

**A STUDY TO ASSESS THE EFFECTIVENESS OF ICE CUBE  
APPLICATION ON ORAL MUCOSITIS, ASSOCIATED WITH  
INJECTION 5 – FLUROURACIL AMONG CANCER PATIENTS IN  
AMALA CANCER CENTRE AND RESEARCH INSTITUTE AT  
TRICHUR DISTRICT.**



COIMBATORE

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

**APRIL - 2014**

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SUBMITTED IN PARTIAL FULFILLMENT OF  
THE REQUIREMENT DOR THE DEGREE OF MASTER OF SCIENCE IN NURSHING  
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## ABSTRACT

Cells are the building blocks of our body, the dreaded disease cancer begins from these cells. Cancer is not just one disease but many diseases. There are more than 100 different types of cancer. As cancer is one of the leading cause of mortality and morbidity globally leads to long hospital stays, higher cost of treatments with various side effects causing huge burden to the family and reduces the quality of life. Among side effects of chemotherapy oral mucositis is an important and big burden to the patient. Hence the researcher planned to conduct a research study to asses the effectiveness of ice cube application on oral mucositis associated with injection 5 Flurouracil among cancer patients.

### OBJECTIVES OF THE STUDY

- To assess the severity of oral mucositis associated with injection 5-flurouracil among cancer patients in experimental and control group.
- To evaluate the effectiveness of ice cube application on oral mucositis associated with injection 5-Flurouracil in experimental and control group.
- To determine the association between the post level severity of oral mucositis associated with injection 5-Flurouracil among cancer patients with their selected demographic variables in experimental and control group.

The study was conducted in Amala cancer center and research institute ,Thrissur. In this study Quasi experimental; research design was adopted with non randomised purposive sampling technique. The sample size was 60. The data collection tool consists of demographic variables and oral mucositis assessment scale and visual analogue pain scale. The intervention is done with oral ice cubes 5 minutes prior to, 5 minutes during and 20 minutes after chemotherapy. The subjects experienced reduced lev

# *CHAPTER - I*

## **CHAPTER - I**

### **INTRODUCTION**

“Cancer does not define me but how I live and fight with cancer does define me”

- Hilary Cooper

Cancer is a generic term for a large group of diseases that can affect any part of the body. Other terms used for this are malignant tumors and neoplasms. Cancer is a potentially fatal disease caused mainly by environmental factors that mutate genes encoding critical cell regulatory proteins.

One defining feature of cancer is the rapid creation of abnormal cells that grow beyond the usual boundaries, that destroy surrounding normal tissue and can spread to vital organs through the lymphatic system or blood stream. This process is referred to as metastasis. There are over 200 different known cancers that affect human being.

Cancer treatment is usually a combination of a number of different modalities. If the tumor is amenable to surgery, then surgery is the single most effective tool. Targeted radiotherapy, and chemotherapy are the most widely used intervention for the treatment of cancer. Although, these treatments are employed to improve patient's quality of life, they are associated with several side effects. Annually, there are approximately 400,000 cases of treatment induced damage to oral cavity.

One of the common acute adverse effect of cancer treatment is mucositis, which is manifested in 80% of patients undergoing chemotherapy and radiotherapy. Oral complications that arise with chemotherapy include mucositis, xerostomia (drymouth), bacterial, fungal or viral infections, dental caries and loss of taste. Oral mucositis also represents a non haematologic complication of cytotoxic chemotherapy associated with



significant morbidity, pain, odynodysphagia, dyseugia, and subsequent dehydration and malnutrition.

Cancer patients undergoing chemotherapy usually become symptomatic four to five days after beginning treatment, reaching a peak at around day 10, and then slowly improving over the course at a few weeks. As a result of cell death in reaction to chemotherapy the mucosal lining of the mouth becomes thin, may slough off, then become red, inflamed and ulcerated; the ulcers may become covered by a yellowish white fibrin clot called a pseudo membrane.

The ulcers may range from 0.5 cm to greater than 4 cm. oral mucositis can be severely painful. The degree of pain is usually related to the extent of tissue damage. Pain is often described as a burning sensation accompanied by reddening. Due to pain the patient may experience trouble speaking, eating or even opening the mouth. Dyseugia (alteration in taste perception), is common, especially in those who are receiving concomitant therapy schedules. Taste blindness or an altered sense of taste is a temporary condition that occurs because of effects on taste buds that are mostly located in tongue, sometimes, only partial recovery of taste occurs. Common complaints are of food tasting too sweeter too bitter or of a continuous metallic taste.

Incidence as well as severity may vary from patient to patient. The probability of developing mucositis is dependent upon the treatment. It is estimated that about 80% of patients treated with standard chemotherapy develops mucositis.

The risk of developing mucosal injury increases with the number of chemotherapy induced mucositis. Similarly, patients, who undergo bone marrow transplantation and who receive high doses of chemotherapy have a 76% chance of getting mucositis.

Patients receiving radiation, particularly to head and neck cancers have a 40% to 80% chance.

Drugs affecting DNA synthesis (methotrexate, 5-fluorouracil, cytarabine) exhibit more pronounced somato-toxic effects. It is estimated that there is an increased risk of mucositis development with bolus and continuous infusions, compared to prolonged or repetitive administration of lower dose of cytotoxic agents. The exact pathophysiology of mucositis is not fully elucidated but it is thought to have two mechanisms direct and indirect mucositis.

Hospitalization is required in 16% of patients with mucositis. It can lead to septicemia, bacteraemia and fungemia, when the patient is neutropenic. Earlier diagnosis could lead to a change in the schedule of treatment and alleviating mucositis and its complications. Assessing the nature of mucositis, becomes essential among patients receiving chemotherapy with drugs such as fluorouracil, methotrexate and cytarabine.

The treatment of mucositis is mainly based on supportive therapies, ie: oral hygiene, consumption of adequate liquids, and application of mouth washes. Patients are recommended to avoid alcohol, citrus fruits and hot foods. Related studies have introduced various substances and agents as effective medications for inhibiting or limiting signs and symptoms of mucositis. In this regard, cryotherapy has been introduced as an effective therapy.

Cryotherapy, is a treatment modality based on the application of low temperatures on a body part. The purpose of this treatment is to reduce inflammation, cellular metabolism, pain and spasm and increase vasoconstriction and cellular survival. Several

studies have assessed the effect of oral cryotherapy on reducing of mucositis and studies support the use of cryotherapy as a cheap and effective method of minimizing oral mucositis.

In conclusion, severe mucositis is a common course of morbidity in patients undergoing chemotherapy. High symptoms burden may have a profound impact on patients quality of life and their level of psychological distress. For minimizing the symptoms of oral mucositis, applying oral ice cube is an effective method.

