an inflammation of oral mucosa resulting from cancer therapy typically manifesting an atrophy, swelling, erythema and ulceration.

Sonis et al.,(2011) explained that a biological model for chemotherapy- and radiotherapy-induced oral Mucositis. The model includes events that have been described in five overlapping stages: initiation, up regulation, message generation, ulceration, and healing. All these events lead to pain and, in neutropenic patients, bacteria may invade the systemic circulation causing bacteremia and sepsis. Following cessation of the injurious therapy, healing occurs and the epithelium appears normal again.

Samin radiat (2009) described that radiation induced mucositis associated symptoms arising during radiation therapy for head and neck cancer are mouth and throat sores " difficulty in swallowing ,pain, altered taste, excessive secretions which may lead to gagging , nausea and vomiting, loss of appetite , fatigue, and weight loss.

Rajesh and lalla (2008) revealed that oral mucositis(OM) can be very painful and can significantly affect nutrition intake, mouth care, and quality of life .Management of oral mucositis is to be focused on nutrition support, pain control, oral decontamination, palliation of dry mouth , management of oral bleeding and therapeutic interventions for oral mucositis.

Jurema fraire (2012) described that the treatment for oral mucositis include laser therapy, cryotherapy , growth factors, analgesics, mouth washes, administration of antimicrobial agents, vitamins and anti inflammatory agents.

Elting , et al.,(2007) stated that a reproducible OM scale is a vital prerequisite for both research into preventing and managing OM and routine clinical patient care. A wide variety of scales have been developed. These focus on symptomatic and functional outcomes such as pain or ability to eat, clinical manifestations based on direct inspection of the oral mucosal surfaces, or a combination of both.

Anne Margrete Gussgard, (2012) explained Oral mucositis (OM) signs were evaluated clinically using the National Cancer Institute (NCI) common toxicity criteria (NCI-CTC) ,oral mucositis assessment scale(OMAS)criteria and Total VAS-OMAS score. OM symptoms were recorded on PROMS-VAS questionnaires.

Henry and Hoffman (2003) stated that commonly used scoring tools are the World Health Organization (WHO) and the National Cancer Institute (NCI) common toxicity criteria (NCI-CTC). The WHO scale is the most widely used and includes criteria which are objective (presence of erythema and ulceration), subjective (oral pain), and functional (patient's ability to eat) to determine an overall score. And the Oral Mucositis Assess -ment Scale (OMAS) has examined utility in a multicenter study, assessing inter examiner and intra examiner reliability, and it represents the only validated mucositis scale that separates mucosal damage from symptoms and oral function.

Roopashri and Jayanthi (2011) explained that Povidone- iodine has a wide antiseptic effects including antiviral, antibacterial and antifungal efficacy and its good tolerability have resulted in frequent use as preventive and therapeutic drug in radiotherapy and chemotherapy induced mucositis.

Hashemi, Bahrololoumi and Khaksar (2015) explored that Normal saline (sodium chloride 0.9% solution) is a harmless bland isotonic oral rinse which has been shown to be beneficial in maintaining appropriate oral hygiene due to its safety, lowest toxicity and physiologic properties.

Ohrn and Wahli (2000) explained that Good oral hygiene maintenance before and during cancer therapy can minimize the complications associated with the treatment and provide greater comfort to patients.

Nurses are the frontline professional of the health care. Nurses today are actively involved generating and publishing best cost effectives evidences in order to improve care and expands nursing knowledge . This has motivated the researcher to identify the best cost effective, non irritating mouth rinse to alleviate the mucositis associated morbidity and enhance the uninterrupted treatment adherence.

Carter, Harris and Kavi,(2009) described that radiotherapy for head and neck cancers and chemotherapy for cancers in general are known to cause various deleterious effects on the oral structures leading to development of mucositis, candida infection, xerostomia, loss of taste sensation, radiation carries, and osteochemo or radionecrosis. These Oral care is essential before and during cancer treatment to prevent oral complications. Nurses have the crucial role in providing bedside supportive care to patients suffering from cancer.

NEEDS FOR THE STUDY:

" Brush your teeth every day, to keep dentist away"
-George Taylor

According to the union for international cancer control (2014) world wide there are approximately 560,000 new cases of head and neck cancer diagnosed and 3, 00,000 deaths each year.

Karthikeyan guru and udaya kumar manor (2012) stated that Cancer is a leading health problem in India, with approximately 1 million cases occurring each year . Over 200,000 cases of head and neck cancer (HNC) occur each year in India versus 30,000 for the USA. Cancer accounts for 8% of the deaths in India. Incidence of HNC primaries has shown to increase with age. Although the functional and cosmetic deficits are very apparent in HNCs, this group of cancers accounts for only 5% of all malignancies.

Shrotriya,Agarwal and Sclafani (2015) described that head and neck squamous cell carcinoma (HNSCC) accounts for around 6% of all cancers in the USA. Few of the greatest obstacles in HNSCC include development of secondary primary tumor, resistance and toxicity associated with the conventional treatments, together decreasing the overall 5-year survival rate in HNSCC patients to ≤50%. Radiation and chemotherapy are the conventional treatment options available for HNSCC patients at both early and late stage of this type of malignancy.

Jemal , Siegel and Ward (2010) explained that approximately 36,540 new cases of oral cavity and pharyngeal cancer are diagnosed in the USA, more than 7,880 people die of this disease. The majority of these cancers are squamous cell carcinomas. Most cases are diagnosed at an advanced stage: 62 percent have regional or distant spread at the time of diagnosis. The five-year survival for all stages combined is 61 percent. Localized tumors (Stage I and II) can usually be treated

surgically, but advanced cancers (Stage III and IV) require radiation with or without chemotherapy as adjunctive or definitive treatment. Therefore, most patients with oral cavity and pharyngeal cancer receive head and neck radiation therapy (RT) as part of their treatment.

Napier, Scheerer and Misra (2014) stated that the National Cancer Institute estimated that there were about 18,000 new cases and more than 15,000 deaths from oesophageal cancer in 2013 (the American Cancer Society estimated that during 2014, about 18,170 new oesophageal cancer cases would be diagnosed, resulting in 15,450 deaths).

Sol Silverman (2006) defined oral mucositis is a common complication in cancer patients receiving chemotherapy or radiation therapy. Nearly all patients undergoing myeloablative therapy for stem-cell or bone marrow transplantation experience oral mucositis. Those receiving radiation therapy for head and neck cancer are at especially high risk. However, this toxicity also occurs with standard-dose chemotherapy and can be seen in association with treatment of many other tumor types. Oral mucositis significantly complicates cancer treatment by contributing to pain, dysphagia, weight loss, depression, higher risk of infection, decreased quality of life, and increased healthcare costs.

Brandwein-Gensler and Smith (2010) explored that the oral complications of head and neck radiation therapy result from radiation injury to the salivary glands, oral mucosa and taste buds, oral musculature, alveolar bone, and skin. They are clinically manifested by xerostomia, oral mucositis, dental caries, accelerated periodontal disease, taste loss, oral infection, trismus, and radiation dermatitis.

Verdi (2005) conducted a descriptive study 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.

Vera-Llonch and Oster (2007)explained that patients treated with radiation therapy for head and neck cancer typically receive an approximately 200 cGy daily dose of radiation, five days per week, for 5–7 continuous weeks. Almost all such patients will develop some degree of oral mucositis. In recent studies, severe oral mucositis occurred in 29–66% of all patients receiving radiation therapy for head and neck cancer . The incidence of oral mucositis was especially high in 1) patients with primary tumors in the oral cavity, oropharynx or nasopharynx, 2) those who also received concomitant chemotherapy, 3) those who received a total dose over 5000 cGy, and 4) those who were treated with altered fractionation radiation schedules (e.g. more than one radiation treatment per day).

Pankaj chaturvedi and Sourav dutta (2014) defined Oral mucositis refers to erythematous and ulcerative lesions of the oral mucosa observed in patients with cancer being treated with chemotherapy and with radiation therapy to the type of radiation and to the total dosage , fractionation and duration of treatment . oral mucositis can occur with cumulative RT doses as or as occur 1000-2000 centigrey with therapy administered of a rate of 200 cg % per day.

American cancer society (2001) explained that The incidence of oral pain is chemotherapy is 40-70 % almost 100% in radiotherapy and 60-85 with radiation induced mucositis.

Talita ribeiro and Tanario franca (2012)described that Radiation induced mucositis typically begins at cumulative doses of about 15 Gy (after about 10

days) and typically reaches full severity at 30 G and lasts for weeks or even months. Patients with oral mucositis are significantly more likely to experience severe pain and weight loss severity of oral mucositis has been correlated with compromised swallowing function in patient resulting in the requirement for feeding via a gastrotomy tube.

Joel Epstein and Stephen sonis (2004) stated that the majority of patients receiving radiation therapy for head and neck cancer are unable to continue eating by mouth due to mucositis pain which make them to receive nutrition through a gastrostomy tube or intravenous line. In one study, approximately 16% of patients receiving radiation therapy for head and neck cancer were hospitalized due to severe oral mucositis . Further 1% of the patients receiving radiation therapy for head and neck cancer had unplanned breaks in radiation theraphy due to severe oral mucositis . Oral mucositis can be very painful and can significantly effect nutritional intake , mouth care and quality of life.

Keefe et al.,(2013) described that Oral mucositis is a frequent, clinically important, and often dose-limiting, complication of cancer therapy. It results from injury to epithelial cells that line the oral cavity and can affect the entire alimentary tract. Damage causes changes ranging from mild atrophy to severe ulceration.

Dolivet and Toussaint (2001) reviled that Current management of oral mucositis of the use of topical anesthesics and anti-inflammatory drugs(eg lidocaine , diphenhydramine) and agents such as colloidal silver solutions, salt and soda rinses or hydrogen. These agents have any significant effect on mucositis although they may improve patient comfort.An ideal oral rinse for patients with head and neck malignancies should reduce the oral microflora,

promote, re-epithelization of soft tissue lesions, normalize the ph of oral fluids have an acceptable taste and be nontoxic.

Orecchia (2008) done a study to assess the effectiveness of povidone iodine in reducing radiation induced oral mucositis. In this study 132 patients were randomly assigned to use normal saline (n=65) or povidone iodine diluted 1:100(n=67) mouth rinse for oral mucositis prophylaxis and treatment after high dose of radiation therapy. The mechanical effect of povidone iodine (1:100) was reducing the incidence of radiation therapy oral mucositis than the control group.

Farrington (2010) did a study to assess the effectiveness of povidone iodine mouthwash on radiation or chemotherapy induced oral mucositis: A randomized double blind clinical study was conducted to determine and compare the efficiency of povidone iodine mouthwash, chamomile and normal saline mouthwash for the treatment of oral mucositis. The study was conducted on 83 patients who received chemotherapy and have oral mucositis. ANOVA and 't'test was used for data analysis. Significant difference was found between povidone iodine mouthwash, chamomile and normal saline group in the score of severity of stomatitis (p=0.017), stomatitis pain (p=0.027). The findings indicated that povidone iodine mouthwash and chamomile have equal efficiency in chemotherapy induced oral mucositis as compared to the normal saline group.

Madan Kumar and Sequeira (2008) done a study to assess the effect of three alcohol-free mouthwashes on radiation-induced oral mucositis in patients with head and neck malignancies scheduled to undergo curative radiotherapy, were randomly assigned to receive one of the three alcohol-free test mouthwashes (0.12% chlorhexidine, 1% povidone-iodine, or salt/soda) or a control.This study demonstrated

that use of alcohol-free povidone-iodine mouthwash can reduce the severity and delay the onset of oral mucositis due to antineoplastic radiotherapy.

The National Comprehensive Cancer Network (2008) stated that the educational program is designed to meet the needs of advanced practice nurses, medical oncologists, radiation oncologists, and hematologists who treat and manage patients with cancer who experience treatment-induced mucositis.

Parker, Epstein and Gupta (2007) stated that the oral health care team serves a vital role in the prevention and management of short- and long-term oral complications of cancer treatment. Hospital-based dentists specially trained in oral oncology treat some of these patients. It is essential that all health professionals caring for the cancer patient be knowledgeable about the diagnosis, prevention and management of oral complications of therapy and their sequelae, in order to work together as a team to minimize the impact of these toxicities on the patient's life.

Barbara, Given and Sandra(2011) described that healthcare providers need to monitor and facilitate adherence by identifying barriers and implementing strategies to assure adherence, and therefore, improve clinical outcomes.

June Eilers and Rita Million(2011) stated that Nurses play a key role in the identification and use of evidence to guide the care of patients at risk for cytotoxic therapy-related oral mucositis.

Radhika and Ravikiran Ongole(2015)explored that the Oncology nurses need to have frequent continuing nursing education specific to cancer patient care, and this requires involvement from a multidisciplinary team involving dentists, radiation oncologists, and medical oncologists on how to perform oral cavity examination and recognize the signs and symptoms of oral changes associated with cancer therapy.

Hijji (2013) revealed that the development and implementation of more specific oral care protocol can lead to promotion of oral health by health care professionals, ensuring that oral care is performed regularly across the hospital, minimizing the severity and duration of radiation-induced, and standard dose chemotherapy-induced oral mucositis and its complications, ensuring that patients' treatment is not compromised because of oral problems as well as there is no extension of length of hospital stay.

Robin(2010)explained that Nurses need to keep abreast of the latest knowledge in oral care of cancer patients, assessment of oral cavity, oral care agents, and evidence-based interventions in care of cancer patients undergoing chemotherapy and radiation therapy.

Jayaram shetty etal., (2008) done a systemic reviews and literatures related to the evidence of mouth rinses in reducing the severity of oral mucositis. Many evidences showed that the preferences and adherence to mouth rinses to prevent mucositis associated pain, difficult swallowing impaired nutrition and thereby it enhanced the refreshes of oral cavity. Nurses are the frontline professional of the health care. Nurses today are actively involved generating and publishing best cost effective evidences in order to improve the care and expand nursing knowledge .Nurses and other health care professionals can positively influence patient care by incorporating the evidences on practices of an oral care protocol improving consistency of care while promoting an intervention of proven benefits against oral mucositis. This motivated the researcher to identify the best cost effective, non irritating mouth rinse to alleviate the mucositis associated morbidity and enhance the uninterrupted treatment adherence.

Effective oral hygiene is a universal preventive strategy and should be considered part of good clinical practice. A growing body of evidence supports the value of reducing bacterial dental plaque relative to reducing oral mucositis. oral mucositis is associated with significant morbidity that can lead to treatment delays and interruption and the use of significant health care resource.

STATEMENT OF THE PROBLEM:

"A study to assess the effectiveness of povidone –iodine (2%) vs normal saline(0.9%) mouth rinsing on oral mucositis among patients receiving external radiation therapy for head and neck malignancy from Devaki Cancer and Research Centre at Madurai".

OBJECTIVES:

- To explore the severity of oral mucositis before and after providing povidone –iodine(2%) and normal saline(0.9%) rinses among patients receiving external radiation therapy for head and neck malignancies.
- To find out the effectiveness of povidone –iodine(2%) mouth rinsing on oral mucosititis among the patients with head and neck malignancies in experimental group I
- To find out the effectiveness of normal saline (0.9%) mouth rinsing on oral mucositis among patient with head and neck malignancies in experimental group II
- To compare the post test level of oral mucositis score between experimental group I and II
- To determine the association between pre test level of oral mucositis score of experimental group I with selected demographical variables(i.e (Age, sex,

occupation, marital status, education status, smoking ,tobacco chewing, betel nuts and pan or kutka chewing)

- To determine the association between pre test level of oral mucositis score of experimental group II with selected demographical variables(i.e (Age, sex, occupation, marital status, education status, smoking ,tobacco chewing, betel nuts and pan or kutka chewing).

HYPOTHESES:

All the hypotheses were tested at 0.05 level of significance

H1: The mean post test oral mucositis score of patient with oral mucositis who receives povidone –iodine (2%) mouth rinse will be significantly lower than the mean pretest oral mucositis score of patient in experimental group I

H2: The mean post test oral mucositis score of patient with oral mucositis who received normal saline (0.9%) will be significantly lower than mean pretest oral mucositis score of patient in experimental group II

H3: There will be a significant difference between the mean post test level of oral mucositis score of experimental group I who received the povidone –iodine (2%) and experimental group II who received the normal saline (0.9%) mouth rinse.

H4: There will be significant association between pretest oral mucositis score, among patient who received povidone –iodine (2%) mouth rinse with selected variables (Age, sex, occupation, marital status, education status, smoking, tobacco chewing, pan ,betel nuts chewing).

H5: There will be a significant association between the post test oral mucositis score among patient who received normal saline (0.9%) rinse with selected

variables (Age, sex, occupation, marital status, education status, smoking, tobacco chewing, pan ,betel nuts chewing).

OPERATIONAL DEFINITIONS:

a) Effectiveness:

Effectiveness is the capability of producing a desired results. In this study, it refers to povidone –iodine (2%) and normal saline (0.9%) mouth rinse in reducing oral mucositis among the patient who received external radiation therapy which was measured by score obtained by the subjects in oral mucositis assessment scale(OMAS).

b) Povidone –iodine (2%):

It has a bactericidal action and is effective against a wide range of bacteria, fungi and even spores. The killing action of vital cytoplasmic substrates, which are necessary for bacterial viability. In this study, it refers to the subjects who were treated with commercially available 10ml of povidone –iodine (2%) mouth rinsing after routine brushing and before bedtime by swishing motion for 2 minutes, this group was termed as experimental group I.

c) Normal saline(0.9%):

Normal saline (0.9%) is a harmless bland isotonic oral rinse which has been shown to be beneficial in maintaining appropriate oral hygiene due to its safety, lowest toxicity and physiologic properties. In this study, it refers to the subjects who was treated with commercially available 20ml of normal saline(0.9%) mouth rinsing after routine brushing and before bedtime by swishing motion for 2 minutes, this group was termed as experimental group II.

d) Mouth Rinse:

An antiseptic solution intended to cleanse, reduce, the microbial load and to treat the disease of mucosa in the oral cavity. In this study, mouth rinsing refers to rinsing of mouth with povidone –iodine (2%) and normal saline (0.9%) after routine brushing and before bedtime using, swishing motion for 2 minutes for a twice day .

e) Oral Mucositis:

Marianna sampaio serpa,(2012) defined oral mucositis as an inflammation of oral mucosa resulting from cancer therapy typically manifesting an atrophy, swelling, erythema and ulceration.

In this study mucositis refers to the mucosal lesion of erythema and ulceration caused by radiation therapy as measured by OMAS.

f) Head and Neck Malignancies:

The term head and neck malignancies refers to a group of biologically similar malignancies originating from the upper digestive tract, including lip, oral cavity, mouth, para nasal sinus, pharynx, larynx and pituitary gland.

g) External radiation therapy:

Radiation therapy is the emission and distribution of energy through space or material medium. The energy produced by radiation, when absorbed into tissue, produces ionizing and excitation. This local energy is sufficient to break chemical bonds in DNA which leads to biological effect.

In this study it refers to patients who were diagnosed with head and neck cancer undergoing treatment by external radiation therapy by linear acceleration in Devaki Cancer and Research Centre, at Madurai during data collection period.

ASSUMPTIONS

1. Oral mucositis associated with significant morbidity that can lead to dose reduction, interruption and non compliance to treatment regimen.
2. Assessment of oral mucositis is an important function of an oncology nurse.
3. Vigilant observation and meticulous mouth care is necessary for intact mucosal lining adherence.
4. Level of mucositis will differ from one individual to other

DELIMITATIONS:

The following delimitation was set for the study.

1. Patients with head and neck cancer who have completed 7sitting of external radiation therapy, attending Devaki Cancer and Research Centre, at Madurai.
2. The data collection period was 6weeks only.
3. The evaluation of oral mucositis level was assessed 7^{th} and 14^{th} day after administration of selected mouth rinses.

PROJECTED OUTCOME:

The study findings will help the nurses to determine the need for regular oral assessment of cancer patients on radiation therapy and help to select appropriate mouthwash to reduce oral mucositis.

CONCEPTUAL FRAME WORK:

The study is based upon the J.W. kenny's open system model. All the living systems are open in that there is a continual exchange of matter, energy and formation. The main concepts of the system model are input, throughput, output and feedback.

- **Input:**

Input refers to matter, and information that enters into the system through the boundary. In this study, the study the input refers to mouth wash given using povidone –iodine(2%) and normal saline (0.9%) to experimental group I and II respectively.