### **NEED FOR THE STUDY**

Among the side effect of chemotherapy, oral mucositis is an important, very common and a big burden to the patient. Some of the patients who are receiving a high dose myeloablative chemotherapy used in hematopoietic stem cell, transplant complaints of mouth pain, and difficulties in swallowing, eating, drinking and talking which are the most prevalent and debilitating symptoms, which may affect many patients throughout the course of oral mucositis, and might cause profound psychological distress and impairment of patient's quality of life and functional status. The incidence of oral mucositis varies widely based on the specific type of cancer and the modalities used for the treatment but about 400,000 people develop oral complication from cancer therapy each year.

It is estimated that about 9 million new cancer cases are diagnosed every year and over 4.5 million people die from cancer each year in the world. According to WHO, India has one of the highest cancer rates in the world. It is estimated that number of new cancer in India per year is about 7 lakhs and over 3.5 lakhs people die of cancer each year. Studies by the Regional Cancer Centre in Trivandrum has a showed a 289 fold rise

in cancer patients in the past three decades in Kerala. In the past one decade there has been 50% growth itself and every year, there are 25000 new cancer cases detected in the state.

People being treated with chemotherapeutic medications such as 5- fluorouracil and cisplatin are most likely to develop oral mucositis. The incidence rate of oral mucositis is 90%. At least 40% and up to 70% of individuals treated with standard chemotherapy regimens can have oral mucositis. People who have cancer of head and neck and receive radiotherapy are particularly at risk-approximately 80% will develop oral mucositis. In those who receive only chemotherapy, the incidence of mucositis is around 48%.It will directly affect the oral intake and leads to weight reduction in cancer patients and may ends in malnourishment in some cases.

There are ofcourse so many treatment modalities to reduce the oral mucositis such as honey application ,calcium phosphate ,vitamin E application but among these oral cryotherapy is found to be cheap ,easily available and effective in cases with oral mucositis . Sucking ice cubes or ice chips was often recommended as a way of providing relief from the symptoms of oral muscositis. However sucking ice cubes can cause the blood vessels to narrow, which may result in the less exposure of chemo therapeutic agent to the tissues that they are supposed to be treating.

An experimental study was conducted to assess the effect of oral cryotherapy on oral mucositis related to infusion of a combination of 5 fluorouracil with leucovorine in among adolescent patients in USA. A sample of 60 patients were randomized, the experimental group (30) were instructed to hold ice cubes in their mouth shortly before, during, and shortly after infusion of 5-FU with leucovorine. The control group received routine care. Oral mucositis in the patients was evaluated at 7, 14, & 21days after

chemotherapy. For analysis of data chi-square and Fisher's tests were used;  $P < 0.05$  was accepted as statistically significant. They found that in the majority of patients receiving cryotherapy, Oral mucositis was observed (Grade 0) at 7<sup>th</sup> and 14<sup>th</sup> day. Similarly, incidence of Grades 1, 2, and 3 oral mucositis in the experimental group was quite a bit lower when compared to the control group ( $P < 0.05$ ). The study concluded that oral cryotherapy has a significant contribution to the protection of oral health by reducing mucositis score according to the WHO mucositis scale, especially on the 7<sup>th</sup> and 14<sup>th</sup> days.

The North American Cancer Society conducted studies on 120 patients receiving their first course of 5-fluorouracil based chemotherapy versus non-therapy. The patients who received oral cryotherapy, had approximately 50% reduction in mucositis. It has been estimated that cooling of oral mucosa with ice chips will reduce the blood flow to the oral mucosa.

Oral mucositis significantly complicates cancer treatment by contributing to pain, dysphagia, weight loss, depression, higher risk of infection, decreased quality of life. Cryotherapy is a treatment modality based on the application of low temperatures on a body part. The purpose of this treatment is to reduce inflammation, cellular metabolism, pain and spasm and increases vasoconstriction and cellular survival. A cochrane systematic review in 2011 reported that among six prophylactic agents, ice chips were the only effective agent in prevention of oral mucositis. Cryotherapy is found to prevent mucositis through a decrease in blood flow to the oral cavity as a consequence of vasoconstriction, leading to the mucosa receiving less exposure to chemotherapy.

Oral mucositis is a distressing treatment related toxicity which exerts both a clinical and economic impact and negatively affects patients quality of life. Severe mucositis extends the length of hospital stay, and increases a patient's susceptibility to

infection and demand for opioid analgesics for pain relief. Sometime it may necessitate breaks in treatment, which in turn can adversely affect the treatment outcome. Being a nurse, we should identify significant measures to prevent such a disease condition especially within a high risk patient groups such as patients undergoing chemotherapy. The above literatures and the researcher's personal experience in the oncology unit motivated the researcher to undertake this study. As ice cubes can be made readily available and cheaper, people undergoing chemotherapy may effectively use this in their due course of therapy. Keeping the above views in mind the researcher has intense curiosity to assess, the effectiveness of ice cubes over oral mucositis among the patients receiving chemotherapy with 5-Flurouracil.

#### STATEMENT OF THE PROBLEM

A study to assess the effectiveness of ice cube application on oral mucositis, associated with injection 5 -flurouracil among cancer patients in Amala Cancer Centre And Research Institute At Trichur District.

#### OBJECTIVES OF THE STUDY

- To assess the severity of oral mucositis associated with injection 5-flurouracil among cancer patients in experimental and control group.
- To evaluate the effectiveness of ice cube application on oral mucositis associated with injection 5-Flurouracil in experimental and control group.
- To determine the association between the post level severity of oral mucositis associated with injection 5-Flurouracil among cancer patients with their selected demographic variables in experimental and control group.

## HYPOTHESES

- H1: There will be a significant difference between the mean pre and post -test, on severity of oral mucositis in experimental group.
- H2: There will be a significant difference between the mean pre and post -test, on severity of oral mucositis in control group.
- H3: There will be a significant difference between the mean post -test, score on severity of oral mucositis in experimental and control group.
- H4: There will be a significant association between the post -test, score on severity of oral mucositis among cancer patients in experimental group with their selected demographic variables.
- H5: There will be a significant association between the post -test, score on severity of oral mucositis among cancer patients in control group with their selected demographic variables.

## OPERATIONAL DEFINITIONS

### ASSESS

In this study 'assess' refers to the statistical estimation of severity of oral mucositis associated with 5-fluorouracil among cancer patients as determined by observation check list.

### EFFECTIVENESS

In this study 'effectiveness' refers to the significant difference in the severity of oral mucositis associated with 5-fluorouracil after the administration of ice cubes among cancer patients.

### ICE CUBES

Ice cubes means, small, cube shaped chips of ice which is prepared by the investigator domestically. These chips will be provided to the experimental group, where they will be instructed to apply ice chips in their mouth for 30 minutes beginning 5 minutes before the administration of chemotherapy.

## ORAL MUCOSITIS

In this study oral mucositis refers to the inflammation of the oral mucous membrane caused by injection: 5-fluorouracil as evidenced by ulceration and erythema, pain and dysphagia as determined by Oral Mucositis Assessment scale and visual analogue pain scale.

## INJECTION 5 – FLUOROURACIL

It is a chemotherapeutic agent, it is an antimetabolite, which interfere with DNA synthesis and folic acid metabolism, thus it has an antitumor activity.

## ASSUMPTIONS

- The severity of oral mucositis may vary in individuals.
- The pain threshold may be unique in each individuals.
- The dose of injection 5-Fluorouracil may vary in different individuals.
- The tolerance of chillness to ice cubes may vary among individuals.

## DELIMITATIONS

The study is limited to :

- Cancer patients who are receiving injection 5-Fluorouracil with oral mucositis.
- Cancer patients receiving chemotherapy with 5-Fluorouracil with in the time period of 6 weeks
- Those who are under the oncology unit in selected cancer hospital in Trichur District.
- Those who are not receiving any drugs for oral mucositis.

## PROJECTED OUTCOME

- The study will help the nurse to assess the severity of oral mucositis associated with injection 5-Fluorouracil among cancer patients.
- The study will help the nurse to evaluate the effectiveness of ice cube application on oral mucositis.
- The study will help the nurse to create awareness about the usage of ice cubes on oral mucositis .
- The study will motivate other nurses to use ice cubes for other patients suffering from oral mucositis .



# *CHAPTER - II*

## **CHAPTER-II**

### **REVIEW OF LITERATURE**

Review of literature is defined as a broad , comprehensive , in depth, systematic and critical review of scholarly publication, un published scholarly print materials, audio visual materials and personal communications. In this study the review of literature is divided in to four sections, section-A, B,C,D.

- Section-A: Reviews related to prevalence of mucositis pain.
  - Section B: Reviews related to relationship between chemotherapy and oral mucositis
  - Section C: Reviews related to relationship between 5-Flurouracil and oral mucositis
  - Section D: Reviews related to usage of ice cubes in reducing oral mucositis
- ❖ Section-A: Reviews related to prevalence of mucositis pain.

P.Biron et .al (2009) conducted a prospective, repeated measure descriptive pilot study with the aim to describe patterns of oral pain and mucositis in patients receiving Bone Marrow transplant or high dose chemotherapy for leukemia. 18 samples were selected by purposive sampling who receiving same prophylactic antimicrobial, antiviral and antifungal agents and the same oral care regimen. Data were collected at baseline, than daily through patient interviews, oral examination and chart review for at least 3 weeks until discharge. Two pain related instruments, Pain Assessment Form (PAF) and the Verbal Descriptor Scale (VDS) was used for patients to report pain. Mucositis was measured with the Oral Assessment Guide (OAG) and Oral Mucositis Index (OMI). Emotional Distress was assessed using 11-item Brief Profile of Mood States (BPOMS) The results showed that there was mild to moderate pain. Nearly 70% patients, described the pain as ‘tender’ ‘irritating’ and ‘sore’. Patients used pain medicines, mouth care and

mental and physical activities to relieve pain, and reported partial overall relief of pain. Mucositis was mild with the tongues, but, buccal mucosa and labial mucosa most affected. With respect to mood disturbances it was found that patterns of pain mucositis, and mood disturbance were consistent each other.

Rubenstein and colleagues (2011) conducted an exploratory, contextual research study to explore the prevalence of oral mucositis in patients receiving chemotherapy in the Eastern and Western cape, in south Africa. Convenient samples of 160 patients were recruited .Data were collected by means of self administered questionnaire. The study showed that 71.7 % (n=76) participants reported to have oral mucositis pain. Pain was not effectively managed as 69.8% (n=53) of respondents used analgesics for mucosal pain.

Stephanie and colleagues (2009) done a prospective cohort study to examine the prevalence of oral mucositis pain in patients receiving chemotherapy. A total of 160 patients in the age group of 18 to 45 years were evaluated. Oral mucositis assessment were daily until 14 days after chemotherapy using Oral Mucositis Daily Questionnaire. The study showed that 78% developed severe oral mucositis pain.12% participants developed moderate oral mucositis pain.

❖ Section B: Reviews related to relationship between chemotherapy and oral mucositis.

Rose-Ped and colleagues (2007) conducted a prospective cohort study to examine the incidence and risk factors associated with oral mucositis, in patients receiving chemotherapy. A total of 140 patients who were between 16-46 years of age were evaluated. Oral mucositis assessments were made daily until 14 days after chemotherapy using the self-report Mouth and Throat Soreness Related questions of oral mucositis

Questionnaire. The study showed that 41 patients developed oral mucositis of these 23% and 18% reported a maximum of MTS score of 2 and 3-4 as the worst oral mucositis, respectively. The meantime of onset of OM was  $4.7 \pm 2.7$  days with a mean duration of  $6.3 \pm 4$  days. Prior OM (RR 1.27 – 1.46), a higher level of anxiety (RR 1.27 – 1.46), WHO grade 1-2 (RR 1.86 – 4.59) and 3 – 4 (RR 3.08 – 9.19) neutropenia were significantly associated with a higher probability of the incidence, earlier onset, and greater severity of OM, after controlling for chemotherapy ( $P < 0.01$ ). OM was associated with indirect cytotoxicity, prior OM, and anxiety level after controlling chemotherapy were neutropenia was found to be the most important factor. The study concluded that several of interventions were found to have some benefit preventing or reducing the severity of mucositis associated with cancer treatment.

Fatemeh Owlia and colleagues in (2007) conducted a study in paediatric haematology unit of children's hospital in Rabat to analyse the incidence and to determine the severity of oral mucositis in young cancer patients treated with standard chemotherapy. Patients under 16 years of age with malignant disease treated by chemotherapy between January 2007 and December 2012 were recorded. The study showed that consecutive patients ( $n = 970$ ) with patients ( $n = 970$ ) with malignant disease were studied. Their ages ranged from 2 months to 16 years (mean  $6.8 \pm 4.1$  years). OM occurred in 540 (55.6%) patients, and 17.9% of them encountered severe grades. Meantime of onset of the lesions was  $10.5 \pm 6.8$  range, 1-22 days and mean duration was  $6.8 \pm 3.1$  (range 2 – 23 days). The study concluded that underlying disease and chemotherapy regimens are the principal risk factors of OM development.