- **Through put**:

Through put refers to the process where the system transfers energy, matter and information. In this study, through put refers to mucosoitis healing process, by the use of povidone –iodine(2%) and normal saline (0.9%) mouth rinse in experimental group I and II.

- **Output:**

Output refers to matter, energy and information that are processed. In this study, output refers to the sample that in group I and II will have an adequate healing after using povidone –iodine(2%) and normal saline (0.9%) mouth rinse.

- **Feed back:**

After processing the input, the system send output (matter, energy & information) to in alter state .Feedback refers to environment response to the systems output using system's adjustment, correction and accommodation to the interaction with the environment. In this study, it used; if there is inadequate wound healing feedback should be given and the sample should undergo assessment process.

CHAPTER II

REVIEW OF LITERATURE

A literature review is a text of a scholarly paper, which includes the current knowledge including substantive findings, as well as theoretical and methodological contributions to a particular topic.(Lamb and David,2014)

The literature is classified under the following headings.

1. Literature related to incidence of oral mucositis among subjects with radiation therapy.
2. Literature related to oral mucositis assessment.
3. Literature related to povidone –iodine and normal saline mouth rinse.
4. Literature related to role of nurse in care of patient with oral mucositis .

Literature related to incidence of oral mucositis among subjects with radiation therapy:

Steven Peter Saldanha and Victoria Almeida (2014) stated that mucositis is the painful inflammation and ulceration of the mucous membrane, usually as an adverse effect of chemotherapy and radiation treatment for cancer. Radiotherapy to the head and neck or to the pelvis or abdomen is associated with the occurrence of oral mucositis, often exceeding 50% of patients. Among patients undergoing head and neck radiotherapy, pain and decreased oral function may persist long after the conclusion of therapy. Fractionated radiation dosage increases the risk of mucositis to >70% of patients in most trials.

Elting, Cooksly and Cambers (2007) conducted a retrospective cohort study, on risk, outcomes, and costs of radiation-induced oral mucositis among patients with head-and-neck malignancies which consisted of 204 consecutive head-and-neck cancer patients who received Radiation Therapy with or without chemotherapy during 2002.Results showed that Oral mucositis occurred in 91% of patients; in 66% it was severe (Grade 3-4). Patients with OM were significantly more likely to have severe pain (54% vs. 6%; $p < 0.001$) and a weight loss of > or =5% (60% vs. 17%; $p < 0.001$).[4]

Trotti , etal., (2003) done a meta analysis to find out the mucositis incidence and severity associated outcomes among patients with head and neck cancer receiving radiation therapy with or without chemotherapy. thirty-three studies (n=6181 patients) met inclusion criteria.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. They concluded that mucositis is a frequent, severe toxicity in patients treated with radiation therapy for head and neck cancer. Recommended to find out the over all impact on all comes related investigation.

Talita Ribeiro and Tenório(2012) described chemotherapy-induced mucositis usually develops within 4–7 days after initiation of treatment and peaks within 2 weeks. Radiation-induced mucositis typically begins at cumulative doses of about 15 Gy (after about 10 days) and typically reaches full severity at 30 Gy, and lasts for weeks or even months . Patients with oral mucositis are significantly more likely to

experience severe pain and weight loss. Severity of oral mucositis has been correlated with compromised swallowing function in patients, resulting in the requirement for feeding via a gastrostomy tube.

University of Pretoria (2010) explained oral mucositis is a complication affecting many patients receiving chemotherapy, head and neck radiation and those undergoing bone marrow transplant therapies. Oral mucositis can develop from the direct effect of cytotoxic drugs on oral mucosa due to the rapid turnover of oral epithelium, although the pathogenesis is probably more complicated than that. Severe mucositis interfere with cancer therapy, the costs can be crippling, and in severe cases lead to discontinuation of cancer therapy.

Komaroff ,Nalysnyk and Zilberberg (2003) did a study to assess the incidence of radiation induced Oral Mucositis . They described Oral mucositis impacts over 400,000 cancer patients each year. Over 40% of cancer patients develop oral mucositis (OM) due to conventional chemotherapy. For patients undergoing conventional radiation therapy for head and neck cancer or bone marrow transplant, OM rates are as high as 97-100%.

Literature related to oral mucositis assessment:

William Bensinger ,Mark Schubert ,Kie-kian ang, David Brizel and Elizabeth Brown(2008) enlisted the oral Assessment Guide (OAG) is an example of a scale developed for routine use by nurses and other support staff. Eight different aspects of the oral cavity are assessed and assigned a point value from 1 to 3 based on whether these aspects are normal or show moderate to severe changes. This scale is primarily used to monitor patient status and trigger interventions when oral health worsens. However, the key issue is to consistently use an accepted grading scale throughout treatment.

Crispian Scully and Joel Epstein(2004) explained the two most commonly used scoring tools are the World Health Organization (WHO) and the National Cancer Institute common toxicity criteria (NCI-CTC). The WHO scale is the most widely used and includes criteria which are objective (presence of erythema and ulceration), subjective (oral pain), and functional (patient's ability to eat) to determine an overall score. A number of additional scales have been developed to be used as nursing or research tools. The choice of mucositis scoring should depend on the specific need of assessment, with different scales used for clinical patient care and for mucositis research. Validation of mucositis scales is required for use in research protocols; one recently validated scale, the Oral Mucositis Assess ment Scale (OMAS) has examined utility in a multicenter study, assessing inter examiner and intra examiner reliability, and it represents the only validated mucositis scale that separates mucosal damage from symptoms and oral function.

Oral Mucositis Assessment Scale was designed by Sonis et al. (1999). It is a valid, reliable and easy to use scale which separates the objective from the functional measurements and can be used by people with minimal training in large scale multi-site clinical trials. The objective measurement divides the mouth into 9 different anatomical areas and gives each a score from zero to three for ulceration and zero to two for erythema. Degree of ulceration and redness in the mouth are primary indicators of OM while oral pain, difficulty in swallowing, and the ability to eat are taken as secondary indicators. A single score is not produced from this scale, rather a score for ulceration and redness based on different locations in the mouth are used.

Malays and Med sci(2008) described that there are many mucositis assessment scales available and some are still under development worldwide. As the scale have been used by radiation oncologists, medical oncologists, head and neck

surgeons, haematologists, somatologists, dentists and nurses, the variability of the use of a particular scale is inevitable. However a unified mucositis tool could be of immense value in a multidisciplinary set up or for inter- institutional comparisons. The most popular mucositis scales are radiation therapy oncology group for radiotherapy, World Health Oraganization for chemotherapy, common toxicity criteria of National Cancer Institute for chemotherapy and radiotherapy. Oral mucositis assessment scale is a recent tool developed to evaluate detail anatomical sites of mucositis and may be appropriate for multidisciplinary healthcare teams.

Medeiros and sixous (2011) says that a wide variety of scales have been used to record the extent and severity of oral mucositis in clinical practice and research. The world health organization scale is simple, easy to use and is suitable for daily use in clinical practice. This scale combines both subjective and objective measures of oral mucositis. The National Cancer Institute(NCI) common terminology criteria for adverse events(CTCAE) version 3.0 includes separate subjective and objective scales for mucositis. The oral mucositis assessment scale is an objective scale, suitable for research purposes, the measures erythema and ulceration at nine different sites in the oral cavity. This scale has been validated in a multicenter trial with high inter-observer reproducibility and strong correlation of objective mucositis scores with patient symptoms.

Literature related to povidone –iodine and normal saline mouth rinse:

Wong ,Dodd and Paul (2006) conducted a study in San Francisco general hospital ,USA to determine the pattern, severity, and time course of Radiation Therapy induced mucositis pain; self-care behaviours (SCBs) used to manage mucositis pain; and the effectiveness of these behaviours in relieving such pain. Forty-nine patients with mucositis were assessed using the MacDibbs Mouth

Assessment Tool to determine the severity of Radiation Therapy induced mucositis pain over their course of Radiation Therapy and at a one-month follow-up visit. All patients developed pain due to Radiation Therapy -induced mucositis. A Self-Care Diary was used weekly by patients to record SCBs and their effectiveness. The most effective SCBs for RT-induced mucositis pain were mouth rinsing and using oral analgesics.

Madan Kumar and Sequeira (2008) done a Study 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 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 salt/soda groups differed significantly from the control group at end of 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 mucositis.

Kamalaksha Shenoy(2008) demonstrated that the use of alcohol-free povidone-iodine mouthwash can reduce the severity and delay the onset of oral mucositis due to antineoplastic radiotherapy, thus improving the quality of life for patients. Hence, use of alcohol-free povidone-iodine mouthwash can be advocated for patients' use during radiotherapy.

Miller and Kearney (2001) explained that 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. A mouth rinse aides in removing debris and keeping the oral tissue moist and clean. Good oral care, defined as frequently rinsing the mouth with saline, may help prevent mouth sores Salt mouthwash can soothe the pain and keep food particles clear so as to avoid infection. Normal saline (o.9%) is a non 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 can be promoted.

Samuel Vokurka , Eva Bystřick and Vladimír Koza(2005) done a comparative Study to see the effectiveness of povidone-iodine with normal saline in Radiation and chemotherapy induced oral mucositis. Study was done with 132 patients by randomization 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 followed by autologous peripheral stem cell transplantation. Difference was found between the groups in respect of OM characteristics. The antimicrobial solution was less tolerable for patients. OM occurred significantly more often in females than in males (86% vs 60%, P=0.0016) and was worse and of longer duration. The study recommended while selecting oral rinses, the patient's individual preference and tolerance of solutions offered should be considered.

Hashemi and Bahrololoumi (2015) says that normal saline (sodium chloride 0.9% solution) is a harmless bland isotonic oral rinse which has been shown to be beneficial in maintaining appropriate oral hygiene due to its safety, lowest toxicity and physiologic properties. Although there are several studies on the preventive effect

of normal saline on oral mucositis in chemotherapy, radiotherapy and/or hematopoietic stem cell transplantation patients, few studies have assessed its effect on prevention of mucositis resulting from chemotherapy . Actually, in one of the mentioned studies normal saline showed inferior effect on preventing chemotherapy induced mucositis compared to chlorhexidine and cryotherapy. In the other one, normal saline was less effective in preventing chemotherapy induced mucositis in comparison to honey plus normal saline and placebo groups.

Berry and Davidson (2006) described that there is some evidence that the use of physiological salt solution can promote healing of oral mucosal lesions. Saldanha and Almeida (2014) evaluated the efficacy of turmeric in preventing radiation induced oral mucositis in patients receiving head and neck cancer which showed that when compared with the cohorts using povidone-iodine gargle, the group using turmeric as a mouth wash had delayed and reduced the levels of radiation-induced oral mucositis and was statistically significant at all time points (:<0.001 to :<0.0001). Additionally, the cohorts using turmeric had decreased intolerable mucositis (:<0.001) and lesser incidence of treatment breaks in the first half of the treatment schedule before 4 weeks (:<0.01) and reduced change in body weight (:<0.001).Gargling with turmeric by head and neck cancer patients undergoing radiation therapy provided significant benefit by delaying and reducing the severity of mucositis. In the present study paired t - test was computed at a level of 0.05 significance between pre intervention on day 1 and post-intervention day 5 and found that the calculated t value(t=17.81) was significantly greater than the tabled value(t=2.093) indicating turmeric mouth wash is effective on radiation induced oral mucositis .

Worthington , Clarkson and Eden (2007) conducted a study to evaluate of the effectiveness of prophylactic agents for oral mucositis in patients with cancer receiving treatment, compared with other potentially active interventions by using Cochrane data base system review. Two hundred and seventy-seven studies were eligible. One hundred and eighty-eight were excluded for various reasons, usually as there was no useable information on mucositis. Of the 89 useable studies all had data for mucositis comprising 7523 randomized patients. Interventions evaluated were: acyclovir, allopurinol mouth rinse, aloe vera, antibiotic pastille or paste, benzydamine, beta carotene, calcium phosphate, camomile, Chinese medicine, chlorhexidine, etoposide, folinic acid, glutamine, granulocyte/macrophage colony-stimulating factor (GM-CSF), histamine gel, honey, hydrolytic enzymes, ice chips, iseganan, keratinocyte GF, misonidazole, pilocarpine, pentoxifylline, povidone, prednisone, propantheline anticholinergic, prostaglandin, sucralfate, systemic antibiotic clarithromycin, traumeel, zinc sulphate. Of the 33 interventions included in trials, 12 showed some evidence of a benefit (albeit sometimes weak) for either preventing or reducing the severity of mucositis. Interventions where there was more than one trial in the meta-analysis finding a significant difference when compared with a placebo or no treatment .

Caballero,Lagares and Garcia(2012) conducted a study in Spain on Cancer treatment-induced oral mucositis which stated that Head and neck cancer represents one of the main oncological problems. RT and CT leads to mucositis, and other side effects. The authors reviewed high-quality evidence published over the last 25 years on the treatment of cancer treatment-induced oral mucositis. A Medline search for double blind randomized controlled clinical trials between 1985 and 2010 was carried out. The different therapeutic approaches found for cancer treatment-induced

oral mucositis included: intensive oral hygiene care; use of topical antiseptics and antimicrobial agents; use of anti-inflammatory agents; cytokines and growth factors; locally applied non-pharmacological methods; antioxidants; immune modulators; and homoeopathic agents. To date, no intervention has been able to prevent and treat oral mucositis on its own.

Literature related to role of nurse in care of patient with oral mucositis:

According to Ministry of Health (2004) oral care is important for patients health and well- being for a variety of reason. Not only is the mouth vital for eating, drinking, breathing, verbal and non- verbal communication, saliva also has antibacterial properties and is part of the body's defense against infection.

Rebecca Hogan(2013) says that oral mucositis is a debilitating side effect that has much clinical significance. Oral mucositis may decrease the effectiveness of treatment as well as decrease the quality of life in the oncology patient. Therefore, it is our responsibility as health care professionals to reduce the incidence and or severity of mucositis as much as possible. One intervention that has been proven to be successful is basic oral hygiene implemented through an oral care protocol. It is important that nurse are educated on the significance of adequate dental hygiene and the process and need for institutional change protocols. Nurses and other health care professionals can positively influence patient care by incorporating the evidence based practice of an oral care protocol improving consistency of care while promoting an intervention of proven benefits against oral mucositis.

Avritscher et al.,(2004) explained that oncology nurses have the potential to serve a pivotal role in the advancement of the state of the art and knowledge of the treatment and prevention of mucositis in patients receiving cancer treatment.

Latino (2015) described that nurse pay role in providing oral care education for patients. The latest clinical practice guidelines for preventing and treating oral mucositis recognize the importance of excellent oral care before and during cancer treatment. Diligent oral hygiene and treatment of pre-existing oral or dental conditions prior to cancer therapy may help reduce the risk and severity of oral mucositis.

Loke Bikram Thapa (2007) explained that the nurse assesses the patient's skin , nutritional status, and general feeling of well being. The skin and oral mucosa are assessed frequently for changes. The skin protected from irritation, and the patient is advised to avoid using ointments, lotions or powders on the area. Gentle oral hygiene is essential to remove debris, prevent irritation, and promote healing. If systemic changes such as weakness and fatigue occur, the patient may need assistance with activities of daily living and personal hygiene.

Haberman (2000) described that oncology nurses have key roles as caregivers, as well as providers of patient and family education, in clinical cancer research, in health care administration, and as advanced oncology nurse practitioners. Cancer nurses also are continuously involved in the enhancement of nursing practice through research, continuing education, and advanced education.

Henke (2001) says that Oncology nurses are challenged on a daily basis to deal with the numerous symptoms patients with cancer and their families encounter as a result of their cancer or its treatment. Nurses triage patient Problems and assist in the evaluation of symptoms and initiation of interventions.

Higgins (2000)explained that the oncology nurses plays a vital role in coordination the multiple and complex technologies now commonly employed in cancer diagnosis and treatment. This coordination encompasses direct to patient care,

documentation in the medical record, participation in therapy, symptom management, organization of referrals to other healthcare providers, both patient and family education, as well as counseling throughout diagnosis, therapy, and follow-up.

Bruner and Haas (2006) described that the nurse plays an important role in identifying, reporting, and helping patients deal with the side effects of radiation and chemotherapy. Educating patients about their treatment regimen, supportive care options (e.g antiemetics, antidiarrheals), and what to expect during the course of treatment is important to help decrease fear and anxiety, encourage adherence, and guide at- home self-management. Before initiating education, however, the patient's ability and desire to process information should be assessed. Teaching should then be customized to meet the patient's and family's learning needs.

Rubenstein and Shubert (2004) says that oral assessment and meticulous intervention to keep the oral cavity moist, clean, and free of debris are essential to prevent infection and to facilitate nutritional intake. The patient should be taught to self- examine the oral cavity. The mucous membranes, characteristics of saliva, and ability to swallow must be assessed. Oral care includes pretreatment evaluation by a dentist to perform all necessary dental work before the initiation of treatment. The patient should also be taught how to perform oral care (proper tooth brushing, flossing, and use of fluoride trays to prevent caries). Oral care should be performed at least before and after each meal and bedtime.

Cuncins-hearn and Saunders(2004) explained that Self- care instruction for patients receiving radiation are provided to assist in the maintenance of skin integrity during the treatments and for several weeks after completion. Follow- up care includes teaching the patient to minimize sun exposure to treat area and reassuring the

patient that minor twinges and shooting pain in the breast are normal after radiation treatment.

It can be concluded from above literature review frequent oral assessments are particularly important in the setting of radiation therapy and chemotherapy to detect and monitor oral mucositis progression. Povidone-Iodine and Normal saline mouth rinses are found to be effective in reducing the severity and delay the onset of oral mucositis due to radiation therapy among patients with Head and Neck Cancer.

CHAPTER-III

RESEARCH METHODOLOGY

"Research methodology is a way to systematically solve the research problem. The techniques used to structure a study and to gather and analyze information in a systematic fashion" (University of Toronto -2002)

This chapter includes the research approach research design, population, sample and criteria for the sample selection. It further deals with the development of tool, procedure of data collection and plan for data analysis.

RESEARCH APPROACH:

Quantitative research approaches were used to check the effectiveness of povidone-iodine (2%) and normal saline (0.9%) rinsing

RESEARCH DESIGN:

A quasi experimental with pretest, post test two experimental group design were used.

In this both the experimental group were exposed for pretest and post test.

The research design is represented in the below table.

GROUP	PRE TEST	TREATMENT	POST TEST	
			7^{th} day	14^{th} day
Experimental Group I	01	X1	O2	O3
Experimental Group II	01	X2	O2	O3

KEYS:

O 1- Pretest level of oral mucositis among experimental group I and experimental group II

O 2- Post test level of oral mucositis among experimental group I and II on 7^{th} day.

O3 - Post test level of oral mucositis among experimental group I and II on 14^{th} day.

X 1- Mouth rinse with povidone-iodine(2%)

X 2- Mouth rinse with normal saline (0.9%)

VARIABLES:

- Independent variables: Povidone iodine(2%) and normal saline (0.9%) mouth rinse
- Dependent variable: Level of oral mucositis

SETTING OF THE STUDY:

This study was conducted at Devaki Cancer and Research Centre, Arasaradi, at Madurai. It is 7.6km away from the Sacred Heart Nursing College, Madurai. This hospital provides all specialized care of all type of cancer and cancer patients on inpatients and out patient basis. The treatment include chemotherapy and radiation therapy, brachy therapy and teletherapy with the help of linear acceleration therapy. The total census of cancer patients in Devaki Cancer and Research Centre was 200 per day among them 150-160 patients undergoing radiation therapy and 100-110 patients were receiving external radiation therapy.

STUDY POPULATION:

The target population of the study subjects were patients receiving external radiation therapy for head and neck malignancies in Devaki Cancer and Research Centre at Madurai.

SAMPLE:

The sample of the study were patients with head and neck cancer who have developed oral mucositis and subject who fit into the inclusion criteria, in Devaki Cancer and Research Centre during data collection period.

SAMPLE SIZE:

The total sample size for the study was 60, among this 30 patients were assigned to experimental group I and 30 patients were assigned to experimental group II.

SAMPLING TECHNIQUE:

Sampling is the process of selection a representative part of the population in the study(Sharma, 2012)

The simple random sampling technique was used by lottery method from the radiation department register maintained in Devaki Cancer and Research Center, at Madurai.