Cheng et. al (2007) conducted a descriptive cross-sectional study in Hong Kong to investigate patient's self reported oral dysfunction in relation to oral mucositis

and to examine the extent to oral mucositis, 88 subjects presenting with WHO Grade > 2 oral mucositis during 7-14 days after the initiation of chemotherapy and the last week of head and neck irradiation were enrolled in the study. Subjects were asked to indicate their intensity and distress of oral mucositis and associated with oral dysfunction using 1-4 and 0-4 point rating scale respectively. Dry mouth and distorted taste reported in 72% subjects separately. 57% and 40% subjects reported weight loss and dysphagia respectively. The intensity of oral mucositis was significantly correlated with the intensity ( $r = .4 - .6$ ) and the distress scores ( $r = .4 - .6$ ) of oral dysfunctions.

❖ Section C: reviews related to relationship between 5-Fluorouracil and oral mucositis.

Brain et. al (2009) conducted an experimental study to identify the increased incidence of oral mucositis among patients undergoing chemotherapy with 5-Fluorouracil, Melphalan and cytarabine. The study was conducted in a sample size of 599 patients who are under chemotherapy. Out of 599 patients 43% developed mucositis due to 5-Fluorouracil. Around 22% developed oral mucositis associated with Melphalan. Around 7 % developed mucositis due to Cytarabine. The study concluded that an even higher percentage (approximately 75% to 80%) of patients developed clinically significant oral mucositis associated with 5-Fluorouracil

Niloletti and colleagues in (2012) conducted a cross-over design experimental study prevention of mucositis among cancer patients receiving 5-fluorouracil using plain versus flavored ice cubes to care their pain and improve their quality of life with fewer complications. The objectives of the study were to assess the oral mucosa before and after the treatment, to identify the experiences of patients during the therapy while sucking the ice cubes and compare the effectiveness of plain ice cubes

versus flavored ice cubes in preventing oral mucositis. In the study 79 pts were randomized to receive each of 2 interventions across 3 cycles of chemotherapy (.1) standard cone plus plain ice & (standard care with flavored ice. Cryotherapy involved swirling icechips in mouth for 5 minutes prior to 5 minutes during & 20 minutes after injection. Oral mucositis was assessed by nurses prior to commencing each of the 3 chemotherapy cycles & evaluation done on the 1<sup>st</sup> day and 3<sup>rd</sup> day of intervention. Data analysis confirmed that both forms of oral cryotherapy, were effective in reducing severity of oral mucositis as compared to the standard care alone. However side effects like nausea, taste problems & headache were reported more frequently with flavored ice.

In a similar study done involving 22 cancer patients receiving 5-flurouracil, the effectiveness of flavored ice versus plain ice was checked using the visual analogue scale. The assessment scores of plain ice cubes were different from the score of the flavored ice cubes on the 3<sup>rd</sup> day as well as the 5<sup>th</sup> day the assessment on 3<sup>rd</sup> day shows that 10 (45.5%) patients who received plain ice cubes had mucositis and remaining 12(54.5%) did not have mucositis on the 5<sup>th</sup> day 20 (90.9%) patients had no mucositis and 2 (9.1%) patients had mucositis. But after sucking the flavored ice cubes no patient had mucositis either on 3<sup>rd</sup> day or 5<sup>th</sup> day. But some patients showed side effects such as headache & nausea.

Section D: Studies relate to usage of ice cubes in reducing oral mucositis.

Edward Li , James. A. conducted a study in (2012) to assess the appropriate prevention and oral care in head and neck cancer patients to provide the oral comfort and function for improving the patient's quality of life. Cryotherapy is found effective in prevention of mucositis associated with short half life, stomato toxic 5-fluorouracil. Patients were instructed to swish ice chips in their mouth for 30 minutes, beginning 5

minutes before the administration of intravenous infusion. Ice chips produce local vasoconstriction and decrease blood flow to the oral mucosa and helps in reducing chemotherapeutic drug exposure and also the risk of mucositis. The study concluded that ice cubes (cryotherapy) is cheap and effective method to control & reduce and mucositis and it help to improve the quality of life and oral function in head and neck cancer patients.

Nicolatou and colleuges (2012) conducted an experimental study to assess effectiveness of oro-dental hygiene and ice cubes in patients undergoing chemotherapy. Samples of 200 patients were randomized to suck ice chips during chemotherapy. The result showed that sucking ice during chemotherapy reduced the incidence of severe oral mucositis, from 14-74%, to 4-21%. Other treatments are no more effective and carry a risk of known or poorly documented adverse effects. Analgesics especially morphine should be used to treat intense pain. Local anaesthetic agents have not been tested in patients with damaged oral mucosa, but they can cause a burning sensation and carry a risk of swallowing disorder due to anesthesia of the oropharyngeal junction. The study concluded that in practice, prevention of oral mucositis due to cancer chemotherapy or radiotherapy is based on oro-dental care and ice rather than drugs.

Mashad Irani et.al (2008) conducted a study to investigate the effect of oral cryotherapy on the development of chemotherapy induced mucositis in patients administered combined chemotherapy in Iran. The study involved 60 patients 30 of whom were in the study group and 30 in control group. Small ice chips, that can be moved easily in the mouth and whose corners have been smoothed in order that they will not cause irritation in the mouth was used in oral cryotheray, in the study group. Oral cryotherapy was initiated five minutes before chemotherapy and maintained during

venous infusions of etoposide, platinol, mitomycin and vinblastine depending chemotherapy course. The rate of mucositis in the study group was 36.7% and control group was 90.0% and the difference was  $< 0.05\%$ . The study conducted that oral cryotherapy makes an important contribution to the protection of oral health by reducing the mucositis.

A randomized controlled study conducted by Heydari, Shriti and Salek (2012) was aimed to assess the effect of oral cryotherapy on the incidence and severity of chemotherapy induced oral mucositis in combined chemotherapy regimens. These regimens include 5-fluorouracil with leucovorin; methotrexate and 5-fluorouracil. In the assessment of oral mucositis degree and severity the WHO mucositis grades and Patient Based Oral Mucositis scales were used. The comparison was done between two groups. Experimental group who used cryotherapy and control groups who did not receive cryotherapy for both groups (Experimental and control) the differences in percentage of patients treated with three various regimens were not statistically significant. The final result indicated that OM was decreased 50% more in the experimental group than Control group. The cryotherapy was applied for 30-60 minutes during the chemotherapy treatment.

Deborah.B.Guyre and colleagues (2009) conducted study to evaluate the effectiveness of ice chips to prevent or reduce oral mucositis in patients treated with 5-fluorouracil. The trial includes 40 patients. 21 patients received ice chips (cryotherapy) 30 minutes prior to treatment and continued to use ice chips for 3 hours. 19 patients received normal saline instead of ice chips for 3 hours. 19 patients received normal saline instead of ice chips severe oral mucositis occurred in 14% of patients treated with ice chips, compared with 74% of patients treated with saline. Individuals treated with ice chips



received few were in narcotics and nutrition through a vein than those treated with saline. The researchers concluded that cryotherapy significantly reduces the incidence of severe oral mucositis in patients receiving treatment with high doses of 5-Fluorouracil.

## CONCEPTUAL FRAME WORK

### WIDEN BACH'S HELPING ART OF CLINICAL THEORY, 1964

This theory is developed by Ernestine Widen bach in the year of 1964. According to Widen bach, this theory views nursing as an art, based on goal directed care.

This theory defines nursing as the practice of identifying a patient's need for help through the observation of presenting behavior and symptoms, exploration of the meaning of those symptoms, determination of the cause of discomfort, the determination of the patient's ability to resolve that discomfort, or determining if the patient has a need of help from the nurse or another health care professional.

This theory is adopted for developing conceptual frame work for this experimental study. Widen bach's vision of nursing practice, closely parallel to the assessment, implementation and evaluation step of nursing process. His theory consists of three components.

- Identification
- Ministration
- Validation

### IDENTIFICATION

According to Widen bach identification means understanding a patient's needs and concerns based on their present situation .In this study cancer patients in Amala cancer centre suffering from oral mucositis associated with injection 5-Fluorouracil were identified and selected based on the demographic variables including age, sex, education and ,any prior problems in the oral cavity, habits like smoking, tobacco chewing ,difficulty in swallowing ,oral intake of food, change in taste, medication taken for oral mucositis and using any dentures. Severity of oral mucositis assessed before the application of oral ice cubes in both experimental and control group using Oral Mucositis Assesment Scale and Visual Analogue Pain Scale.

## MINISTRATION

According to Widenbach, ministration means developing goals and directing the activities related to the medical plan to improve the patient's condition. In this study, after identification, the researcher planned to reduce the severity of oral mucositis by applying ice cubes orally, 5 minutes prior to, and 5 minutes during and 20 minutes after the administration of 5-Fluorouracil in the experimental group.

## VALIDATION

Based on this theory, validation means evaluation of fulfillment of the central purpose (ministration), and the factors that influence the central purpose. After the application of ice cubes, the researcher monitored and evaluated the severity of oral mucositis by using the Oral Mucositis Assessment Scale and Visual Analogue Pain Scale in both experimental and control groups. Validation is done through monitoring and through testing the significance of its results.

# *CHAPTER - III*

## CHAPTER- III

### METHODOLOGY

Research methodology is a way to find out the result of a given research problem, on a specific matter. In methodology researcher uses different criteria, for solving the research problem. The word “Methodology” is the way of searching or solving the research problem.

#### RESEARCH APPROACH

The research approach used for this study is evaluative approach. An evaluative approach is the systematic assessment of the research operation and the outcomes of a research programme or policy, compared to a set of explicit or implicit standards.

#### RESEARCH DESIGN

Experimental research is one in which the researcher makes changes in independent variables and studies their effects on dependent variables under controlled conditions. In this study Quasi experimental research design is adopted.

GROUP	PRE-TEST	INTERVENTION	POST-TEST
E	O <sub>1</sub>	X (ICE CUBES)	O <sub>2</sub>
C	O <sub>1</sub>	-	O <sub>2</sub>

Fig-1

**KEY**

E : Experimental group

C : Control group

O 1: Pre-test assessment of experimental and control group

X : Ice cube application for experimental group

O2: Post-test assessment of experimental and control group

**VARIABLE OF STUDY:**

A variable is a potentially measurable component of an object or event that may fluctuate in quantity or quality from one individual object or event to another individual or event of the same general class. Dependent variables are those that changes as the independent variable is manipulated by the researcher. Independent variables those variables, that is purposely manipulated or changed by the researcher. In this study the following are the dependent and independent variable

Dependent variable -	}	Reducing severity at oral mucositis in cancer patients.
Independent variable-	}	Application of ice cubes on oral mucositis associated with injection 5- flurouracil

**EXTRANEIOUS VARIABLES:** are those variables that may affect the outcome of the study, which cannot be manipulated by the researcher. In this study age of the participants, their sex, weight, their level of immunity, stage of malignancy, and dose of chemotherapy drug, prior existing infections in the oral cavity, duration of chemotherapy are some of the extraneous variable.