CRITERIA FOR SAMPLE SELECTION:

The samples were selected based on the following inclusion and exclusion criteria

Inclusion criteria:

- Patients with head and neck malignancies aged 18 years and above
- Patients who have received radiation therapy for minimum of 7 sitting .
- Both male and female patients with mild to moderate level of oral mucositis as per oral mucositis assessment scale.
- Patients who are willing to participate.

Exclusion criteria:

- Patients who are not willing to participate
- Patients who are not able to follow the instruction
- Patients with HIV infection, oral candidiasis, herpes simplex infection
- Patients using any other prophylactic mouthwashes.
- Patients who suffers with known allergic to povidone-iodine(2%) and normal saline(0.9%).
- Patients with severe oral mucositis as per OMAS

RESEARCH TOOL AND TECHNIQUE:

The instrument which was used in this study has two parts.

Part I:

(a)Demographic profile:

In consists of demographic profile such as age, education, occupation, marital status, history of betel, nuts, or tobacco chewing, smoking, pan or kutka chewing

(b) Clinical profile:

- Location of the tumor (lip, oral cavity, mouth, pharynx, larynx, primary tumor, pituitary gland, salivary glands and nasal cavity)
- Severity of the tumor(tumor, node involvement, metastasis)
- Dose of radiation therapy per day (200-400 Gy)

Part II – Instrument profile:

Oral mucositis assessment scale is standardized tool. This tool was downloaded from internet at free of cost. The validity and reliability of the tool was

examined. The tool separates the mucosal damage from symptoms and other oral function.

- This tool has 9 items. The 9 items assessed in two different criteria i.e ulceration and erythema. Each item was scored between 0,1,2, and 3. In ulceration 0 refers to no ulceration, 1 indicates less than 1cm, 2 indicates ulcer size from 1.1cm- 3 cm and scoring of 3 indicates above 3.1cm.
- In erythema 0 refers to no erythema, 1 refers to non- severe erythema and 2 refers to severe erythema. Based on the scores obtained the subject grouped into various categories.

SCORING PROCEDURE

The total score of 27 was categorized in ulceration and 18 was categorized in erythema.

- ✓ In ulceration the Score between 1-9 falls under mild ulceration, and between 10-18 is categorized as a moderate ulceration and scoring of 19- 27 is categorized under severe ulceration.
- ✓ In erythema 1-9 scores are categorized as not a severe erythema and 10-18 categorized as a severe erythema.

Ulceration			**Erythema**		
Categories	**Scoring**	**Total**	**Categories**	**Scoring**	**Total**
No ulcer	0	0	No erythema	0	0
Mild	1	1 – 9	Not severe	1	1 – 9
Moderate	2	10 – 18	Severe	2	10 – 18
Severe	3	19 – 27			

TESTING OF TOOL:

Validity:

To evaluate the content validity of the tool, the tool was submitted to seven experts. Five experts from the field of medical surgical nursing and two experts from the field of radiation oncology. Validation of the tool were based on their suggestions.

Reliability:

Reliability of the tool was obtained by inter rater method. Karl pearson`s co-efficient of correlation method were used to find out reliability. The reliability of oral mucositis assessment scale for ulceration r = 0.99, for erythema r = 0.94. This tool was found to be highly reliable.

DEVELOPMENT OF INTERVETION:

The intervention strategy was based on review of literature. The amount of povidone –iodine(2%) and normal saline (0.9%) selected for mouth rinsing was decided based on expert opinion.

STEPS OF INTERVENTION:

DEFINITION:

A medicated solution used to cleanse or treat the disease of oral mucositis.

PURPOSES:

- ✓ To prevent the mucosal damage
- ✓ To reduce the oral micro flora
- ✓ To promote re-epithelization of soft tissue
- ✓ To reduce the pain
- ✓ To relieve the discomfort
- ✓ To enhance the sense of well being and comfort

ARTICLES:

- Face towel
- Tumbler or feeding cup containing water to wash the face
- Mouth rising solution

a. Povidone-iodine(2%) for experimental group I

b. Normal saline(0.9%) for experimental group II

- K-basin or emesis basin
- Measuring cup or ounce glass

STEPS OF PROCEDURE

NURSING ACTION FOR EXPERIMENTAL GROUP I	NURSING ACTION FOR EXPERIMENTAL GROUP II	RATIONALE
1. Inspect the lips (upper and lower) buccal mucosa (right and left) soft and palate, tongue (dorsal and ventral floor of the tongue.	1. Inspect the lips(upper and lower) buccal mucosa(right and left) soft and palate, tongue(dorsal and ventral floor of the tongue.	1. Determine the status of oral mucosa.
2. Explain the procedure to the patient.	2. Explain the procedure to the patient.	2. Reduce the anxiety and promote patient participation.
3.Measure 10ml of mouth rinse (Povidone-iodine 2%) for experimental group I	3.Measure 20ml of mouth rinse(Normal saline 0.9%) for experimental group II	3.Swishing motion helps to remove the debris and oral micro flora
4.Allow the patient to rinse mouth with Povidone-iodine(2%) by swishing motion for 2 minutes. Make the patient to ensure rinsing should cover all mucosal lining of the oral cavity.	4.Allow the patient to rinse mouth with Normal saline 0.9% by swishing motion for 2minutes.Make the patient ensure mucosal rinsing should cover all lining of the oral cavity.	4.Promote sense of comfort
5. Receive the waste in k-basin or ask the patient to spit in a wash basin.	5 .Receive the waste in k-basin or ask the patient to spit in a wash basin.	
6. Assist the patient to wipe the face with face towel.	6. Assist the patient to wipe the face with face towel.	
7. Ask the patient to record the time of procedure. Instruct the patient that the same techniques should be repeated in a night time also.	7.Ask the patient to record the time of procedure Instruct the patient that The same techniques should be repeated in a night time also.	

PILOT STUDY:

In order to find out the feasibility of the study, pilot study was conducted in similar manner of the original study among 6 patients , three in the experimental group I and in experimental II study was conducted in subjects who were staying in Deveki Cancer and Research Centre, Madurai. The study was found to be feasible. The pilot study participants were excluded from the main study.

DATA COLLECTION PROCEDURE:

After obtaining a ethical committee approval, a formal permission from Devaki Cancer and Research Centre and informed consent from study subjects the data collection procedure was proceeded. The total number of 60 samples were chosen by using purposive sampling techniques. 30 samples were assigned to experimental group I and 30 samples were assigned to experimental group II. Pretest level of oral mucositis was assessed by using oral mucositis assessment scale. After collecting the pretest steps of mouth rinsing was demonstrated by the researcher. The study subjects of experimental group I was instructed to rinse the oral cavity with 10ml of povidone iodine 2%without dilution respectively for 2 minutes, and the experimental group II to rinse the oral cavity with 20 ml of Normal saline 0.9% for 2 minutes after their regular brushing in the morning and before going to bed in night (a twice day). The subjects were provided with measuring a cup to measure the quantity of oral rinse. Each subjects were received the information about mouth rinsing technique. Then the researcher ask the study subjects to maintain the diary indicating the time for mouth rinsing .This was continued for 14 days. Level of oral mucositis among all subjects were examined at the end of 7^{th} day and 14^{th} day during their radiation therapy schedule.

PROTECTION OF HUMAN SUBJECTS:

Research proposal was approved by dissertation committee of sacred heart nursing college, Madurai. Permission was obtained from Devaki Cancer and Research Centre, prior to study. Informed written consent taken from each subjects was obtained before starting data collection. Assurance was given to the subjects, that confidentiality will be maintained. The subjects were explained that they have rights to withdraw from study. There was absence of physical and psychological strain to study subjects.

CHAPTER- IV

ANALYSIS AND INTERPRETATION OF DATA

The fourth chapter deals with description of samples, classification, analysis and interpretation of data collected to evaluate the achievement of the objectives of the study and discussion of the study findings, a data is tabulated and described as follows.

PRESENTATION OF THE FINDINGS OF STUDY

Section I

- Demographic characteristics of the sample.

Section II

- Frequency and percentage distribution of sample according to oral mucositis.
- Frequency and percentage distribution of sample according to oral mucositis before and after the use of povidone iodine mouth rinsing in experimental group I.
- Frequency and percentage distribution of sample according to oral mucositis before and after the use of normal saline mouth rinsing in experimental group II.

Section III

- Comparison of mean oral mucositis score among the experimental group I before and after use of povidone iodine mouth rinse.
- Comparison of mean oral mucositis score among the experimental group II before and after use of normal saline mouth rinse.

- Comparison of mean post test oral mucositis score among the experimental group I and II after use of povidone iodine and normal saline mouth rinse.

Section IV

- Association between oral mucositis score of the experimental group I and II with selected demographic variables.

SECTION – I

Demographic variable of the samples:

This section deals with demographic variables of the subjects such as Age, Sex, Education, Occupation, and Marital status, History of smoking, tobacco, betel nut, pan (or) kutka chewing.

TABLE 1:

Frequency and percentage distribution of the subject with regard to selected demographic variables.

N = 60

Demographic Characteristic	Experimental group I n= 30		Experimental group II n= 30			
	F	%	F	%	Total	%
Age (in year)						
18 – *28*	-	-	-	-		-
29 – 38	6	20	4	13.33	10	16.66
39 – 48	14	46.66	15	50	29	48.33
49 – 58	10	33.33	11	36.66	21	35
Sex						
Male	23	76.66	17	56.66	40	66.66
Female	7	23.33	13	43.33	20	33.33
Education status						
Illiterate	14	46.66	12	40	26	43.33
Literature	16	53.33	18	60	34	56.66
Occupation						
Sedentary worker	19	63.33	22	73.33	41	68.33
Moderate worker	11	36.66	8	26.66	19	31.66

Table cont……

N = 60

Demographic Characteristic	Experimental group I n= 30		Experimental group II n= 30			
	F	%	F	%	Total	%
Marital status						
single	-	-	-	-		-
Married	28	93.33	27	90	55	91.66
Unmarried	-	-	-	-		-
widow	2	6.66	3	10	5	8.33
H/o smoking						
Yes	19	63.33	12	40	31	51.66
No	11	36.66	18	60	29	48.33
H/o betel nut chewing						
Yes	13	43.33	14	46.66	27	45
No	17	56.66	16	53.33	33	55
H/O pan/ kutka chewing						
Yes	1	3.33	1	3.33	2	3.33
No	29	96.66	29	96.66	58	96.66

- The data in table 1 shows that the most of the sample 14(46.66%) were between the age of 39-48 years in experimental group I and 15(50%) belongs to 39-48 years in experimental group II.
- Regarding sex in both experimental group I and II majority of the samples were male 23(76.66%) and 17 (56.66%) respectively.
- Regarding education status both experimental group I and II most of them were literate 16 (53.33%) and 18 (60%) respectively.
- Regarding occupation majority of the samples are sedentary workers in both experimental group I 19 (63.33%)and in experimental group II 22(73.33%).

- Regarding marital status most of them are married in experimental group I 28(93.33%) and in the experimental group II 27(90%) respectively.
- With regards to smoking history most of them had the habits of smoking in experimental group I 19(63.33%) and in experimental group II 12(40%) respectively.

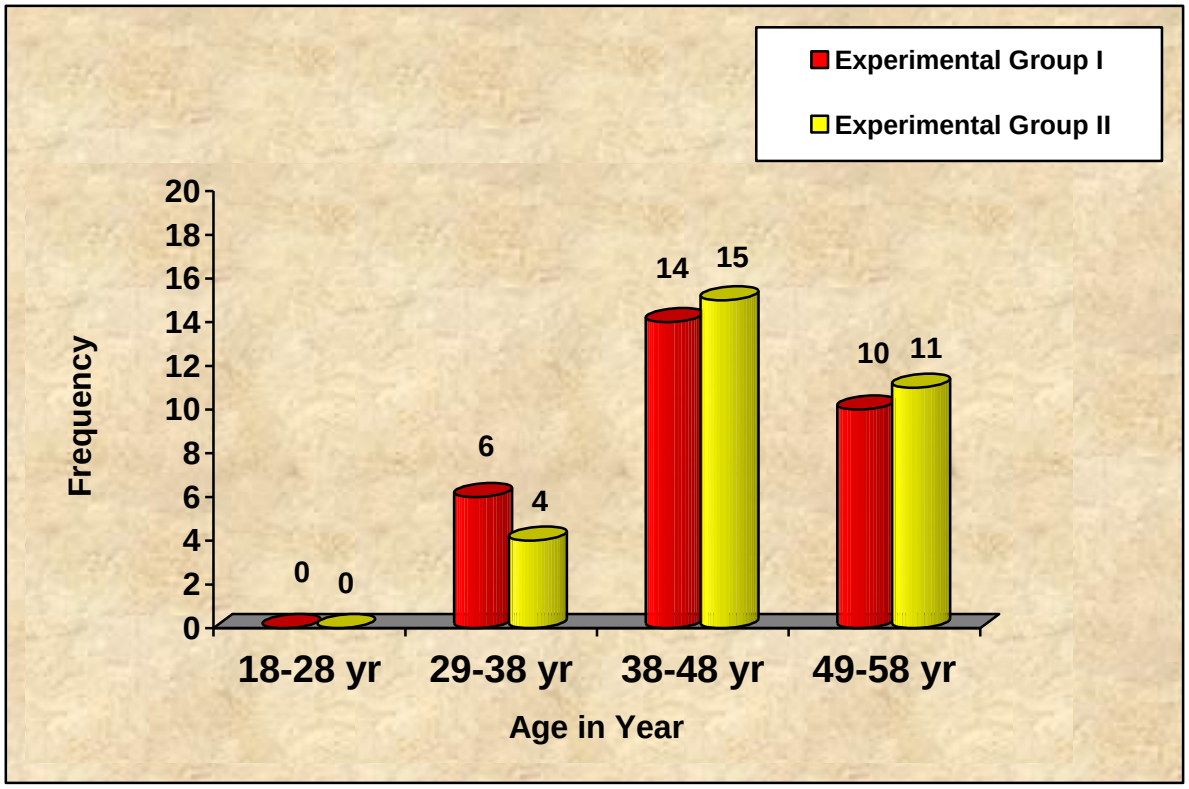


***FIGURE 2*: Distribution of the subject with according to age in experimental group I and experimental group II**

Clinical profile of the samples

This section deals with clinical variables of the subjects such as location of the tumor, severity of the tumor, dose of radiation therapy per day.

TABLE 2:

Frequency and percentage distribution of the subject with regard to selected clinical variables.

N = 60

Demographic Characteristic	**Experimental group I n= 30**		**Experimental group II n= 30**			
	F	**%**	**F**	**%**	**Total %**	
Location of the tumor						
Lip	2	6.66	1	3.33	3	5
Mouth	4	13.33	3	10	7	11.66
Pharynx	8	26.66	10	33.33	18	30
Larynx	13	43.33	14	46.66	27	45
Pituitary gland	3	10	2	6.66	5	8.33
Severity of tumor						
Tumor size(Tx – T4b)	20	66.66	19	63.33	39	65
Node involvement	3	10	1	3.33	4	6.66
Metastasis	7	23.33	10	33.33	17	28.33

Table cont……

N = 60

Demographic Characteristic		Experimental group I n= 30		Experimental group II n= 30		
		F	**%**	**F**	**%**	**Total %**
Dose of radiation therapy per day						
a)	100cGy	-	-	-	-	-
b)	200cGy	30	30	30	30	100
c)	300cGy	-	-	-	-	-
d)	400cGy	-	-	-	-	-

- The data in table 2 shows that majority of the sample had cancer larynx, 13(43.33%) in experimental group I and experimental group II 14(46.66%).
- Regarding severity of the tumor in both experimental group I and II majority of the samples had tumor size ranging from (Tx – T4b), 20(66.66%) and 19 (63.33%)
- Regarding the dose of radiation administered per day for all the samples(100%)in both experimental group I and II were similar in receiving dose of 200 cGy per day.

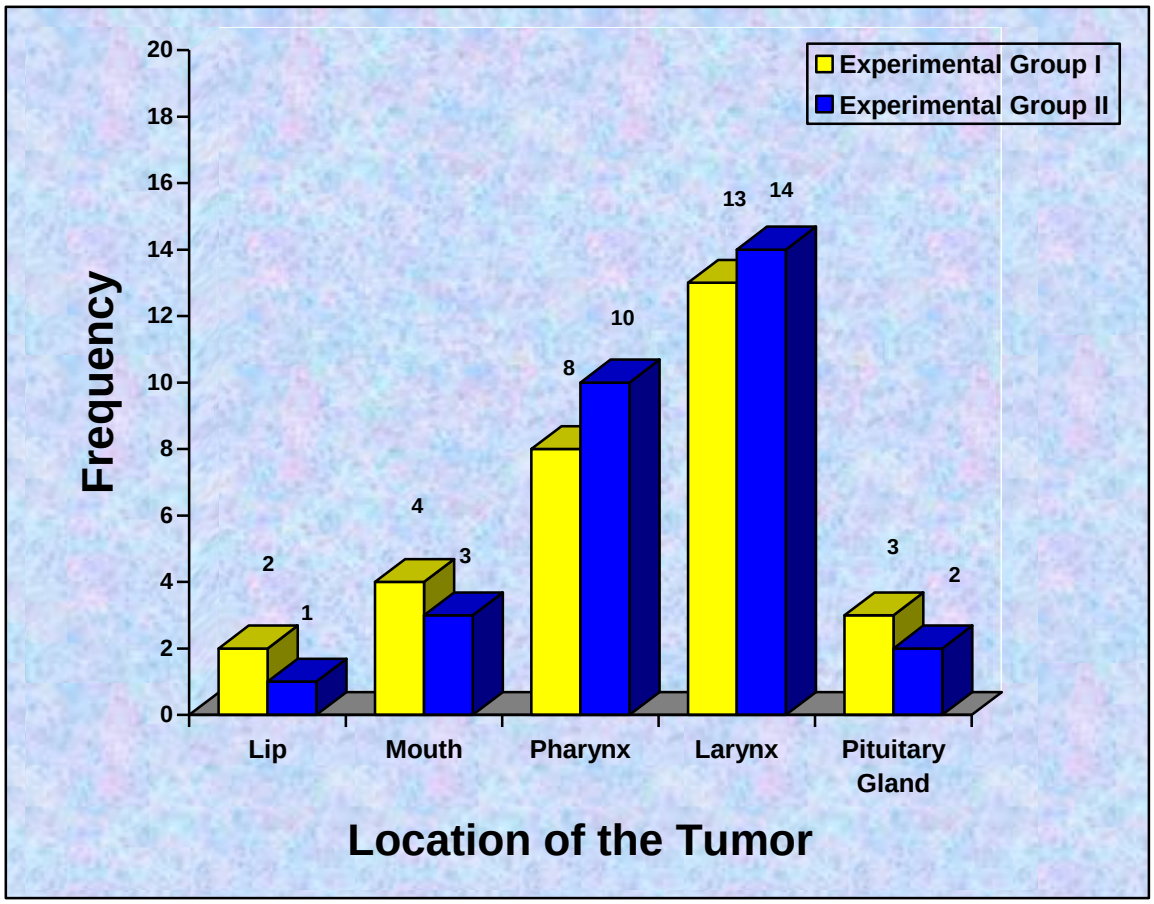


FIGURE 3: **Distribution of the subject according to location of the tumor in experimental group I and experimental group II**

SECTION –II

Distribution of samples according to the level of oral mucositis

TABLE 3:

Distribution of subject according to the level of oral mucositis before and after use of povidone- iodine in experimental group I

N = 30

Level of mucositis	**Experimental group I**					
	Pre Test		**Post Test**			
			7th day		**14th day**	
	F	**%**	**F**	**%**	**F**	**%**
Ulceration						
No ulcer	-	-	-	-	10	33.33
Mild	10	33.33	22	73.33	18	60
Moderate	20	66.66	8	26.66	2	6.66
Erythema						
No erythema	-	-	4	13.33	8	26.66
Not severe	30	100	26	86.66	22	73.33

Data on table – 3 based on mucositis level obtained. The subjects were classified into 4 group. No ulcer (0), mild (1-9), moderate (10-18), severe (18- 30). A higher score indicate poor oral mucositis status, where as a low score indicate reduction in oral mucositis level.