## SCHEMATIC REPRESENTATION

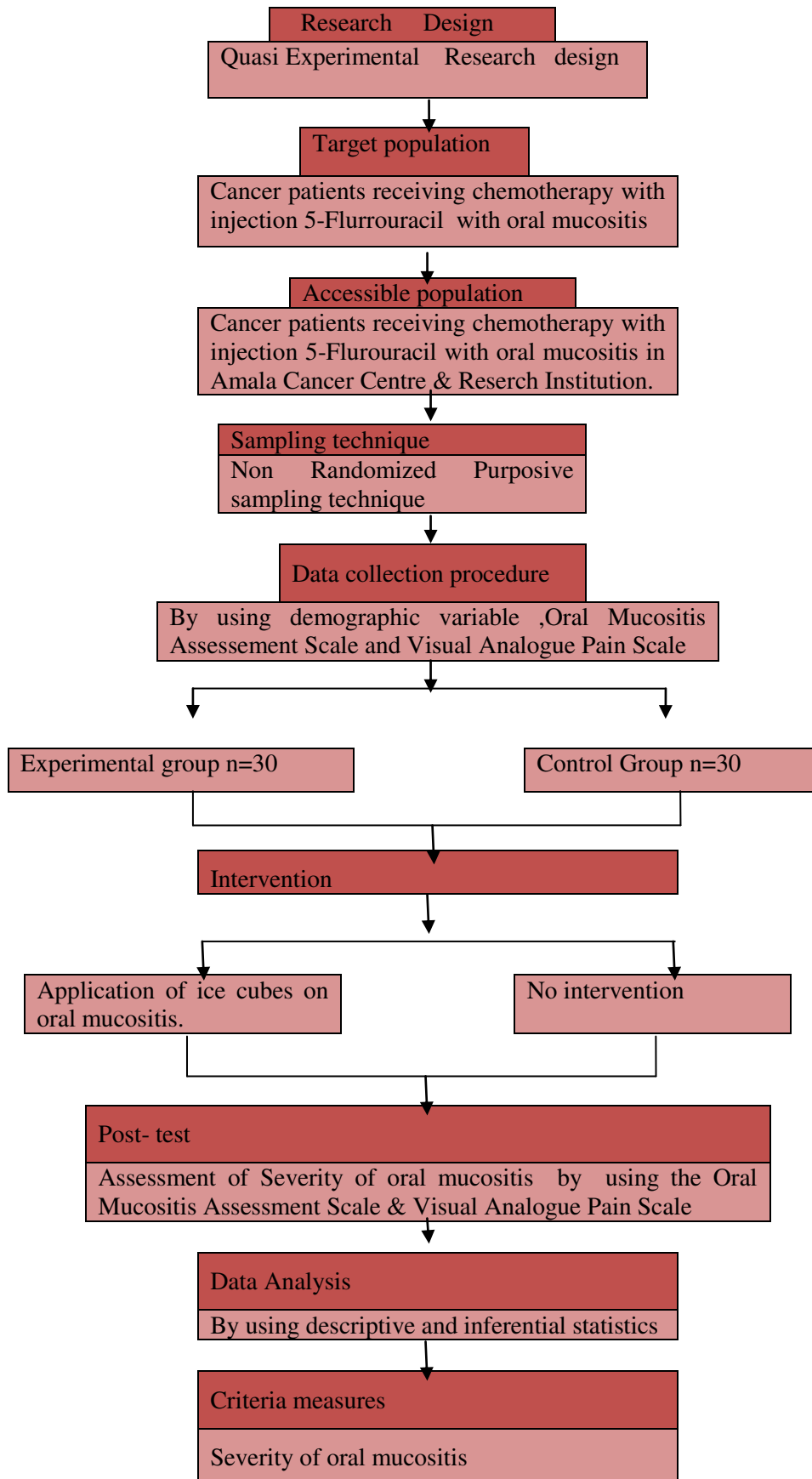


Fig-2

#### SETTING:

The research setting is the physical, social and cultural site in which the researcher conducts the study. The setting is Amala Cancer Centre and Research Institute, which is located in Amala Nagar Thrissur District Kerala which was established in 1982 with various departments and have an inpatient capacity of 550 beds. This centre is ICMR, NABH recognised and it undertakes scientific research in the area of cancer and other related areas of medical science.

#### POPULATION :

Population refers to a total category of persons or objects that meets the criteria for the study, established by the researcher. In this study cancer patients under chemotherapy is the population. Target population refers to the population that the researcher wishes to study the population about which the researcher wishes to make generalization. Cancer patients receiving chemotherapy with injection 5- fluorouracil and suffering from oral mucositis is the target population. Accessible population refers to the aggregate of cases which conform to the designated criteria, and which is accessible to the researcher as a pool of subject for the study. Cancer patients suffering with oral mucositis associated with injection 5- fluorouracil in Amala Cancer Centre And Research Institute is the accessible population. Around 8 patients undergoing chemotherapy every day in this institution .

#### SAMPLE:

A sample is a selected proportion of the defined population. It is the subset of the population of interest Cancer patients receiving chemotherapy with 5- fluorouracil treatment, who are identified with oral mucositis at Amala Cancer Centre a Research Institute considered as samples.

## SAMPLING TECHNIQUE

Sampling techniques are the strategies applied by the researcher during the statistical sampling process in order to improve the accuracy and efficiency of estimation. Purposive sampling technique is used in this study.

## SAMPLE SIZE

Sampling size of a statistical sample is the number of observations that constitute it. The sample size is 60 cancer patients receiving chemotherapy, 30 in the experimental group and 30 in the control group.

## SAMPLING CRITERIA

It is the list of characteristics of the elements that we have determined before and that are essential for eligibility to form part of the sample

### INCLUSION CRITERIA:

- Cancer patients who are receiving chemotherapy with 5-fluorouracil.
- Who are having oral mucositis.
- Who are willing to participate in this study.
- Who are not receiving radiation therapy.
- Who are not receiving any medication for oral mucositis.
- Who are present at the time of data collection.

### EXCLUSION CRITERIA:

- Who are having mucositis but not receiving 5-Fluorouracil.
- Those who are in critical condition.
- Those who are not an inpatient of Amala Cancer Centre & Research Institute Thrissur



## DESCRIPTION OF DATA COLLECTION TOOL :

The data collection tool consists of 2 parts, section -A and section- B.

### SECTION -A

Section –A consists of demographic data with questions regarding age, gender, weight, educational status, any prior problems in oral cavity, any habits like smoking and tobacco chewing, using dentures by the patients, type of cancer and duration of chemotherapy.

### SECTION-B

Section –B consists of two scales to assess the severity of oral mucositis. It includes Oral Mucositis Assessment Scale and Visual Analogue Pain Scale.

#### I. ORAL MUCOSITIS ASSESSMENT SCALE (OMAS) :

This scale was developed and tested by Sonis, Eilers, Epstein et al (1999) for the purpose of investigative applications by a panel of experts including physicians, nurses, dental hygienists, dentists, statisticians and representatives of pharmaceutical and bio technology industries. The OMAS is an objective scale suitable for research purposes , that measure, erythema and ulceration at 9 different sites in the oral cavity.

It ranges from : 0-3 Grades on oral ulceration.

0-2 Grades on erythema

#### ORAL MUCOSITIS ASSESSMENT SCALE. (OMAS)

ORAL CAVITY FOR ULCERATION		ORAL CAVITY FOR ERYTHEMA	
Grade - 0	No lesion	Grade - 0	None
Grade - I	Lesion < 1 cm <sup>2</sup>	Grade - I	Not severe
Grade - II	Lesion 1-3 cm <sup>2</sup>	Grade - II	Severe
Grade - III	Lesion > 3 cm <sup>2</sup>		

## II. VISUAL ANALOGUE PAIN SCALE :

This scale is a unidimensional measure of pain intensity which was developed and tested by Wewers and Lowe in (1990) and is widely used in diverse adult population and consists of a linear line with marks spaced 1cm apart ranging from '0' (no pain) to '10' (worst possible pain) and the samples are asked to mark a point of line indicating the intensity of pain. It is widely preferred by national and international investigators for its applicability and clarity in determining pain intensity.

It includes: 0- No pain.

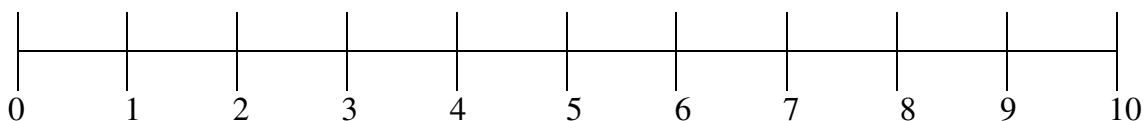
1-3 Mild pain.

4-6 Moderate pain.

7-9 Severe pain.

10 - Worst possible pain.

### **VISUAL ANALOGUE PAIN SCALE**



### **INTERVENTION**

After obtaining permission from the concerned authority, a survey is conducted by the researcher to find out the severity of oral mucositis in cancer patients receiving chemotherapy with 5-fluorouracil. Informed consent is taken from the concerned authority. The sample is obtained on the basis of inclusion criteria. Initially the investigator developed a rapport with the participants. Then the researcher conducted a

pretest by assessing the severity of oral mucositis associated with 5- fluorouracil among cancer patients along with the collection basic demographic data.