Table – 3 shows that before using of povidone- iodine mouth rinsing there was 10(33.33%) clients had mild ulceration and 20(66.66%) clients had moderate ulceration. After povidone- iodine mouth rinsing, on 7th day 22(73.33%) clients had

mild ulceration and 8(26.66%) clients had moderate ulceration, on 14th day 10(33.33%) clients had no ulcer, 18(60%) clients had mild ulceration and 2(6.66%) clients had moderate ulceration. For erythema during pre test 30(100%) client had not severe erythema . After using of povidone- iodine mouth rinsing, on 7th day 4(13.33%) clients had no erythema and 26(86.66%) clients had not severe erythema, on 14th day 8(26.66%) clients had no erythema and 22(73.33%) client had not severe erythema. This difference may be due to effect of povidone- iodone mouth rinsing.

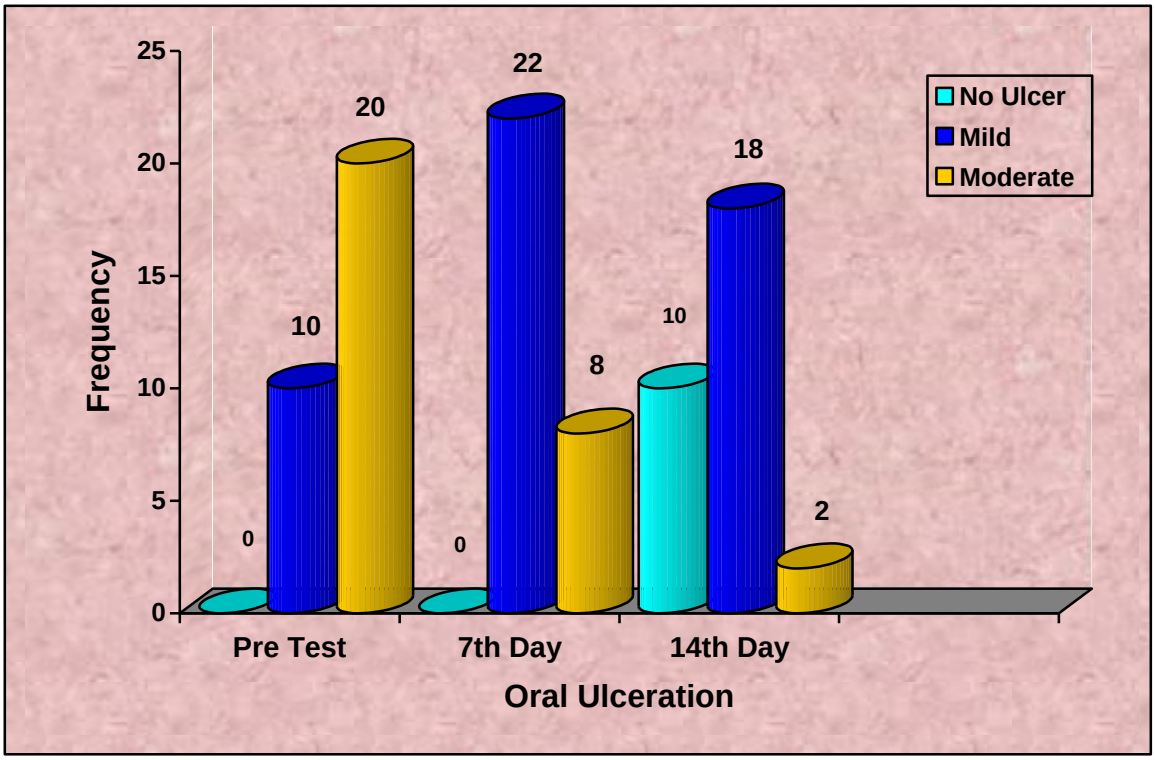


FIGURE 4: **Distribution of subjects according to oral ulceration status in experimental group- I**

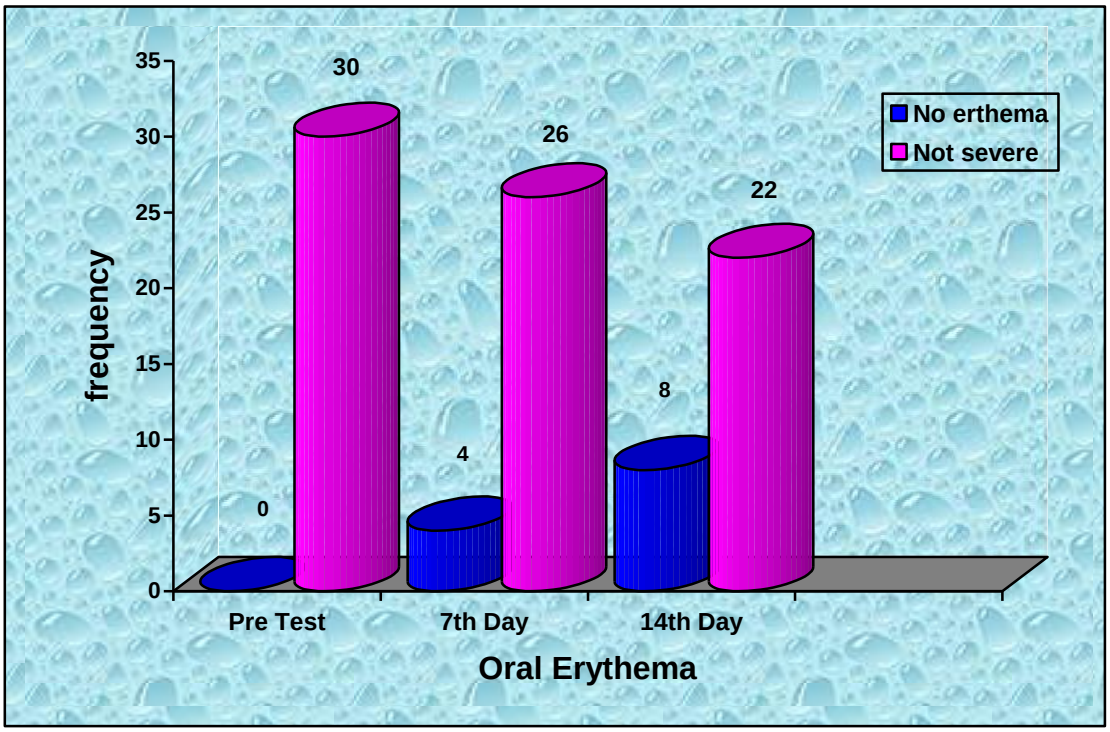


FIGURE 5 : **Distribution of subjects according to oral erythema status in experimental group- I**

TABLE 4:

Distribution of subjects according to the level of oral mucositis before and after use of normal saline in experimental group II.

N = 30

Level of mucositis	Experimental group II					
	Pre Test		Post Test			
			7th day		14th day	
	F	%	F	%	F	%
Ulceration						
No ulcer	-	-	-	-	5	16.66
Mild	15	50	21	70	19	63.33
Moderate	15	50	9	30	6	20
Erythema						
No erythema	-	-	3	10	6	20
Not severe	30	100	27	90	24	80

Table – 4 shows that before using of normal saline mouth rinsing there was 15(30%) samples had mild ulceration and 15(30%) samples had moderate ulceration. After using of normal saline mouth rinsing, on 7th day 21(70%) samples had mild ulceration and 9(30%) samples had moderate ulceration, on 14th day 5(16.66%) clients had no ulceration and 19(63.33%) samples had mild ulceration and 6(20%) samples had moderate ulceration. This is due to the effect of normal saline mouth rinsing. For erythema during pretest 30(100%) samples had not severe erythema, on 7th day 3(10%) samples had no erythema and 27(90%) samples had not severe erythema, on 14th day 6(20%) samples had no erythema and 24 (80%) samples had not severe erythema.

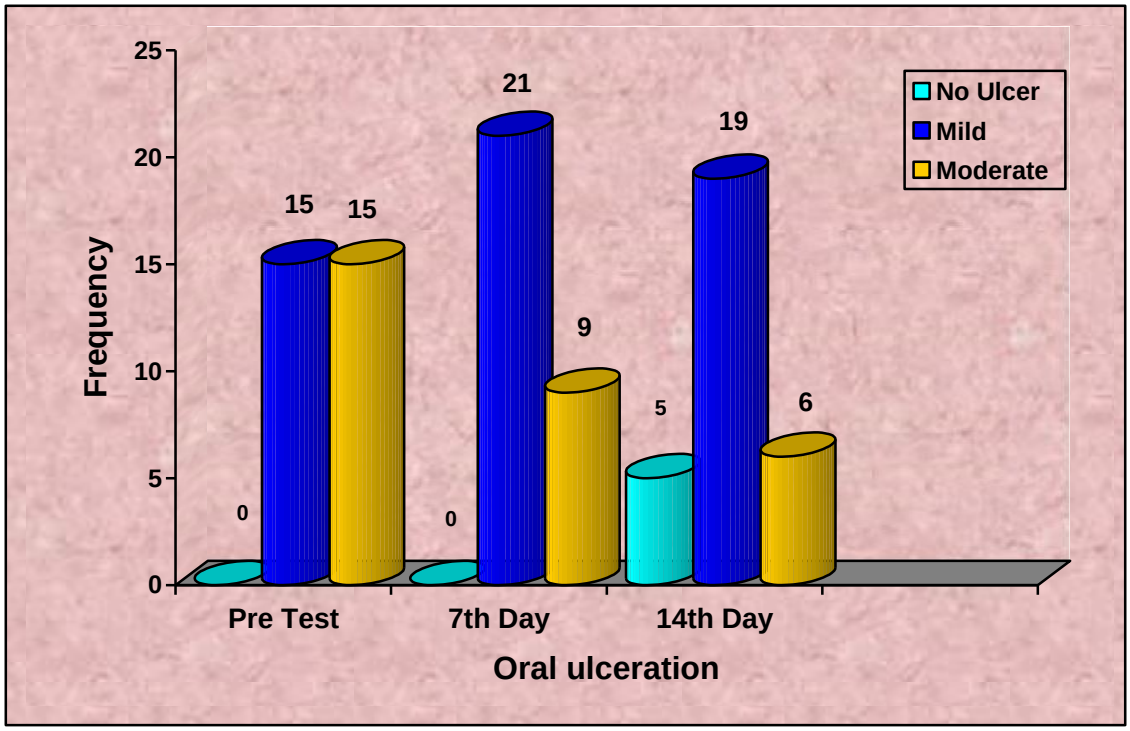


FIGURE 6 **: Distribution of subjects according to oral ulceration status in experimental group- II**

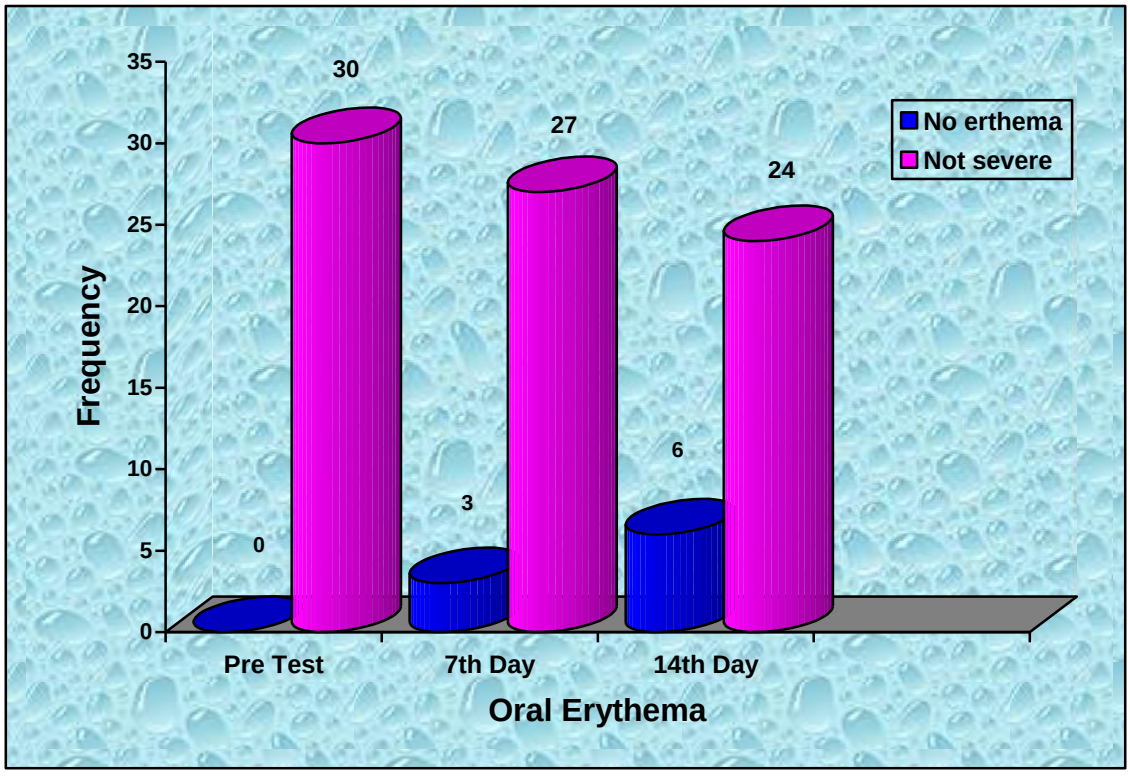


FIGURE 7 **: Distribution of subjects according to oral erythema status in experimental group- II**

TABLE 5:

Distribution of subjects according to the post test level of oral mucositis in experimental group I and experimental II

N= 60

Level of mucositis	Experimental group I				Experimental group II			
	7th day		14th day		7th day		14th day	
	F	%	F	%	F	%	F	%
Ulceration								
No ulcer	-	-	10	33.33	-	-	5	16.66
Mild	22	73.33	18	60	21	70	19	63.33
Moderate	8	26.66	2	6.66	9	30	6	20
Erythema								
No erythema	4	13.33	8	26.66	3	10	6	20
Not severe	26	86.66	22	73	27	90	24	80

Data on table -5 shows that in experimental group I 22(73.33%) client had mild ulceration and 8(26.66%) client had moderate ulceration on 7th day, on 14th day 10(33.33%) client had no ulceration and 18(60%) client had mild ulceration and 2(6.66%) client had moderate ulceration. Where as in the experimental group II on 7th day 21(70%) client had mild ulceration and 9(30%) client had moderate ulceration. On 14th day 5(16.66%) client had no ulceration and 19 (63.33) client had no ulceration and 6(20%) client had moderate ulceration.

On 7th day 4(13.33%) clients had no erythema and 26(86.66%) clients had not severe erythema . on 14th day 8(26.66%) clients had no erythema and 22(73%) clients had not severe erythema. Where as in the experimental group II on 7th day 3(10%) clients had no erythema and 27 (90%) clients had not severe erythema, on 14th day 6(20%) clients had no erythema and 24 (80%) clients had not severe erythema.

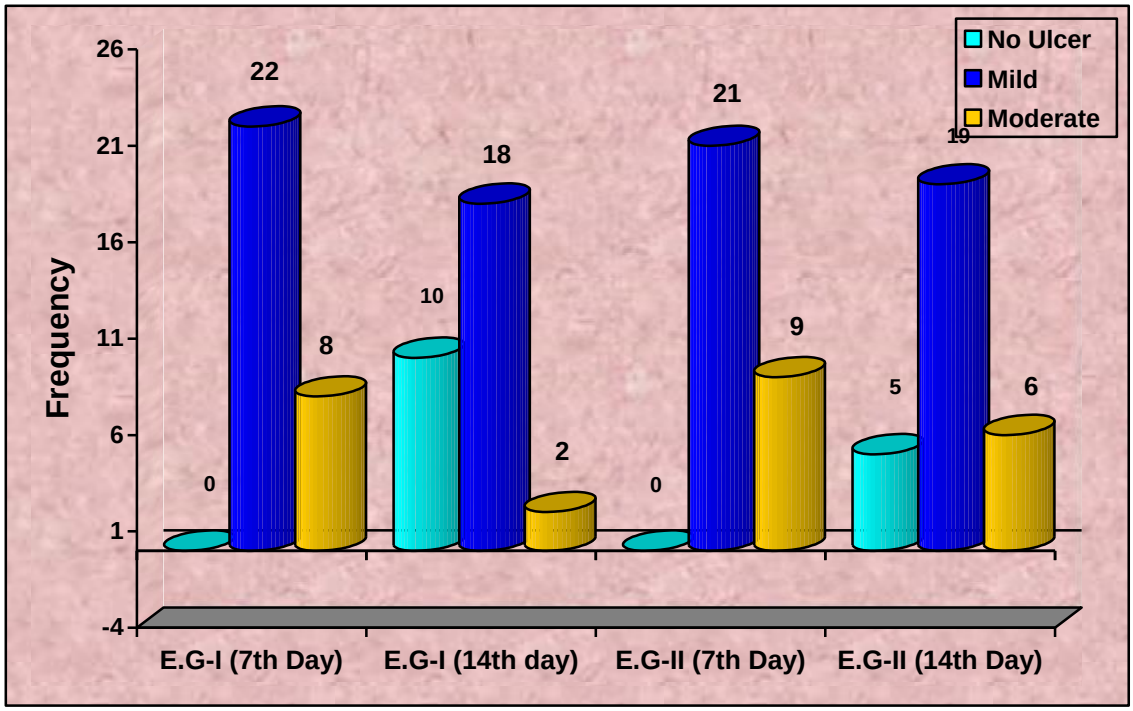


FIGURE 8 **: Distribution of subjects according to the post test level of oral ulceration in experimental group- I and II**

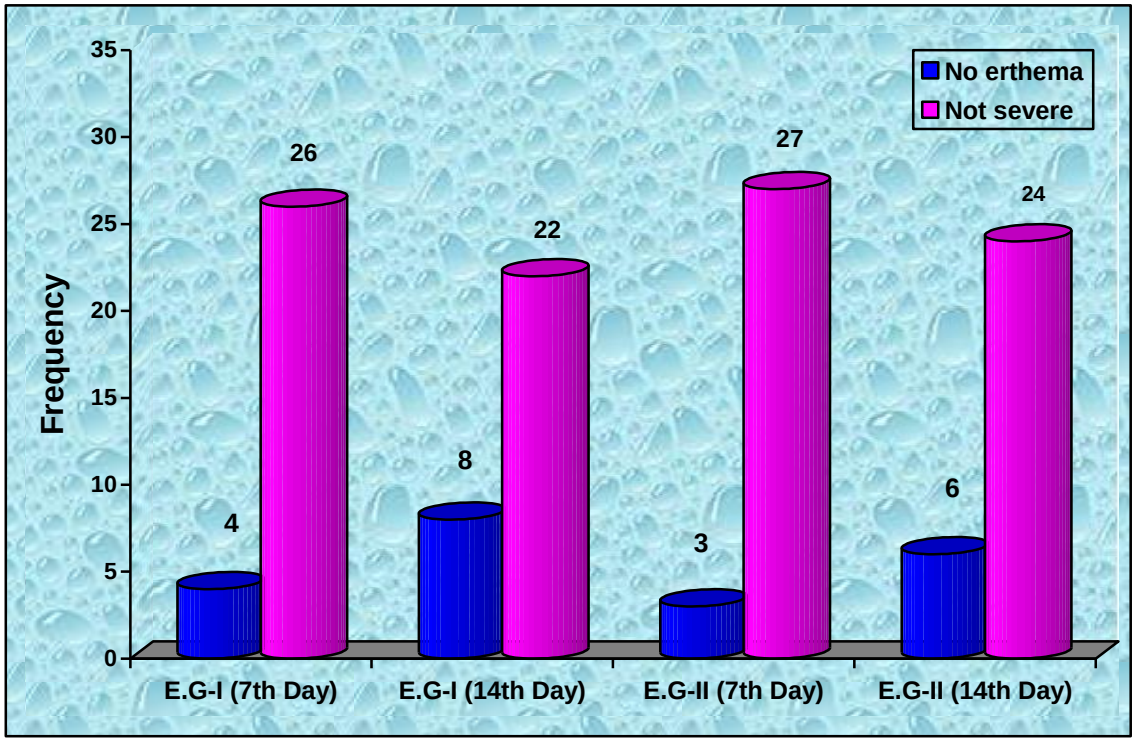


FIGURE 9 : **Distribution of subjects according to the post test level of oral erythema in experimental group- I and II**

SECTION – III

Comparison of povidone- iodine mouth rinsing in reducing oral mucositis

TABLE 6:

Comparison of mean pre test and post level of oral mucositis -ulceration among patients receiving radiation therapy after the povidone- iodine mouth rinsing in experimental group – I on 14th day

N =30

Measurement	N	Mean	SD	t = value
Pre test	30	11.06	2.81	
Post test	30	4.03	3.33	18.5*

*Significant at 0.05 level.

To find out if there is any difference between the mean level of oral ulceration before and after use of povidone iodine mouth rinsing, the null hypothesis was stated as follows

H1:

The mean post test oral mucositis score in experimental group I who received povidone- iodine will not be significantly lower than their mean pre test oral mucositis score. In the present study mucositis status was measured by OMAS scale. A higher score indicates increased oral mucositis status where the lower score indicates decreased oral mucositis status.

Data on table -6 shows that the mean post test level of povidone- iodine mouth rinsing (4.03) was lower than the pre test mean (11.06). The obtained 't' value of (2.042) was significant at 0.05 level. This indicates that the difference has not occurred by chance. So the researcher rejects the null hypothesis and accepts the research hypothesis.

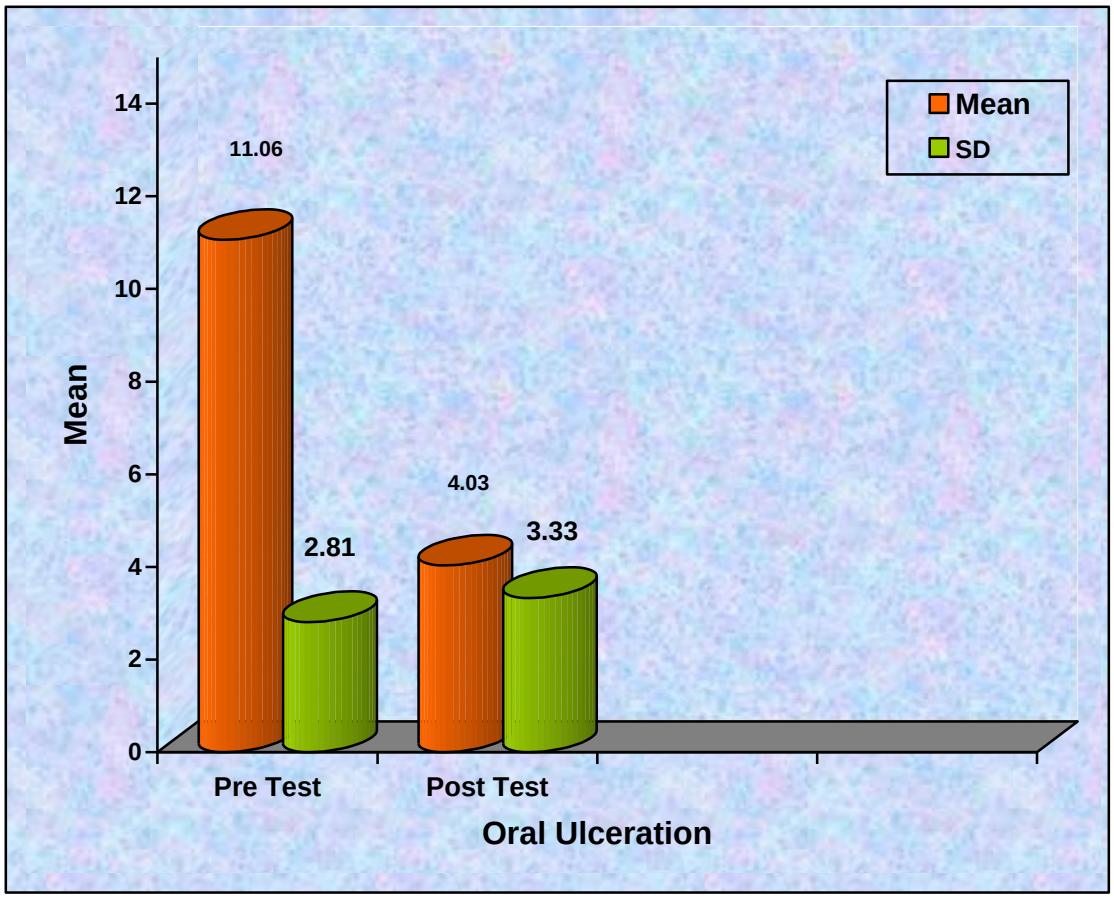


FIGURE 10: **Comparison of mean pre test and post level of oral ulceration among patients receiving radiation therapy after the povidone- iodine mouth rinsing in experimental group – I on 14th day**

TABLE 7:

Comparison of mean pre test and post level of oral mucositis - erythema among patients receiving radiation therapy after the povidone- iodine mouth rinsing in experimental – I on 14th day

N =30

Measurement	N	Mean	SD	t = value
Pre test	30	6.6	1.85	
Post test	30	1.33	0.94	25.05*

*Significant at 0.05 level.

To find out if there is any difference between the mean level of oral erythema before and after use of povidone iodine mouth rinsing the null hypothesis was stated as follows

H1:

The mean post test level of oral erythema in experimental group I who received povidone iodine will not be significantly lower than their mean pre test oral erythema level.

Data on table -7 shows that the mean post test level of povidone- iodine mouth rinsing of the experimental group I(1.33) was lower than the pre test mean oral erythema level (6.6). The obtained 't' value of 25.05 (P =2.042) was significant at 0.05 level. This indicates that the difference has not occurred by chance. So the researcher rejects the null hypothesis and accepts the research hypothesis.

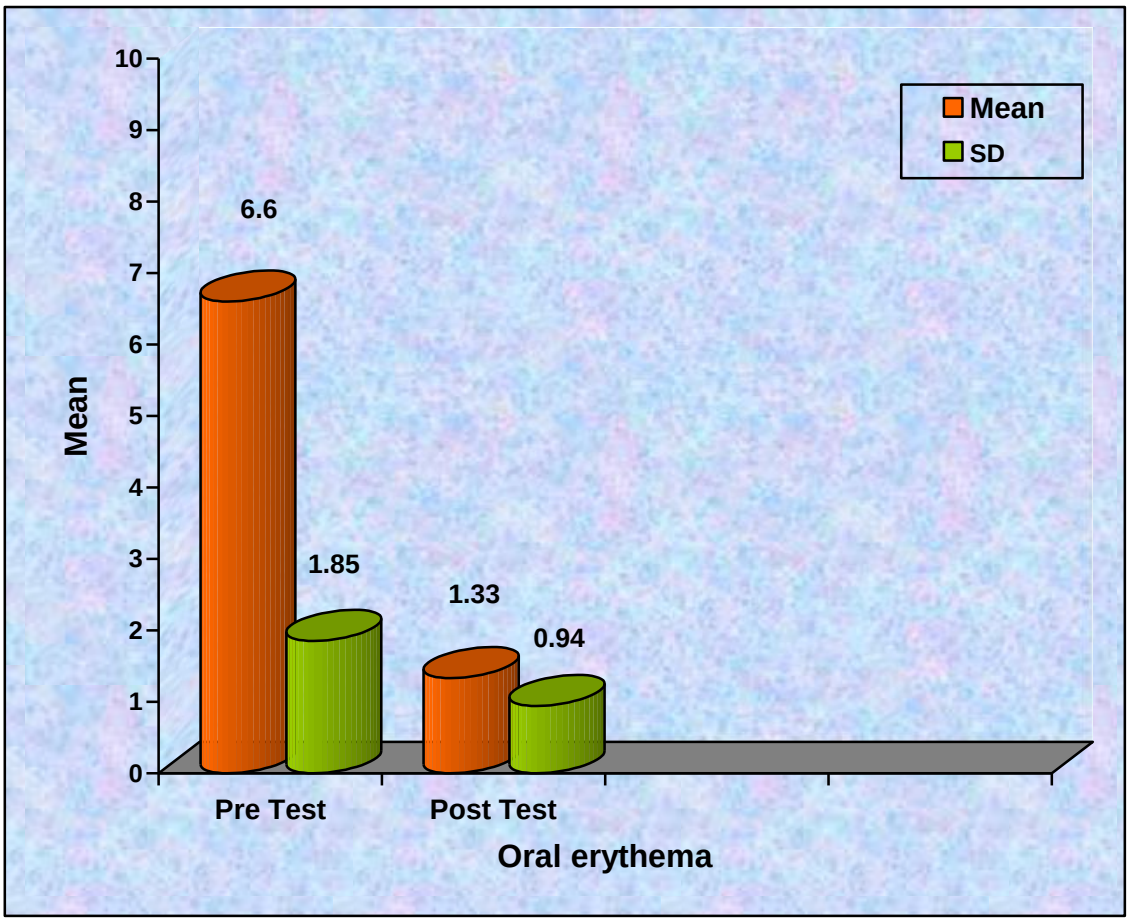


***FIGURE 11*: Comparison of mean pre test and post level of oral erythema among patients receiving radiation therapy after the povidone- iodine mouth rinsing in experimental – I on 14th day**

TABLE 8:

Comparison of mean pre test and post level of oral mucositis- ulceration among patients receiving radiation therapy after the normal saline mouth rinsing in experimental - II on 14th day

N = 30

Measurement	N	Mean	SD	t = value
Pre test	30	10.23	3.71	
Post test	30	4.8	3.52	23.58*

*Significant at 0.05 level.

To find out if there is any difference between the mean level of oral ulceration before and after use of normal saline mouth rinsing the null hypothesis was stated as follows

H2:

The mean post test level of oral ulceration in experimental group II who received normal saline will not be significantly lower than their mean post test oral erythema level.

Data on table -8 shows that the mean post test oral mucositis level of normal saline mouth rinsing sample of the experimental group II(4.8) was lower than the pre test mean oral mucositis score (10.23). The obtained 't' value of 23.58 at df 29 was significant at 0.05 level. This indicates that the difference has not occurred by chance. So the researcher rejects the null hypothesis and accepts the research hypothesis.

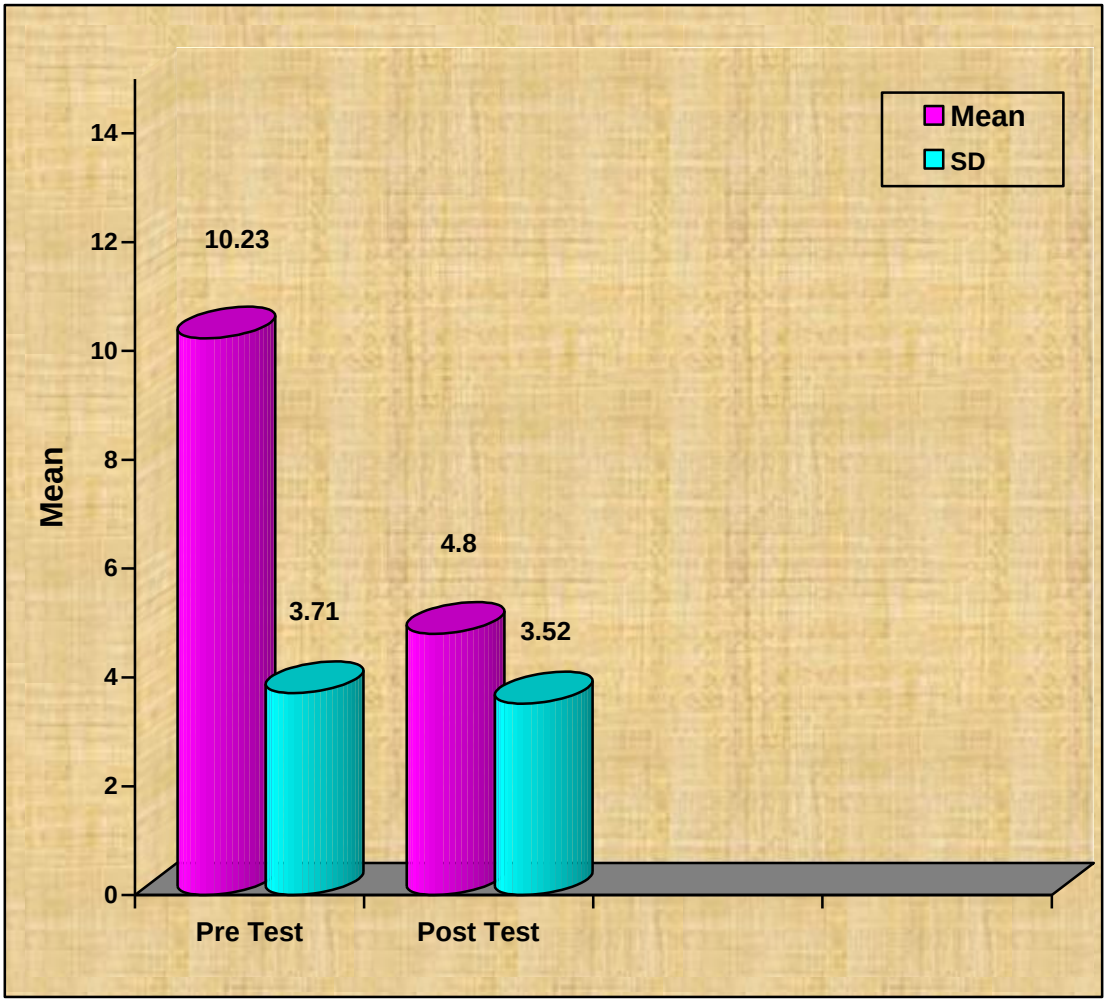


FIGURE 12: **Comparison of mean pre test and post level of oral ulceration among patients receiving radiation therapy after the normal saline mouth rinsing in experimental - II on 14th day**

TABLE 9:

Comparison of mean pre test and post level of oral mucositis- erythema among patients receiving radiation therapy after the normal saline mouth rinsing in experimental - II on 14th day

N = 30

Measurement	N	Mean	SD	t = value
Pre test	30	6.7	1.18	
Post test	30	1.3	0.9	33.31*

*Significant at 0.05 level.

To find out if there is any difference between the mean level of oral eryhtema before and after use of normal saline mouth rinsing the null hypothesis was stated as follows

H2:

The mean post test level erythema in experimental group II who received normal saline will not be significantly lower than their mean post test oral erythema level.

Data on table -9 shows that the mean post test oral mucositis level of normal saline mouth sample rinsing of the experimental group II(1.3) was lower than the mean pre test oral mucositis score (6.7). The obtained‘t’ value of 33.31 at df 29 was significant at 0.05 level. This indicates that the difference has not occurred by chance. So the researcher rejects the null hypothesis and accepts the research hypothesis.

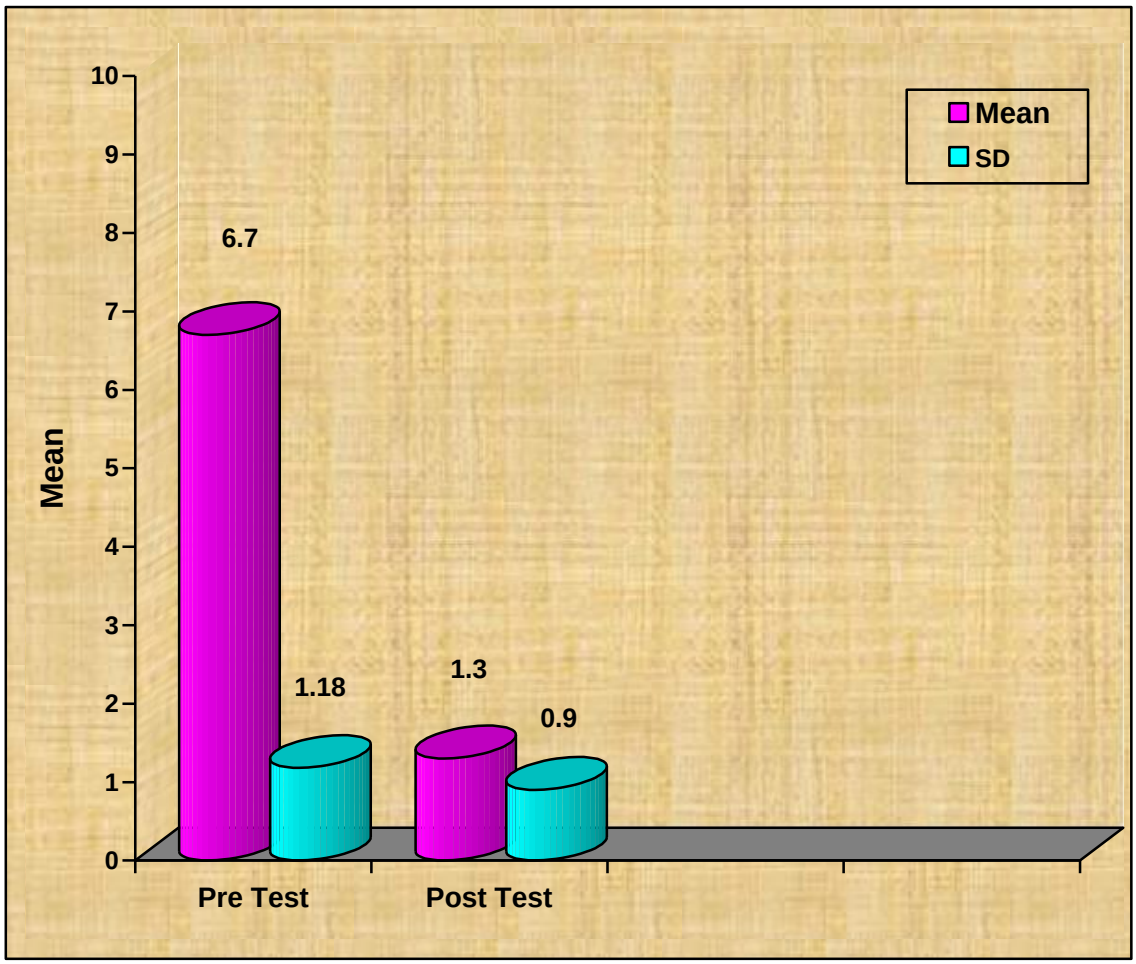


FIGURE 13: **Comparison of mean pre test and post level of oral erythema among patients receiving radiation therapy after the normal saline mouth rinsing in experimental - II on 14th day**

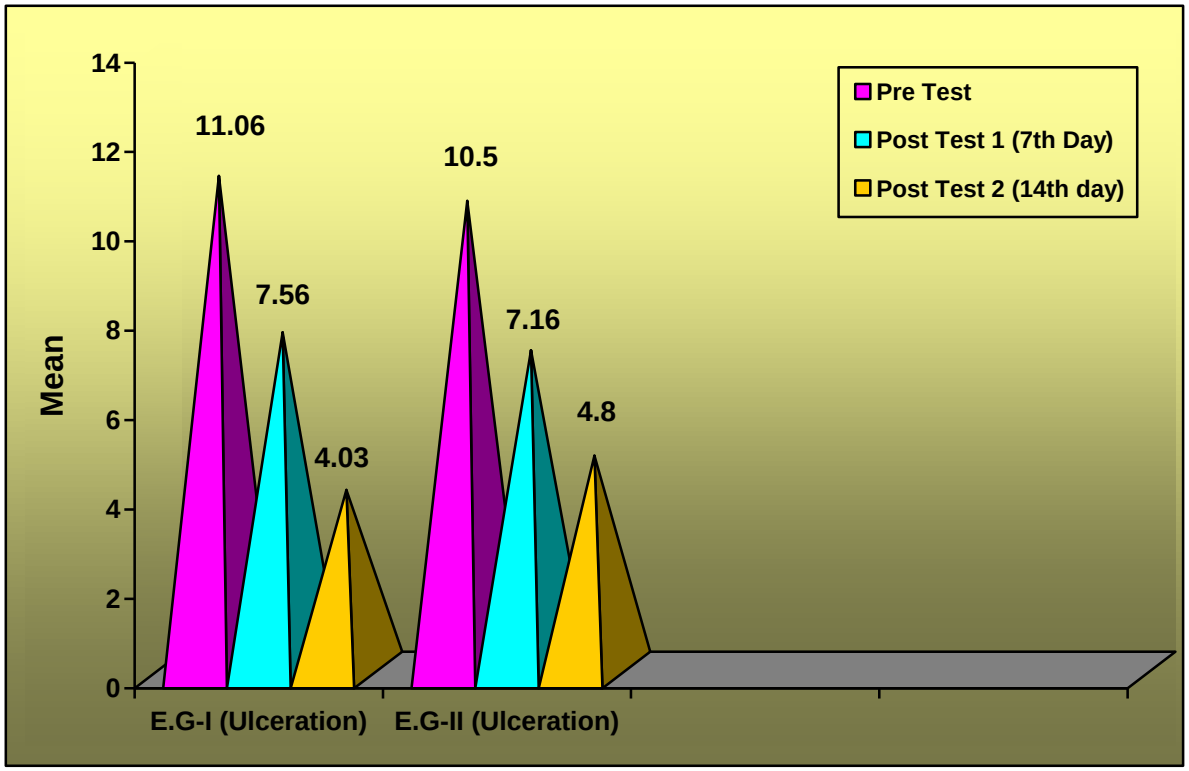
TABLE 10:

Comparison of oral mucositis scores within the group of pre test - post test 1 and post test 2 by repeated measures of ANOVA method

Test	Experimental group I						Experimental group II					
	Ulceration			Erythema			Ulceration			Erythema		
	Mean	SD	F-value	Mean	SD	F-value	Mean	SD	F-value	Mean	SD	F-value
Pre test	11.06	2.81		6.6	1.85		10.5	2.66		6.7	1.18	
Post test 1 (7^{th} day)	7.56	2.83	40.15*	3	1.45	97.45*	7.16	3.40	23.03*	3.23	1.15	185.61*
Post test 2 (14^{th} day)	4.03	3.33		1.33	0.94		4.8	3.52		1.3	0.9	

The table 13 shows that the mean oral score in pre test (11.06) and after giving intervention the post test 1 value is (7.56) and post test 2 value is (4.03) in experimental group I. ulceration score and the obtained 'F' value is (40.15) is statistically significant at $P < 0.001$ level ,Regarding erythema score mean in pre test (6.6) and after giving intervention post test 1 value is (3) and post test 2 value is (1.33) and the obtained 'F' value is (97.45) is statistically significant at $P < 0.001$ level .So, the intervention is effective in reducing the level of oral mucositis among patient receiving external therapy.