On the same day ice cubes (cube shaped chips of ice prepared by the investigator domestically) are given to the participants in the experimental group and the researcher instructed them to sip the ice cubes 5 minutes prior to and 5 minutes during and 20 minutes after chemotherapy.

Post test is conducted by the researcher to assess the severity of oral mucositis after the ice cube application using the Oral Mucositis Assessment Scale and Visual Analogue Pain Scale on 1<sup>st</sup> day and 7<sup>th</sup> day of chemotherapy.

#### CONTENT VALIDITY

It refers to the adequacy of the sampling of the domain being studied. Content validity has obtained from seven experts, two doctors and five nursing personnel in the department of medical and surgical nursing. The researcher made necessary changes in the study based on the expert opinion, in order to maintain the validity of the tool. It was done from 5.5.2014 to 24.5.2014.

#### RELIABILITY

Reliability is defined as the extent to which an instrument yields the same results on repeated measures. The test-retest reliability of this tool has been shown to be good (0.91). The researcher selected the tool based on the character of the study, variables of the study and based on the projected outcome.

#### PILOT STUDY

Pilot study is the miniature version or preliminary investigation of the planned research to identify and correct problems which could affect the research process. A pilot study was conducted by the researcher in Amala Cancer Centre And Research Institute,

Thrissur, after getting permission of the institution. A sample size of 10 patients, 5 in experimental group and 5 in control group were done after getting verbal consent from the patient during 11.6.2014 month 21.6.2014 year .The pilot study showed a “t” value of ( 3.074) at 0.05 level of significance at three degrees of freedom.

#### DATA COLLECTION PROCEDURE

The data collection period was 21.7.2014 to 30.8.2014 After obtaining permission from the concerned authority, a survey is conducted by the researcher to find out the severity of oral mucositis in cancer patients receiving chemotherapy with 5-fluorouracil. Informed consent is taken from the concerned authority. The sample is obtained on the basis of inclusion criteria. Initially the investigator developed a rapport with the patients. Then the researcher conducted a pretest by assessing the severity of oral mucositis associated with 5-fluorouracil among cancer patients along with the collection basic demographic data.

On the same day ice cubes (cube shaped chips of ice prepared by the investigator domestically) are given to the participants in the experimental group and the researcher instructed them to sip the ice cubes 5 minutes prior to and 5 minutes during and 20 minutes after chemotherapy.

Post test is conducted by the researcher to assess the severity of oral mucositis after the ice cube application using the Oral Mucositis Assessment Scale and Visual Analogue Pain Scale on 1<sup>st</sup> day and 7<sup>th</sup> day of chemotherapy. The data thus collected were compiled for data analysis.

#### SCHEDULE OF DATA COLLECTION

The duration of data collection was 6 weeks starting from 4.Aug.2014 to 24.Aug.2014. The researcher collected the data from the participants through the following pattern.

## SCHEDULE OF DATA COLLECTION

SL.NO	Pre-Test	NO: of patient in experimental group	NO:of patients in control group	Post-Test Day 1 and day 7
1	24.7.14	2	3	25.7.14, 1.8.14
2	25.7.14	2	2	26.7.14, 28.14
3	27.7.14	2	2	28.7.14, 3.8.14
4	29.7.14	3	3	30.7.14, 6.8.14
5	2.8.14	2	3	3.8.14, 10.8.14
6	3.8.14	3	2	4.8.14, 11.8.14
7	5.8.14	2	3	6.8.14, 13.8.14
8	6.8.14	2	4	7.8.14, 14.8.14
9	9.8.14	3	2	10.8.14, 17.8.14
10	11.8.14	4	2	12.8.14, 19.8.14
11	14.8.14	3	3	15.8.14, 22.8.14
12	16.8.14	2	1	17.8.14, 24.8.14

## PLAN FOR DATA ANALYSIS

The data were planned to be analysed by means of descriptive statistics and inferential statistics.

### ❖ DESCRIPTIVE STATISTICS :

- Frequency, table will be used to describe demographic variable
- Mean and standard deviation will be used to assess the severity of oral mucositis associated with 5 fluorouracil.

### ❖ INFERENCE STATISTICS

- Paired 't' test will be used to compare the pre-test and post test regarding the severity of oral mucositis among patients receiving chemotherapy
- $\chi^2$  -Test will be used to find out the association between the mean post-test scores on severity on oral mucositis among cancer patients in experimental and control group with their selected demographic variables.

## PROTECTION OF HUMAN RIGHTS

The researcher got permission from the ethical committee of Ellen college of nursing and concern authority of Amala Cancer Centre and Research Institute. Before the intervention the researcher explained the procedure to the participants and got verbal consent from them. Though the study requires intervention the researcher emphasized the protection of human rights, subjects were protected from all type of harm and their confidentiality and anonymity are maintained.

## CHAPTER IV DATA ANALYSIS AND INTERPRETATION

This chapter shows a detailed picture of data analysis and interpretation of results, with the data obtained. When the data is collected it has to be analysed in accordance with the outline shown for the purpose at the time of developing research plan. This is essential for a scientific study, to ensure, coding, classification, and tabulation of collected data for analysis.

The term data analysis refers to a number of closely related operations which are, performed with the purpose of, organizing, summarizing and computing in such a manner that the collected data, is subject to statistical tests of significance to determine or answer the relationships, differences supporting or conflicting with original hypothesis.

The data were analysed on the basis of the 'objectives' of the study by using both descriptive and inferential statistics. The objectives of the study were.

- ➔ To assess the severity of oral mucositis associated with injection 5 fluorouracil among cancer patients in experimental and control group.
- ➔ To evaluate the effectiveness of ice cube application on oral mucositis associated with injection 5 fluorouracil in experimental and control group.
- ➔ To determine the association between the post level severity of oral mucositis associated with injection 5 fluorouracil among cancer patients with their selected demographic variables in experimental and control group.

# *CHAPTER - IV*



Organization of the study findings:-

The data collected were presented under the following headings:

- |             |  |
|-------------|--|
| Section I   | Data on demographic variables of the cancer patients with oral mucositis in experimental and control group.              |
| Section II  | Data on assessment of severity of oral mucositis among cancer patients in experimental and control group.                |
| Section III | Data on effectiveness of ice cube application oral mucositis among cancer patients.                                      |
| Section IV  | Data on association between level of severity of oral mucositis among cancer patients in experimental and control group. |

SECTION I  
DATA ON DEMOGRAPHIC VARIABLES OF THE CANCER PATIENTS WITH ORAL MUCOSITIS IN EXPERIMENTAL AND CONTROL GROUP.