In experimental group II the ulceration score mean in pre test (10.5) and after giving intervention post test 1 value is (7.16) and post test 2 value is (4.8) and the obtained 'F' value is (23.03) is statistically significant at $P < 0.001$ level, In view to erythema mean score in pre test (6.7) and after giving intervention post test 1 value is (3.23) and post test 2 value is (1.3) and the obtained 'F' value is (185.61) is statistically significant at $P < 0.001$ level .So, the intervention is reducing the oral mucositis symptoms effectively.



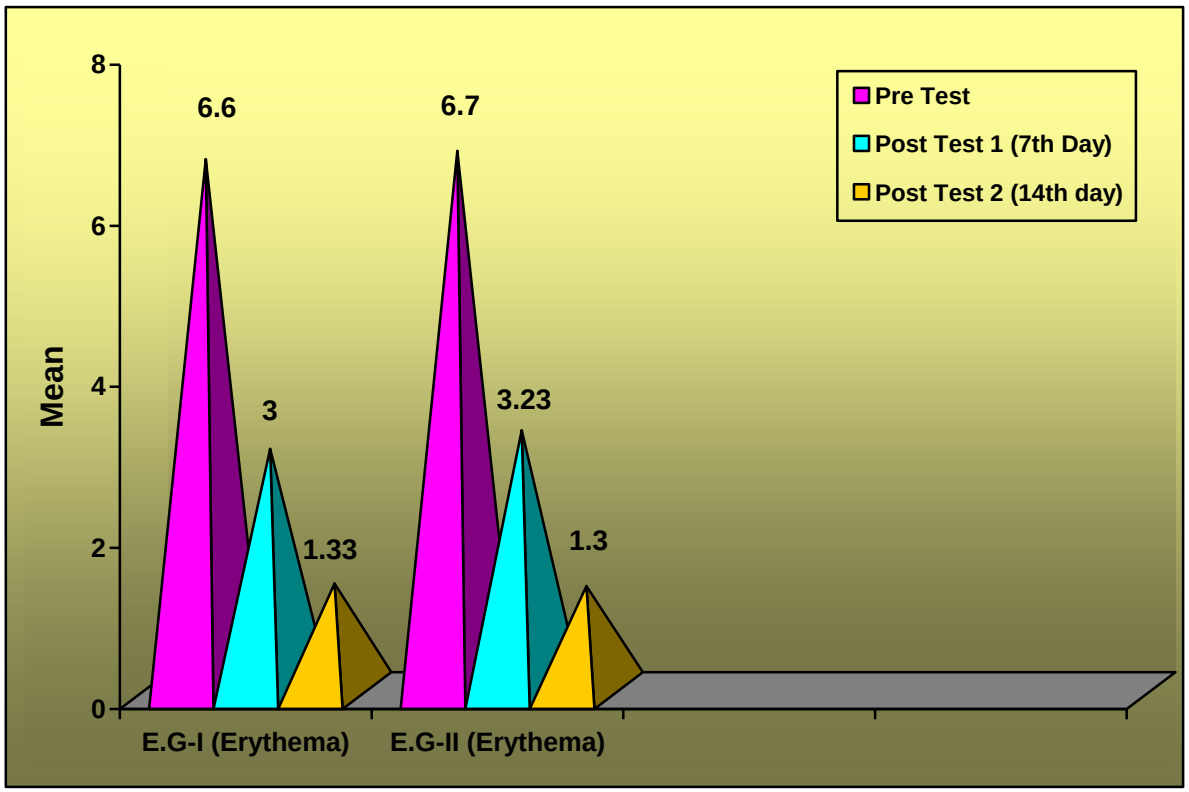


***FIGURE 14*: Comparison of with the group Pretest, Post test 1 and Post test 2 oral mucositis scores by repeated measures of ANOVA method.**

TABLE 11:

Comparison of mean post test oral mucositis among the experimental – I and experimental - II after povidone- iodone and normal saline mouth rinse on 14th day

N = 30

Group	N	Mean	SD	t - value	P -Value
Ulceration					
Experimental I	30	4.03	3.33	18.5	2.05*
Experimental II	30	4.8	3.52	23.58	2.05*
Erythema					
Experimental I	30	1.33	0.94	25.04	2.05*
Experimental II	30	1.3	0.9	33.31	2.05*

*Significant at 0.05 level.

To find out if there is any difference between the mean level oral mocositis of experimental group I and experimental group II after povidone- iodine and normal saline mouth rinse, the null hypothesis was stated as follows

H3:

The mean post test oral mucositis score of subject's received povidone- iodine mouth rinse will not be higher than the mean post test level of oral mucositis of patient received normal saline mouth rinse.

Data on table -10 shows the post test mean oral mucositis score of experimental group I (4.03) after povidone- iodine mouth rinse is significantly lower than the experimental group II(4.8)who received normal saline mouth rinse. The obtained 't' value of (P = 2.05) was significant at 0.05 level. This difference between

the mean (0.77) is a true difference, and has not occurred by chance. It can be inferred that povidone -iodine mouth rinse has significant role in reducing oral mucositis level. So the researcher reject null hypothesis and accept the research hypothesis. The mean post test erythema score of experimental group I(1.33) is significantly higher than the experimental group II(1.3).

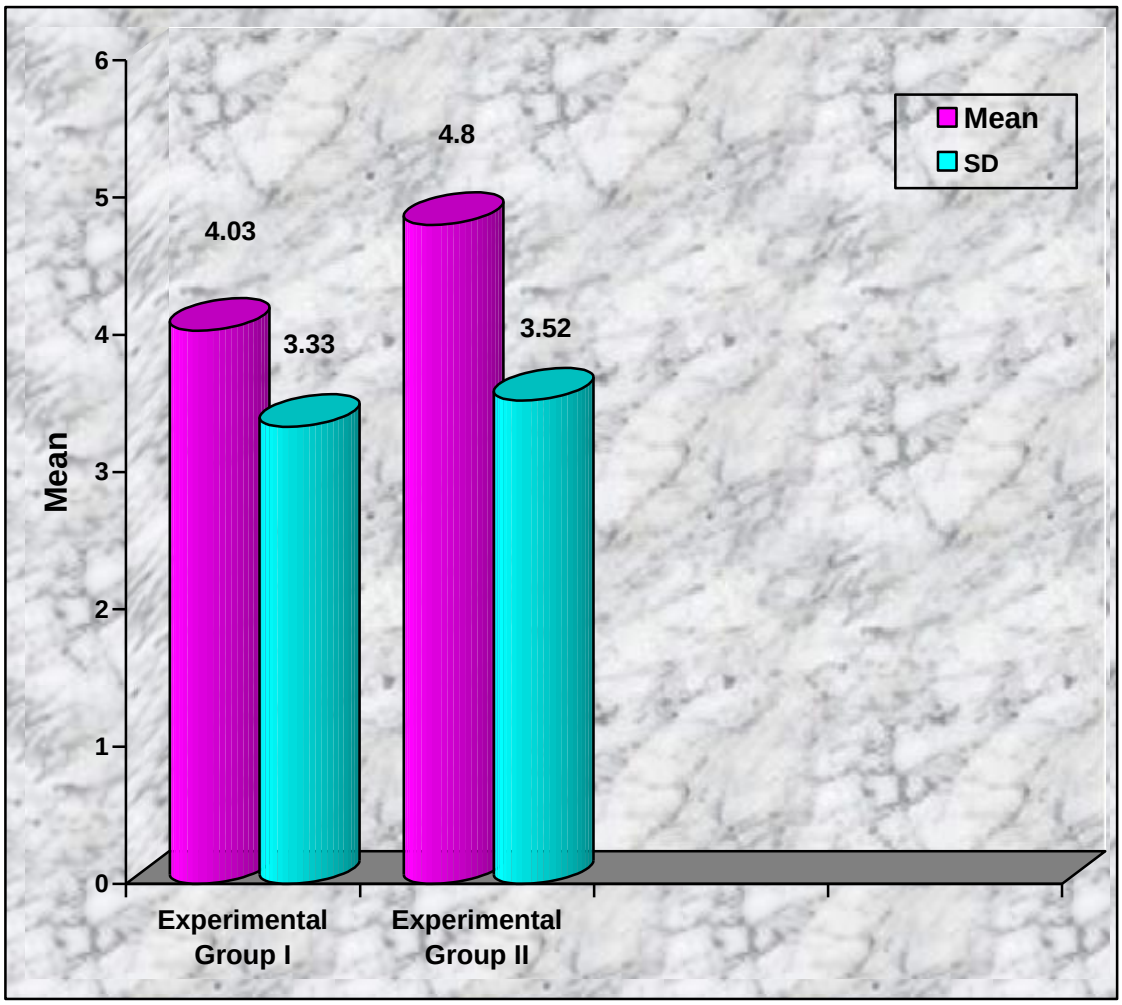


***FIGURE 15*: Comparison of mean post test oral mucositis among the experimental – I and experimental - II after povidone- iodine and normal saline mouth rinse on 14th day**

TABLE 12:

Comparison between groups of pre test, post test 1 and post test 2 oral mucositis score by repeated measures of ANOVA method

Test	Ulceration				Erythema			
	Mean	**SD**	**F- value**	**P- value**	**Mean**	**SD**	**F- value**	**P- value**
Pre test (Exp.group I)	11.06	2.81			6.6	1.85		
Pre test 2 (Exp.groupII)	10.5	2.66			6.7	1.18		
Post test 1 (E.G-I,7th day)	7.56	2.83	13.44	6.85*	3	1.45	59.57	6.85*
Post test 1 (E.G-II,7th day) I)	7.16	3.40			3.23	1.15		
Post test 2 (E.G- I,14th day)	4.03	3.33	41.39	6.85*	1.33	0.94	167.35	6.85*
Post test 2 (E.G- II,14th day)	4.8	3.52			1.3	0.9		

The table 12 shows that the mean oral ulceration of score experimental group I and II, on 7th day was found statistically significant with the 'F' value of 13.44(P<0.001), whereas on 14th day the mean oral ulceration score was found statistically significant with the 'F' value of 41.39(P<0.001).

Regarding the mean oral erythema score of experimental group I and II, on 7th day was found statistically significant with the 'F' value of 59.57(P<0.001), likewise on 14th day the mean oral erythema score was found statistically significant with the 'F' value of 167.35(P<0.001).

This denotes the healing pattern is different in both group in consequent days. The healing was faster in experimental group I when compared to experimental group II, and 7th day itself. This change was statistically seen.

SECTION – IV

This section deal with the association between pre test oral mucositis level of experimental group I select demographic variables Age, Sex, Education, Occupation, Marital status, History of smoking, History of betel chewing, History of pan/ kutka.

TABLE 13:

Association between the levels of oral mucositis of the experimental group I before the use of povidone-iodine mouth rinsing with demographic variables.

Variables	Level of ulceration		Df	chi square	P value
	Above mean	Below mean			
Age(in year):					
29 – 38 year	5	1	3	2.81	7.82#
39 – 48 year	5	9			
49 – 58 year	6	4			
Sex:					
Male	13	10	1	0.13	3.84#
Female	3	4			
Education status:					
Illterature	8	6	1	0.41	3.84#
Literature	8	8			
Occupation:					
Sedentary worker	8	11	1	0.32	3.84#
Moderate worker	8	3			
Marital status:					
Single	-	-	3	0.24	7.82#
Married	15	13			
Unmarried	-	-			
Widow	11	1			

Variables	Level of ulceration				
	Above mean	Below mean	Df	chi square	P value
H/o smoking:					
Yes	11	8	1	1.13	3.84#
No	5	6			
H/o betel chewing:					
Yes	7	6	1	1.06	3.84#
No	8	9			
H/o pan/ kutka:					
Yes	1	0	1	0.94	3.84#
No	15	14			

*Significant at 0.05 level

not Significant at 0.05 level

To find out if there is any association between oral mucositis score of the subjects and the selected or demographic and clinical variables of samples such as age, sex, education, occupation, marital status, history of smoking, history of betel nut chewing, history of pan/ kutka chewing, the null hypothesis was selected as follows

H4:

There will be no significant association between the experimental group I oral mucositis score and demographic and clinical variables such as age, sex, education, occupation, marital status, history of smoking, history of betel nut chewing, history of pan/ kutka chewing.

- In order to find out the association between the mucositis score and age the chi-quare test was computed. The obtained chi-quare value of 2.81 was not significant at 0.05 level (df -3)
- Regarding oral mucositis score and sex the calculated value 0.13 at (df -1) was not significant at 0.05 level.

- Regarding oral mucositis score and education status the calculated value 0.41 at (df -1) was not significant at 0.05 level.
- Regarding oral mucositis scale and sex the calculated value 0.13 at (df -1) was not significant at 0.05 level.
- Regarding oral mucositis score and occupation the calculated value 0.32 at (df -1) was not significant at 0.05 level.
- Regarding oral mucositis score and marital status the calculated value 0.24 at (df -1) was not significant at 0.05 level.
- It was found that there was no association between history of smoking, betel, pan/ kutka chewing. The chi- square value 1.13 and 1.06 and 0.94 (df -1) was not significant at 0.05 level.

There is no significant association between the pre test oral mucositis score and selected demographic variables such as age, sex, education, occupation, marital status, history of smoking, history of betel nut chewing, history of pan/ kutka chewing.

So the researcher accepts the null hypothesis, and reject the research hypothesis.

***TABLE 14*:**

Association between the levels of oral mucositis of the experimental group II before the use of normal saline mouth rinsing with demographic variables.

Variables	Level of ulceration				
	Above mean	Below mean	Df	chi square	P value
Age(in year):					
29 – 38 year	3	1			
39 – 48 year	6	9	3	86.8	7.82*
49 – 58 year	3	8			
Sex:					
Male	8	9	1	1.2	3.84#
Female	4	9			
Education status:					
Illterature	6	6	1	0.06	3.84#
Literature	6	12			
Occupation:					
Sedentary worker	9	13	1	0.97	3.84#
Moderate worker	2	6			
Marital status:					
Single	-	-			
Married	12	16	3	3.32	7.82#
Unmarried	-	-			
Widow	0	2			
H/o smoking:					
Yes	4	8	1	1.81	3.84#
No	8	10			

(Table continued ….)

Variables	Level of ulceration				
	Above mean	Below mean	Df	chi square	P value
H/o betel chewing:					
Yes	6	8	1	0.52	3.84#
No	6	10			
H/o pan/ kutka:					
Yes	0	1	1	1.02	3.84#
No	0	17			

*Significant at 0.05 level

not Significant at 0.05 level

To find out if there is any association between oral mucositis score of the subjects and the selected demographic and clinical variables of such as age, sex, education, occupation, marital status, history of smoking, history of betel nut chewing, history of pan/ kutka chewing, the null hypothesis was selected as follows

H5:

There will be no significant association between the experimental groupI I oral mucositis score and demographic and clinical variables of such as age, sex, education, occupation, marital status, history of smoking, history of betel nut chewing, history of pan/ kutka chewing.

- Regarding oral mucositis score and age the calculated value 86.8 at (df -1) was significant at 0.05 level.
- Regarding oral mucositis score and sex the calculated value 1.2 at (df -1) was not significant at 0.05 level.
- Regarding oral mucositis score and education status the calculated value 0.06 at (df -1) was not significant at 0.05 level.

- Regarding oral mucositis scale and ocupation the calculated value 0.97 at (df - 1) was not significant at 0.05 level.
- Regarding oral mucositis score and marital status the calculated value 3.32 at (df -1) was not significant at 0.05 level.
- It was found that there was no association between history of smoking, betel, pan/ kutka chewing. The chi- square value 1.81 and 0.52 and 1.02 (df-1)

There is no significant association between the pre test oral mucositis score and selected demographic variables such as Sex, Education, Occupation, Marital status, History of smoking, History of betel nut chewing, History of pan/ kutka chewing.

Since the association was found only between the pre test oral mucositis score and age (χ^2 =86.8) after administration of normal saline mouth rinse, the researcher is unable to reject the null hypothesis and hence accept the research hypothesis.

CHAPTER -V

DISCUSSION

A study to assess the effectiveness of povidone- iodine Vs normal saline mouth rinsing on oral mucositis among patient with head and neck malignancies who is receiving radiation therapy from selected hospital in Madurai. This study was conducted among patients with head and neck cancer who receiving radiation therapy. The tool used for study was oral mucositis assessment scale (OMAS)

MAJOR FINDINGS OF THE STUDY

DEMOGRAPHIC VARIABLES OF SAMPLES:

- Regarding the age most of the sample 14(46.66%) were between the age of 39-48 years in experimental group I and 15(50%) belongs to 39-48 years in experimental group II.
- Regarding sex in both experimental group I and II majority of the samples were male 23(76.66%) and 17 (56.66%) respectively.
- Regarding education status both experimental group I and II most of them are literate 16 (53.33%) and 18 (60%) respectively.
- Regarding occupation majority of the samples are sedentary workers in both experimental group I 19 (63.33%)and in experimental group II 22(73.33%).
- Regarding marital status most of them are married in experimental group I 28(93.33%) and in the experimental group II 27(90%) respectively.
- With regards to smoking history most of them had the habits of smoking in experimental group I 19(63.33%) and in experimental group II 12(40%) respectively.

CLINICAL PROFILE:

- The majority of the sample had cancer larynx, 13(43.33%) in experimental group I and experimental group II 14(46.66%).
- Regarding severity of the tumor in both experimental group I and II majority of the samples had tumor size ranging from(Tx – T4b), 20(66.66%) and 19 (63.33%).
- Regarding dose of radiation therapy administered to the all the sample 30(100%) were similar in the dose of 200c Gy in both experimental group I and II.

The present study finding is similar to study findings of Saldanha and Almeida (2014),described that majority of the subjects 18 (90%) in group I and 16 (80%) in group II had cancer of head and neck, whereas 2 (10%) in group I and 4 (20%) in group II had cancer of other origin. The study findings are in accordance with the findings of a study conducted in USA to characterize the risks and clinical consequences of oral mucositis (OM) in patients with Head and Neck Carcinoma (HNC) which showed that primary tumor locations included the oropharynx (26.4%), larynx (26.4%), oral cavity including the lip (24.4%), hypo pharynx (13.6%), and nasopharynx (9.1%).

1.The first objects is to explore the severity of oral mucositis before and after providing povidone –iodine(2%) and normal saline(0.9%) rinses among patients receiving external radiation therapy for head and neck malignancies.

As per the Table – 3 shows that before using of povidone- iodine mouth rinsing there was 10(33.33%) clients had mild ulceration and 20(66.66%) clients had moderate ulceration. After povidone iodine mouth rinsing, on 7^{th} day 22(73.33%) clients had mild ulceration and 8(26.66%) clients had moderate ulceration, on 14^{th} day

10(33.33%) clients had no ulcer, 18(60%) clients had mild ulceration and 2(6.66%) clients had moderate ulceration. For erythema non of them had no erythema, 30(100%) sample had not severe erythema during prê test. After using of povidone-iodine mouth rinsing, on 7th day 4(13.33%) clients had no erythema, 26(76.66%) clients had not severe erythema, on 14th day 8(26.66%) clients had no erythema, 22(73.33%) had not severe erythema. This difference may be due to effect of povidone- iodine mouth rinsing.

As per the Table – 4 shows that before using of normal saline mouth rinsing there was 15(50%) samples had mild ulceration and 15(50%) samples had moderate ulceration . After using of normal saline mouth rinsing, on 7th day 21(70%) samples had mild ulceration and 9(30%) samples had moderate ulceration, on 14th day 5(16.66%) clients had no ulceration and 19(63.33%) samples had mild ulceration and 6(20%) samples had moderate ulceration. This is due to the effect of normal saline mouth rinsing. For erythema during pretest 30(100%) samples had not severe erythema, on 7th day 3(10%) samples had no erythema and 27(90%) samples had not severe erythema, on 14th day 6(20%) samples had no erythema and 24 (80%) samples had not severe erythema.

The present study findings is similar to findings of Elting , Cooksley and Chambers(2007), they have explained that Patients treated with radiation therapy for head and neck cancer typically receive an approximately 200 cGy daily dose of radiation, five days per week, for 5–7 continuous weeks. Almost all such patients developed some degree of oral mucositis, severe oral mucositis occurred in 29(66%)of all patients receiving radiation therapy for head and neck cancer. The incidence of oral mucositis was especially high in 1) patients with primary tumors in the oral cavity, oropharynx or nasopharynx, 2) those who also received concomitant

chemotherapy, 3) those who received a total dose over 5000 cGy, and 4) those who were treated with altered fractionation radiation schedules (e.g. more than one radiation treatment per day).

2.To find out the effectiveness of povidone –iodine(2%) mouth rinsing on oral mucosititis among the patients with head and neck malignancies in experimental group I.

As per the table -6 shows that the mean post test level of povidone iodine mouth rinsing (4.03) was lower than the pre test ulceration mean (11.06). The obtained 't' value of 18.5 (P=2.042) was significant at 0.05 level. As per the table -7 shows that the mean post test level of povidone iodine mouth rinsing of the experimental group I(1.33) was lower than the pre test erythema mean (6.6). The obtained 't' value of 25.05 (2.042) was significant at 0.05 level. This indicates that the difference between the mean was (7.03) was a true difference. The difference between the mean could be due to the effect of povidone iodine.

The present study finding is similar to study findings of Fleischer (2007) A prospective randomized controlled trial was conducted to assess the efficiency of povidone iodine mouthwash on radio and chemotherapy treatment with 40 patients undergoing radiation or chemotherapy in head and neck region. Twenty patients rinsed povdone iodine mouthwash four times daily while other group for comparison rinsed with sterile water. Clinical examination of oral mucositis was done weekly. In povidone iodine group the mean oral mucositis grade was 1 and in the comparison group mean oral mucositis grade was 3. The study also showed that duration of healing of oral mucositis in povidone iodine group was 2.75 weeks and in the control group it was 9.25 weeks. This showed that the incidence, severity and duration of

radiotherapy and chemotherapy induced oral mucositis can be significantly reduced by oral rinsing with povidone iodine mouthwash.

3.To find out the effectiveness of normal saline (0.9%) mouth rinsing on oral mucosititis among patient with head and neck malignancies in experimental group II

As per the table -8 shows that the mean post test oral mucositis level of normal saline mouth rinsing sample of the experimental group II(4.8) was lower than the pre test mean (10.23). The obtained 't' value of 23.58 at df 29 was significant at 0.05 level. As per the table -9 shows that the mean post test level mucositis score of normal saline mouth rinsing sample of the experimental group II(1.3) was lower than the mean pre test mucositis score (6.7). The obtained 't' value of 33.31 at df 29 was significant at 0.05 level. This indicates that the difference between the mean was (5.43) was a true difference. The difference between the mean could be due to the effect of normal saline.

The present study finding is similar to study findings of Yoneda, Imai and Hanada, et al.,(2008) stated that The MASCC/ISOO guidelines recommend use of a standardized oral care protocol including brushing with a soft toothbrush, flossing and the use of non-medicated rinses (e.g. saline or sodium bicarbonate rinses). Patients and caregivers should be educated regarding the importance of effective oral hygiene. Alcohol-containing chlorhexidine mouth rinse may be difficult for patients to tolerate during clinical oral ulceration, thus formulations without alcohol are used at some centers. Multiple studies have examined the role of chlorhexidine mouth rinse in oral mucositis but have not demonstrated significant efficacy in reducing severity of mucositis. Therefore, the MASCC/ISOO guidelines recommend against the use of chlorhexidine mouth rinse for prevention or treatment of oral mucositis.

Wuketich and Hienz (2002) described that 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. A mouth rinse aides in removing debris and keeping the oral tissue moist and clean. Good oral care, defined as frequently rinsing the mouth with saline, may help prevent mouth sores Salt mouthwash can soothe the pain and keep food particles clear so as to avoid infection. Normal saline (0.9%) 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.

4.To compare the post test level of oral mucositis score between experimental group I and II.

Data on table -11 shows the post test mean mucositis score of experimental group I (4.03) after povidone iodine mouth rinse is significantly lower than the experimental group II(4.8)who received normal saline mouth rinse. The obtained 't' value of (P = 2.05) was significant at 0.05 level. This difference between the mean (0.77) is a true difference, and has not occurred by chance. It can be inferred that povidone iodine mouth rinse has significant role in reducing mucositis level. So the researcher reject null hypothesis and accept the research hypothesis. The mean post test erythema score of experimental group I (1.33) is significantly higher than the experimental group II(1.3).

The table 12 shows that the mean oral ulceration of score experimental group I and II, on 7^{th} day was found statistically significant with the 'F' value of 13.44 ($P<0.001$), whereas on 14^{th} day the mean oral ulceration score was found statistically significant with the 'F' value of 41.39($P<0.001$).

Regarding the mean oral erythema score of experimental group I and II, on 7th day was found statistically significant with the 'F' value of 59.57(P<0.001), likewise on 14th day the mean oral erythema score was found statistically significant with the 'F' value of 167.35(P<0.001). This denotes the healing pattern is different in both group in consequent days. The healing was faster in experimental group I when compared to experimental group II, and 7th day itself. This change was statistically seen.

The present study finding is similar to study findings of Potting (2006), He conducted a study of effectiveness of commonly used mouthwashes for the prevention and treatment of chemotherapy-induced oral mucositis. A systemic review was conducted 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 povidone-iodine mouthwash as compared with sterile water in a single randomized controlled trial. These results do not support the use of chlorhexidine mouthwash to prevent and treat oral mucositis.

5.To determine the association between pre test level of oral mucosititis score of experimental group I with selected demographical variables (i.e. Age, sex, occupation, marital status, education status, smoking ,tobacco chewing, betel nuts and pan or kutka chewing).

As per table – 13 findings, there is no significant association between the pre test mucositis score of experimental group I and selected demographic variables such as Age, Sex, Education, Occupation, Marital status, History of smoking, History of

betel nut chewing, History of pan/ kutka chewing. So the researcher accepts the null hypothesis, and rejects the research hypothesis.

6.To determine the association between pre test level of oral mucosititis score of experimental group II with selected demographical variables(i.e. Age, sex, occupation, marital status, education status, smoking, tobacco chewing, betel nuts and pan or kutka chewing).

- As per the table -14 findings, Regarding mucositis score and age the calculated value 86.8 at (df -1) was significant at 0.05 level.
- There is no significant association between the pre test mucositis score and selected demographic variables such as Sex, Education, Occupation, Marital status, History of smoking, History of betel nut chewing, History of pan/ kutka chewing

The present study finding is similar to study findings of, Mountzios (2015) stated that head and neck cancer (HNC) represents the sixth most common malignancy and accounts for approximately 6% of new cancer cases annually worldwide. As life expectancy constantly increases, the onset of head neck cancer in patients older than 65 years of age at diagnosis is not rare and up to one fourth of cases occurs in patients older than 70 years at age. Because elderly cancer patients are severely under-represented in clinical trials, there is a clear need to address the particular aspects of this specific patient group, especially in the context of novel multidisciplinary therapeutic approaches. The frailty of elderly patients with head neck cancer is attributed to the high incidence of smoking and alcohol abuse in this malignancy and the presence of substantial cardiovascular, respiratory or metabolic co morbidities.

CHAPTER -VI

SUMMARY, CONCLUSION, IMPLICATIONS AND RECOMMENDATIONS

This chapter deals with the summary, conclusion and implications of the study in the field of nursing. It also presents the recommendations for the future research.

SUMMARY OF THE STUDY:

" A study to assess the effectiveness of povidone –iodine (2%) vs normal saline(0.9%) mouth rinsing on oral mucositis among patients receiving external radiation therapy for head and neck malignancy from Devaki Cancer and Research Centre at Madurai".

The following objectives were set for the study,

- To explore the severity of oral mucositis before and after providing povidone –iodine(2%) and normal saline(0.9%) rinses among patients receiving external radiation therapy for head and neck malignancies.
- To find out the effectiveness of povidone –iodine(2%) mouth rinsing on oral mucosititis among the patients with head and neck malignancies in experimental group I
- To find out the effectiveness of normal saline (0.9%) mouth rinsing on oral mucosititis among patient with head and neck malignancies in experimental group II
- To compare the post test level of oral mucositis score between experimental group I and II

- To determine the association between pre test level of oral mucosititis score of experimental group I with selected demographical variables (i.e (Age, sex, occupation, marital status, education status, smoking ,tobacco chewing, betel nuts and pan or kutka chewing)
- To determine the association between pre test level of oral mucosititis score of experimental group II with selected demographical variables (i.e (Age, sex, occupation, marital status, education status, smoking ,tobacco chewing, betel nuts and pan or kutka chewing).

HYPOTHESES:

H1:

The mean post test oral mucositis score of patient with oral mucositis who receives povidone –iodine (2%) mouth rinse will be significantly lower than the mean pretest oral mucositis score of patient in experimental group I.

H2:

The mean post test oral mucositis score of patient with oral mucositis who received normal saline (0.9%) will be significantly lower than mean pretest oral mucositis score of patient in experimental group II.

H3:

There will be a significant difference between the mean post test level of oral mucositis score of experimental group I who received the povidone –iodine (2%) and experimental group II who received the normal saline (0.9%) mouth rinse.

H4:

There will be significant association between pretest oral mucositis score, among patient who received povidone –iodine (2%) mouth rinse with selected

variables(Age, sex, occupation, marital status, education status, smoking ,tobacco chewing, pan ,betel nuts chewing).

H5:

There will be a significant association between the post test oral mucositis score among patient who received normal saline (0.9%) rinse with selected variables(Age, sex, occupation, marital status, education status, smoking ,tobacco chewing, pan ,betel nuts chewing).

An experimental approach was used for the study. The design adopted was quasi experimental pre test – post test design with two experimental groups. The study was conducted in Devaki Cancer and Research Centre, Madurai which is 7.6km away from the Sacred Heart Nursing College, Madurai. Simple random sampling was used to select the samples. A total 60 samples were selected and among that 30 samples were treated with povidone – iodine and remaining 30 samples were treated with normal saline. Oral mucositis assessment scale was used for data collection. Data collection procedure was done for six weeks. After data collection, data was organized, tabulated, summarized and analyzed.

MAJOR FINDINGS OF THE STUDY:

I. Demographic characteristics of the samples:

- Regarding the age, most of the sample 14(46.66%) were between the age of 39-48 years in experimental group I and 15(50%) belongs to 39-48 years in experimental group II.
- Regarding sex in both experimental group I and II majority of the samples were male 23(76.66%) and 17 (56.66%) respectively.

- Regarding education status both experimental group I and II most of them are literate 16 (53.33%) and 18 (60%) respectively.
- Regarding occupation majority of the samples are sedentary workers in both experimental group I 19 (63.33%) and in experimental group II 22(73.33%).
- Regarding marital status most of them are married in experimental group I 28(93.33%) and in the experimental group II 27(90%) respectively.
- With regards to smoking history most of them had the habits of smoking in experimental group I 19(63.33%) and in experimental group II 12(40%) respectively.

II. Clinical profile:

- The majority of the sample had cancer larynx, 13(43.33%) in experimental group I and experimental group II 14(46.66%).
- Regarding severity of the tumor in both experimental group I and II majority of the samples had tumor size ranging from (Tx – T4b), 20(66.66%) and 19 (63.33%)
- Regarding the dose of radiation administered per day for all the samples(100%)in both experimental group I and II were similar in receiving dose of 200 cGy per day.
- The above data shows that experimental group I and group II were similar in the form of demographic variables such as age, sex, education status, occupation, marital status, history of smoking, location of the tumor, severity of tumor, dose of radiation therapy.

III. Distribution of participants according to level of mucositis healing in experimental group – I showed that 10(33.33%) clients had mild ulceration and

20(66.66%) clients had moderate ulceration. After povidone- iodine mouth rinsing, on 7th day 22(73.33%) clients had mild ulceration and 8(26.66%) clients had moderate ulceration, on 14th day 10(33.33%) clients had no ulcer, 18(60%) clients had mild ulceration and 2(6.66%) clients had moderate ulceration. For erythema 8(26.66%) clients had mild erythema, 22(73.33%) had moderate erythema. After using of povidone iodine mouth rinsing, on 7th day 4(13.33%) clients had no erythema, 26(76.66%) clients had mild erythema. This difference may be due to effect of povidone- iodine mouth rinsing.

IV. Distribution of participants according to level of mucositis healing in experimental group- II showed that 15(30%) samples had mild ulceration and 15(30%) samples had moderate ulceration . After using of normal saline mouth rinsing, on 7th day 21(70%) samples had mild ulceration and 9(30%) samples had moderate ulceration, on 14th day 5(16.66%) clients had no ulceration and 19(63.33%) samples had mild ulceration and 6(20%) samples had moderate ulceration. This is due to the effect of normal saline mouth rinsing. For erythema during pretest 30(100%) samples had mild erythema, on 7th day 3(10%) samples had no erythema and 27(90%) samples had mid erythema, on 14th day 6(20%) samples had no erythema and 24 (80%) samples had mid erythema.

V. The mean post test level of povidone iodine mouth rinsing (4.03) was lower than the pre test mean (11.06).

VI. The mean post test level of povidone iodine mouth rinsing of the experimental group I(1.33) was lower than the pre test mean (6.6).

VII. The mean post test level of normal saline mouth rinsing of the experimental group II(4.8) was lower than the pre test mean (10.23).

VIII. The mean post test level of normal saline mouth rinsing of the experimental group II(1.3) was lower than the pre test mean (6.7).

IX. The post test mean ulceration score of experimental group I (4.03) after povidone iodine mouth rinse is significantly lower than the experimental group II(4.8).

X. The mean post test erythema score of experimental group I(1.33) is significantly higher than the experimental group II(1.3).

XI. There was a significant association between the pre test mucositis score of experimental group II and age the calculated value (86.8) at (df- 3) was significant at 0.05 level.

CONCLUSION:

The following conclusions were drawn from the study,

- The level of oral mucositis status of subjects after use of povidone – iodine was lower than the level of oral mucositis status before use of povidone – iodine mouth rinse.
- The level of oral mucositis status of subjects after use of normal saline was lower than the level of oral mucositis status before use of normal saline mouth rinse.
- The povidone – iodine mouth rinse was found effective in improving the oral mucositis status of patient with oral mucositis when compared with normal saline mouth rinse.
- There was no significant association between the pre test oral mucositis score of experimental group I and selected demographical variables such as a age, sex,

education status, occupation, marital status, history of smoking, betel chewing, pan or kutka.

- There was a significant association between the pre test mucositis score of experimental group II and age the calculated value X2 - 86.8 at (df -3) was significant at o.o5 level.

IMPLICATION:

The findings of the study have practical application. The study could be discussed in four areas namely nursing practice, nursing administration, nursing education and research.

a) Implication for nursing practice:

- Early identification and prevention of oral mucositis among patient with head and neck cancer is essential.
- As povidone- iodone and normal saline is less expensive and have no adverse effects, nurse can use readily.
- Nurse must assess the oral cavity of the patients receiving radiation therapy by using oral mucositis assessment scale to measure the mucositis status and treat accordingly.
- The study findings will help the nursing personal to includes these nursing interventions in the management of oral mucositis.
- There should be a routine practice of using povidone –iodine and normal saline mouth rinse among patient who develops oral mucositis.

b) Implication for nursing education :

- This study has clearly proved that povidone – iodine mouth rinse was more effective in treating the oral mucositis.
- These findings would help the nursing faculty to give importance to use povidone – iodine mouth rinse in the management of oral mucositis and motivate the nursing student to use of this in the management of oral mucositis among whom undergoing cancer treatment.
- Different type of oral mucositis scale can be used in the nursing curriculum.

c) Implication for nursing research:

- There is a need for extensive and intensive research in this area. One of thise aims of nursing research is to expand and broaden the scope of nursing. Findings of this study will provide base line data about the oral mucositis healing and it can be used for further studies in these area.

d) Implication for nursing administration:

- Nursing administration can encourage the nursing personnel to conduct research on oral mucositis among patient with cancer and give care based on findings.
- Periodic conference, seminars and symposium can be arranged for nursing personnel regarding care of oral mucositis among patient with cancer therapy.
- Education should be given to clinical nurses and educators to updates knowledge regarding management of oral mucositis among patient with cancer.

- Nursing administrator's should prepare procedure manuals and protocols regarding administration of mouth rinsing and use them in the wards and ensure the availability.

LIMITATIONS:

- Because of the small sample size and setting selection, The findings must be interpreted with caution.
- Intervention given only for 14 days.

RECOMMENDATIONS OF THE STUDY:

- The study can be conducted by using large population to generalize the findings.
- A longitudinal study can be conducted to assess the effectiveness of selected nursing interventions on reducing radiation induced oral mucositis.
- Effectiveness of various other mouth rinse on oral mucositis can be done as comparative study in different settings.
- The effectiveness of mouth rinse can be tested for other type of oral mucositis.
- Qualitative study can be conducted to identify the in-depth oral ulcer problems experienced by the patients who are receiving radiation therapy.
- Incidence of oral mucositis level can be assessed among cancer patient.
- The same study can be repeated using true experimental design.
- The study can assess the pain level of oral mucositis among patients with head and neck cancer receiving radiation therapy.
- An explorative study can be done to find out the side effects of radiation therapy among patients with head and neck cancer.

CHAPTER -VI

SUMMARY, CONCLUSION, IMPLICATIONS AND RECOMMENDATIONS

This chapter deals with the summary, conclusion and implications of the study in the field of nursing. It also presents the recommendations for the future research.

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The following objectives were set for the study,

- To explore the severity of oral mucositis before and after providing povidone –iodine(2%) and normal saline(0.9%) rinses among patients receiving external radiation therapy for head and neck malignancies.
- To find out the effectiveness of povidone –iodine(2%) mouth rinsing on oral mucosititis among the patients with head and neck malignancies in experimental group I
- To find out the effectiveness of normal saline (0.9%) mouth rinsing on oral mucosititis among patient with head and neck malignancies in experimental group II
- To compare the post test level of oral mucositis score between experimental group I and II

- To determine the association between pre test level of oral mucosititis score of experimental group I with selected demographical variables (i.e (Age, sex, occupation, marital status, education status, smoking ,tobacco chewing, betel nuts and pan or kutka chewing)
- To determine the association between pre test level of oral mucosititis score of experimental group II with selected demographical variables (i.e (Age, sex, occupation, marital status, education status, smoking ,tobacco chewing, betel nuts and pan or kutka chewing).

HYPOTHESES:

H1:

The mean post test oral mucositis score of patient with oral mucositis who receives povidone –iodine (2%) mouth rinse will be significantly lower than the mean pretest oral mucositis score of patient in experimental group I.

H2:

The mean post test oral mucositis score of patient with oral mucositis who received normal saline (0.9%) will be significantly lower than mean pretest oral mucositis score of patient in experimental group II.

H3:

There will be a significant difference between the mean post test level of oral mucositis score of experimental group I who received the povidone –iodine (2%) and experimental group II who received the normal saline (0.9%) mouth rinse.

H4:

There will be significant association between pretest oral mucositis score, among patient who received povidone –iodine (2%) mouth rinse with selected

variables(Age, sex, occupation, marital status, education status, smoking ,tobacco chewing, pan ,betel nuts chewing).

H5:

There will be a significant association between the post test oral mucositis score among patient who received normal saline (0.9%) rinse with selected variables(Age, sex, occupation, marital status, education status, smoking ,tobacco chewing, pan ,betel nuts chewing).

An experimental approach was used for the study. The design adopted was quasi experimental pre test – post test design with two experimental groups. The study was conducted in Devaki Cancer and Research Centre, Madurai which is 7.6km away from the Sacred Heart Nursing College, Madurai. Simple random sampling was used to select the samples. A total 60 samples were selected and among that 30 samples were treated with povidone – iodine and remaining 30 samples were treated with normal saline. Oral mucositis assessment scale was used for data collection. Data collection procedure was done for six weeks. After data collection, data was organized, tabulated, summarized and analyzed.

MAJOR FINDINGS OF THE STUDY:

I. Demographic characteristics of the samples:

- Regarding the age, most of the sample 14(46.66%) were between the age of 39-48 years in experimental group I and 15(50%) belongs to 39-48 years in experimental group II.
- Regarding sex in both experimental group I and II majority of the samples were male 23(76.66%) and 17 (56.66%) respectively.

- Regarding education status both experimental group I and II most of them are literate 16 (53.33%) and 18 (60%) respectively.
- Regarding occupation majority of the samples are sedentary workers in both experimental group I 19 (63.33%) and in experimental group II 22(73.33%).
- Regarding marital status most of them are married in experimental group I 28(93.33%) and in the experimental group II 27(90%) respectively.
- With regards to smoking history most of them had the habits of smoking in experimental group I 19(63.33%) and in experimental group II 12(40%) respectively.

II. Clinical profile:

- The majority of the sample had cancer larynx, 13(43.33%) in experimental group I and experimental group II 14(46.66%).
- Regarding severity of the tumor in both experimental group I and II majority of the samples had tumor size ranging from (Tx – T4b), 20(66.66%) and 19 (63.33%)
- Regarding the dose of radiation administered per day for all the samples(100%)in both experimental group I and II were similar in receiving dose of 200 cGy per day.
- The above data shows that experimental group I and group II were similar in the form of demographic variables such as age, sex, education status, occupation, marital status, history of smoking, location of the tumor, severity of tumor, dose of radiation therapy.

III. Distribution of participants according to level of mucositis healing in experimental group – I showed that 10(33.33%) clients had mild ulceration and

20(66.66%) clients had moderate ulceration. After povidone- iodine mouth rinsing, on 7th day 22(73.33%) clients had mild ulceration and 8(26.66%) clients had moderate ulceration, on 14th day 10(33.33%) clients had no ulcer, 18(60%) clients had mild ulceration and 2(6.66%) clients had moderate ulceration. For erythema 8(26.66%) clients had mild erythema, 22(73.33%) had moderate erythema. After using of povidone iodine mouth rinsing, on 7th day 4(13.33%) clients had no erythema, 26(76.66%) clients had mild erythema. This difference may be due to effect of povidone- iodine mouth rinsing.

IV. Distribution of participants according to level of mucositis healing in experimental group- II showed that 15(30%) samples had mild ulceration and 15(30%) samples had moderate ulceration . After using of normal saline mouth rinsing, on 7th day 21(70%) samples had mild ulceration and 9(30%) samples had moderate ulceration, on 14th day 5(16.66%) clients had no ulceration and 19(63.33%) samples had mild ulceration and 6(20%) samples had moderate ulceration. This is due to the effect of normal saline mouth rinsing. For erythema during pretest 30(100%) samples had mild erythema, on 7th day 3(10%) samples had no erythema and 27(90%) samples had mid erythema, on 14th day 6(20%) samples had no erythema and 24 (80%) samples had mid erythema.

V. The mean post test level of povidone iodine mouth rinsing (4.03) was lower than the pre test mean (11.06).

VI. The mean post test level of povidone iodine mouth rinsing of the experimental group I(1.33) was lower than the pre test mean (6.6).

VII. The mean post test level of normal saline mouth rinsing of the experimental group II(4.8) was lower than the pre test mean (10.23).

VIII. The mean post test level of normal saline mouth rinsing of the experimental group II(1.3) was lower than the pre test mean (6.7).

IX. The post test mean ulceration score of experimental group I (4.03) after povidone iodine mouth rinse is significantly lower than the experimental group II(4.8).

X. The mean post test erythema score of experimental group I(1.33) is significantly higher than the experimental group II(1.3).

XI. There was a significant association between the pre test mucositis score of experimental group II and age the calculated value (86.8) at (df- 3) was significant at 0.05 level.

CONCLUSION:

The following conclusions were drawn from the study,

- The level of oral mucositis status of subjects after use of povidone – iodine was lower than the level of oral mucositis status before use of povidone – iodine mouth rinse.
- The level of oral mucositis status of subjects after use of normal saline was lower than the level of oral mucositis status before use of normal saline mouth rinse.
- The povidone – iodine mouth rinse was found effective in improving the oral mucositis status of patient with oral mucositis when compared with normal saline mouth rinse.
- There was no significant association between the pre test oral mucositis score of experimental group I and selected demographical variables such as a age, sex,

education status, occupation, marital status, history of smoking, betel chewing, pan or kutka.

- There was a significant association between the pre test mucositis score of experimental group II and age the calculated value X2 - 86.8 at (df -3) was significant at o.o5 level.

IMPLICATION:

The findings of the study have practical application. The study could be discussed in four areas namely nursing practice, nursing administration, nursing education and research.

a) Implication for nursing practice:

- Early identification and prevention of oral mucositis among patient with head and neck cancer is essential.
- As povidone- iodone and normal saline is less expensive and have no adverse effects, nurse can use readily.
- Nurse must assess the oral cavity of the patients receiving radiation therapy by using oral mucositis assessment scale to measure the mucositis status and treat accordingly.
- The study findings will help the nursing personal to includes these nursing interventions in the management of oral mucositis.
- There should be a routine practice of using povidone –iodine and normal saline mouth rinse among patient who develops oral mucositis.

b) Implication for nursing education :

- This study has clearly proved that povidone – iodine mouth rinse was more effective in treating the oral mucositis.
- These findings would help the nursing faculty to give importance to use povidone – iodine mouth rinse in the management of oral mucositis and motivate the nursing student to use of this in the management of oral mucositis among whom undergoing cancer treatment.
- Different type of oral mucositis scale can be used in the nursing curriculum.

c) Implication for nursing research:

- There is a need for extensive and intensive research in this area. One of thise aims of nursing research is to expand and broaden the scope of nursing. Findings of this study will provide base line data about the oral mucositis healing and it can be used for further studies in these area.

d) Implication for nursing administration:

- Nursing administration can encourage the nursing personnel to conduct research on oral mucositis among patient with cancer and give care based on findings.
- Periodic conference, seminars and symposium can be arranged for nursing personnel regarding care of oral mucositis among patient with cancer therapy.
- Education should be given to clinical nurses and educators to updates knowledge regarding management of oral mucositis among patient with cancer.

- Nursing administrator's should prepare procedure manuals and protocols regarding administration of mouth rinsing and use them in the wards and ensure the availability.

LIMITATIONS:

- Because of the small sample size and setting selection, The findings must be interpreted with caution.
- Intervention given only for 14 days.

RECOMMENDATIONS OF THE STUDY:

- The study can be conducted by using large population to generalize the findings.
- A longitudinal study can be conducted to assess the effectiveness of selected nursing interventions on reducing radiation induced oral mucositis.
- Effectiveness of various other mouth rinse on oral mucositis can be done as comparative study in different settings.
- The effectiveness of mouth rinse can be tested for other type of oral mucositis.
- Qualitative study can be conducted to identify the in-depth oral ulcer problems experienced by the patients who are receiving radiation therapy.
- Incidence of oral mucositis level can be assessed among cancer patient.
- The same study can be repeated using true experimental design.
- The study can assess the pain level of oral mucositis among patients with head and neck cancer receiving radiation therapy.
- An explorative study can be done to find out the side effects of radiation therapy among patients with head and neck cancer.

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- Ncbi.nlm.nih.gov/pmc/article/PMC29022123
- https://mascc.org/mucositis
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- https://express-script.com/art/corporate/pdf
- Who.int/cancer

APPENDIX – I

COPY OF LETTER SEEKING PERMISSION TO CONDUCT THE STUDY IN DEVAKI CANCER AND RESEARCH CENTRE, MADURAI

Dr.NALINI JEYAVANTHA SANTHA
PRINCIPAL

4/235, COLLEGE ROAD,
THASILDAR NAGAR,
MADURAI – 625020
PHONE:2534593

Ref.UT:SHNC: 2016 **DATE:**

To,

The manager,
Devaki Cancer and Research Centre,
Arasaradi,
Madurai.

Respected Sir/ Madam,

Sub : Sacred Heart Nursing College, Madurai – project work of M.SC (Nursing) student –permission requested- Reg.

We wish to state that **Miss.Rajathi. R**, Final year M.SC(Nursing) students of our college has to conducted a research project, which is to be submitted to the Tamil Nadu Dr.M.G.R. Medical university, Chennai in partial fulfillment of university requirements.

The topic of research project is "A study to assess the effectiveness of povidone –iodine (2%) vs normal saline(0.9%) mouth rinsing on oral mucositis among patients receiving external radiation therapy for head and neck malignancy from Devaki Cancer and Research Centre at Madurai".

We therefore request you to kindly permit her to do the research work in your organization under your valuable guidance and suggestion.

Thanking you,

Yours faithfully ,

Principal

(Dr.NaliniJeyavanthyaSantha)

DEVAKI DIAGNOSTIC PVT LTD 28, Theni Main Road, Arasaradi, MADURAI-16

DR. NALINI JEYAVANTH SANTHA, M.Sc., Ph.D.
Principal
SACRED HEART NURSING COLLEGE
Madurai - 625 020.

APPENDIX – II

SACRED HEART NURSING COLLEGE

ULTRA TRUST

4 / 235, COLLEGE ROAD,
THASILDAR NAGAR,
MADURAI - 625 020.
TAMILNADU, INDIA.
PHONE : 0452 - 2534593
Email : ultratrust@rediffmail.com

Ref : UT : SHNC: Ph.D(N) : 2015

Date : 23.07.2015

ETHICAL COMMITTEE

The following members of the ethics committee were present at the meeting held on 23.07.2015 at 2.30 pm in Sacred Heart Nursing College.

CHAIR PERSON

1. **Dr. SABHESAN, M.B.B.S. DPM, MNAMS, Ph.D.**
   Head, Department of Psychiatry
   CSI Mission Hospital, Madurai.

DEPUTY CHAIRMAN

2. **Dr. NALINI JEYAVANTH SANTHA, M.Sc., (N) Ph.D.**
   Principal, Sacred Heart Nursing College, Madurai – 625 020.

MEMBER SECRETARY

3. **Prof. S.CHANDRAKALA, M.Sc., (N) Ph.D**
   Vice Principal, Sacred Heart Nursing College, Madurai – 625 020.

MEMBERS

4. **Prof. JULIET SYLVIA, M.Sc., (N) Ph.D.**
   Head, Department of Community Health Nursing,
   Sacred Heart Nursing College, Madurai–625 020.

5. **Dr. VIJAYA, M.Pharm., Ph.D**
   Dean, Clinical Pharmacologist
   Ultra College of Pharmacy, Madurai

6. **Mr. CHINNAKARUPPAN M.A., B.L., DCFSC**
   Advocate and Notary Public,
   14, Asari Street, Thallakulam, Madurai – 2.

...2...

SACRED HEART NURSING COLLEGE
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Ref : UT : SHNC: Ph.D(N) : 2015 Date : 23.07.2015

7. Dr. RAJASEKARAN, M.B.B.S, D.F.M. D.Diab
Pathologist
Best Dental Science College,
Ultra Trust, Madurai.

8. Paster. GLADY PAUL SAMUEL, D.DIV
Theologist
47-Alayar Nagar,
K.Pudur, Madurai-7.

RESOLUTION – 9/2015

It is resolved to accept **Ms. R. RAJATHI** to conduct " a study to compare the effectiveness of Povidone iodine Vs Normal Saline mouth rinsing on oral mucositis among patients receiving external radiation therapy for head & neck malignancy from Devaki Cancer Institute at Madurai.

The institutional Ethics Committee expects to be informed about the progress of the study, any changes in the protocol, patient information and asks to be provided a copy of the final report.

Yours Sincerely

Chair Person
Ethics Committee
23/7/15
Dr.SABHESAN, M.B.B.S. DPM, MNAMS, Ph.D.

Member Secretary
Ethics Committee
23/7/15
Prof. S.CHANDRAKALA M.Sc., (N) Ph.D
Prof. S. CHANDRAKALA. MSc. (N)
VICE PRINCIPAL. HOD OF MED. SUR. DEPT.
SACRED HEART NURSING COLLEGE
ULTRA TRUST. MADURAI-20

APPENDIX – III

LETTER REQUESTING OPINION AND SUGGESTIONS OF EXPERTS FOR ESTABLISHING CONTENT VALIDITY AND VALIDITY OF TOOL

From:

Miss. Rajathi,
M.SC (N) II year,
Sacred Heart Nursing,
Madurai- 20

To,

Respected Sir/ Madam:

Sub: Requesting opinions and suggestion of experts for the content validity and validity of tool.

I am a post graduate student (Medical Surgical Specialty) of the Sacred Heart Nursing College. I have selected the below mentioned topic of the research project submitted to the Tamilnadu DR.M.G.R. Medical university, Chennai as a fulfillment of Master of Science in nursing.

Title of the topic:

" A study to assess the effectiveness of povidone –iodine (2%) vs normal saline(0.9%) mouth rinsing on oral mucositis among patients receiving external radiation therapy for head and neck malignancy from Devaki Cancer and Research Centre at Madurai".

With regard to this may I kindly request you to do the content validity and validate my tool for its relevancy. I am enclosing the objectives of the study. I would be highly obliged and remain thankful if you could validate and send it as early as possible.

Thanking you

Place: Madurai yours faithfully

Date: (Rajathi. R)

APPENDIX – IV

LIST OF EXPERTS

1. **Dr.K.S.Kirshna Kumar, M.B,B.S.,(RT)**
   Radiation Oncologist,
   Meenakshi Mission, Madurai.

2. **Dr.Krishna Kumar Rathnam, M.D.,D.M.,DNB.,PDCR.,EUMO**
   Radiation Oncologist,
   Meenakshi mission, Madurai.

3. **Dr.Nalini Jeyavantha Santha, M.Sc(N).,Ph.D.,**
   Principal,
   Sacred Heart Nursing College, Madurai.

4. **Dr.Devakirubai, M.Sc(N)., Ph.D.,**
   Professor,
   Sacred Heart Nursing College, Madurai .

5. **Mrs. Manjula, M.Sc(N)., Ph.D.,**
   Professor,
   Sacred Heart Nursing College, Madurai.

6. **Mrs. Thangapappa, M.Sc(N).,**
   Professor,
   Sacred Heart Nursing College, Madurai.

7. **Mrs.Andal, M.Sc(N)., Ph.D.,**
   Professor,
   Sacred Heart Nursing College, Madurai .

APPENDIX – V (English)

CONSENT FORM

All the details of this study had been explained to me. I am aware that the information collected from me will be used for the purpose of the study. I am also assured that there is no complication in doing mouth rinsing by using povidone-iodine(2%) and normal saline, and that all the information collected will be highly confidential. Thereby I am willing to participate in this study on my own interest and wish.

Plalce: **Participant's Signature**

Date:

Researcher's Signature

APPENDIX –V (Tamil)

xg;g[jy; gotk;

vdf;F ,e;j Muha;r;rpapd; KG tpsf;fKk; vLj;Jiuf;fg;gl;lJ/ ehd; ,e;j Muha;r;rpapd; nehf;fj;ij mwpe;J ehd; KG jfty;fis bjhptpf;fpnwd;/ ehd; ,e;j Muha;r;rpapy; ve;j gpd; tpist[fSk; ,y;iy vd;gij mwpe;njd;/ ehd; bfhLj;j tptu';fs; midj;Jk; ghJfhf;fg;gLtij mwpe;njd;/ ,jdhy; ehd; vd;Dila KG rk;kjj;ij ,jpy; fye;J bfhs;tjw;F bjhptpf;fpnwd;/

,lk;? fye;J bfhs;gthpd; ifbahg;gk;

njjp ?

Muha;r;rpahshpd; ifbahg;gk;

APPENDIX – VI

CERTIFICATE FROM EDITOR

TO WHOMSOEVER IT MAY CONCERN

I hereby certify that the editing work related to the dissertation entitled, " A study to assess the effectiveness of povidone –iodine (2%) vs normal saline(0.9%) mouth rinsing on oral mucositis among patients receiving external radiation therapy for head and neck malignancy from Devaki Cancer and Research Centre at Madurai". By **Miss.Rajathi. R**, 2nd year M.Sc Nursing student of Sacred Heart Nursing College, Madurai, was done by me.

Date:

Place: Signature of the Editor

APPENDIX - VII

TOOL TO ASSESS THE ORAL MUCOSITIS LEVEL

PART -I

a)Demographic Variables :

1	Age	a)18-28year b)29-38year c)39-48year d)49-58year
2	Sex	a)Male b)Female
3	Education	a)Illiterate b)Literate
4	Occupation	a)Sedentary worker b)Moderate worker
5	Marital status	a)Single b)Married c)Unmarried d)Window
6	History of tobacco, betel nut, pan or kutka chewing	a)Yes/ No If yes duration b)No of cigarette/ beedi per day

b) Clinical Profile:

1	Location of the tumor	a)Lip b)Oral cavity c)Mouth d)Pharynx e)Larynx d)Pituitary gland
2	Severity of tumor	a)Tumor(Tx-T4b) b)Node involvement c)Metastasis
3	Dose of radiation therapy for per day	a)100cGy b)200cGy c)300cGy d)400cGy

APPENDIX – VIII

PART - II

ORAL MUCOSITIS ASSESSMENT SCALE

LOCATION	ULCERATION	PRE TEST	POST TEST		ERYTHEA	PRE TEST	POST TEST	
			DAY				DAY	
			7th	14th			7th	14th
LIP * Lower	0-None 1-<1cmsq 2-<1.1- 3cm sq 3-<3.1 cm sq				0-None 1-Not severe 2-Severe			
*Upper	0-None 1-<1cmsq 2-<1.1- 3cm sq 3-<3.1 cm sq				0-None 1-Not severe 2-Severe			
BUCCAL MUCOSA *Right	0-None 1-<1cmsq 2-<1.1- 3cm sq 3-<3.1 cm sq				0-None 1-Not severe 2-Severe			
*Left	0-None 1-<1cmsq 2-<1.1- 3cm sq 3-<3.1 cm sq				0-None 1-Not severe 2-Severe			
TONGUE VENTROLATERAL * Right	0-None 1-<1cmsq 2-<1.1- 3cm sq 3-<3.1 cm sq				0-None 1-Not severe 2-Severe			

LOCATION	ULCERATION	PRE TEST	POST TEST		ERYTHEA	PRE TEST	POST TEST	
			DAY				DAY	
			7th	14th			7th	14th
*Left	0-None 1-<1cmsq 2-<1.1- 3cm sq 3-<3.1 cm sq				0-None 1-Not severe 2-Severe			
*Floor of mouth	0-None 1-<1cmsq 2-<1.1- 3cm sq 3-<3.1 cm sq				0-None 1-Not severe 2-Severe			
PALATE *Soft	0-None 1-<1cmsq 2-<1.1- 3cm sq 3-<3.1 cm sq				0-None 1-Not severe 2-Severe			
*Hard	0-None 1-<1cmsq 2-<1.1- 3cm sq 3-<3.1 cm sq				0-None 1-Not severe 2-Severe			

INTERPTETATION:

Ulceration			Erythema		
Categories	**Scoring**	**Total**	**Categories**	**Scoring**	**Total**
No ulcer	0	0	No erythema	0	0
Mild	1	1 – 9	Not severe	1	1 – 9
Moderate	2	10 – 18	Severe	2	10 – 18
Severe	3	19 – 27			