Table: 1.2

FREQUENCY AND PERCENTAGE DISTRIBUTION OF CANCER PATIENTS WITH ORAL MUCOSITIS IN CONTROL GROUP BASED ON DEMOGRAPHIC VARIABLES

N=60

SL.NO	DEMOGRAPHIC VARIABLES	FREQUENCY n=30	PERCENTAGE %
1.	Age: a) 16-25 b) 26-35 c) 36-45 d) 46-55 e) 56-65 f) 66-75	7 4 5 6 4 4	23% 13% 17% 20% 13% 13%
2.	Gender: a) Male b) Female	15 15	50% 50%
3.	Weight In Kg: a) 36-45 b) 46-55 c) 56-65	10 9 11	33% 30% 37%
4.	Educational Status a) Up to 10 <sup>th</sup> std b) Graduate c) Post graduate	18 7 5	60% 23% 17%
5.	Prior Oral Problems a) Yes b) No	8 22	27% 73%
6.	Habits like smoking a) Yes b) No	8 22	27% 73%
7.	Habits like tobacco chewing a) Yes b) No	4 26	13% 87%
8.	Habits of using dentures a) Yes b) No	3 27	10% 90%
9.	Type of cancer a) Leukeamia b) Breast cancer c) Lung cancer	14 8 8	46% 27% 27%
10.	Duration of chemotherapy a) 1-5 days b) 6-10 days c) 11-15 days d) 16-20 days	2 12 13 3	7% 40% 43% 10%

Regarding age, majority of cancer patients 7 (23%) belongs to the age group 16-25 yrs, 4 (13%) belongs to the age group of 26-35 yrs. 5(17%) belongs to the age group of 36-45 yrs. 6(20% belong to 46-55 yrs. 4(13%) belongs to 56-65 yrs and 66-75 yrs each.

Regarding gender 15(50%) belongs to male and 50% were females.

Regarding weight 11 (37%) were belongs to 56-65kg, 10(33%) belongs to 36-45 kg and 9(30%) belongs to 46-55 kg.

Regarding educational status majority 18(66%) were studied up to 10<sup>th</sup> standard 7 (23%) were graduates 5(17%) were post graduates.

Regarding prior problems in the oral cavity majority 22(73%) were not having any prior oral problems and 8 (27%) has prior oral problems.

Regarding smoking, majority 22(73%) were not having the habit of smoking 8 (27%) were, had the habit of smoking.

Regarding habits like tobacco chewing, majority 26(87%) were not having any habit of tobacco chewing and 4 (13%) were had the habit of tobacco chewing.

Regarding use of dentures 27(90%) were not using and 3(10%) were using dentures.

Regarding type of cancer majority 14(46%) were leukemia patients, 8(27%) were having Breast cancer and 8 (27%) were having lung cancer.

Regarding duration of chemotherapy 13 (43%) were in 11-15 days of chemotherapy, 12(40%) were in 6-10 days of chemotherapy and 3(10%) were in 16-20 days of chemotherapy and 2(7%) were in 1-5 days of chemotherapy.

Table: 1.2

FREQUENCY AND PERCENTAGE DISTRIBUTION OF CANCER PATIENTS WITH ORAL MUCOSITIS IN EXPERIMENTAL GROUP BASED ON DEMOGRAPHIC VARIABLES

N=60

SL.NO	DEMOGRAPHIC VARIABLES	FREQUENCY n=30	PERCENTAGE %
1.	Age: a) 16-25 b) 26-35 c) 36-45 d) 46-55 e) 56-65 f) 66-75	7 4 4 5 5 5	23% 13% 13% 17% 17% 17%
2.	Gender: a) Male b) Female	17 13	56% 44%
3.	Weight In Kg: a) 36-45 b) 46-55 c) 56-65	9 15 6	30% 56% 14%
4.	Educational Status a) Up to 10 <sup>th</sup> std b) Graduate c) Post graduate	12 11 7	40% 37% 23%
5.	Prior Oral Problems a) Yes b) No	9 21	30% 70%
6.	Habits like smoking a) Yes b) No	7 23	23% 77%
7.	Habits like tobacco chewing a) Yes b) No	5 25	17% 83%
8.	Habits of using dentures a) Yes b) No	3 27	10% 90%
9.	Type of cancer a) Leukeamia b) Breast cancer c) Lung cancer	21 3 6	70% 10% 20%
10.	Duration of chemotherapy a) 1-5 days b) 6-10 days c) 11-15 days d) 16-20 days	1 15 12 2	3% 50% 40% 7%

The data prested in table 4(II) describes the demographic variables as follows.

In experimental group regarding age, majority 7(23%) were belongs to the age group of 16-25 yrs. 4(13%) belongs to 26-35 yrs. Each 5(17%) belongs to the age group of 46-55 yrs, 56-65 yrs, 66-75 yrs.

Regarding gender, 17(56%) were males and 13(44%) were females.

Regarding weight, majority 15(56%) were belongs to 46-55 kg and 9 (30%) belongs to 36-45kg and 6(14%) were belongs to 56-65 kg.

Regarding educational status 12 (40%) were had the educational status of up to 10<sup>th</sup> standard 11(37%) were graduates, 7(23%) were postgraduates.

Regarding prior problems in the oral cavity majority 21(70%) were not having any prior oral problems, 9 (30%) were has prior oral problems.

Regarding, smoking habits majority 23(77%) were not having habit of smoking but 7(23%) were had the habit of smoking.

Regarding habits take tobacco chewing majority 25(83%) were not having any habit of tobacco chewing, but 5 (17%) were has the habit of tobacco chewing.

Regarding habits of using any dentures, 27(90%) were not having the habit of using any dentures and 3(10%) were has the habit of using dentures.

Regarding the type of cancer majority 21(70%) were leukemia patients, 3(10%) were having breast cancer and 6(20%) were lung cancer patients.

Regarding the duration of chemotherapy majority 15 (50%) were in 6-10 days of chemotherapy 12(40%) were in 11-15 days of chemotherapy and 2 (7%) were in 16-20 days of chemotherapy and 1 (3%) were in 1-5 days of chemotherapy.

SECTION II DATA ON ASSESSMENT OF SEVERITY OF ORAL MUCOSITIS  
AMONG CANCER PATIENTS IN EXPERIMENTAL AND  
CONTROL GROUP.

Table : 2.1

Frequency and percentage distribution of severity of oral mucositis in pretest of experimental and control group

N=60

Level of severity of oral Muscositis	Experimental group		Control group	
	n Frequency	Percentage%	n Frequency	Percentage%
Mild	5	17%	7	23%
Moderate	20	66%	19	63%
Severe	5	17%	4	14%

In pretest, majority 20 (66%) were having moderate level of oral mucositis, and 5 (17%) were having mild and 5(17%) were having severe oral mucositis in experimental group. In control group, majority 19(63%) were having moderate level of oral mucositis and 7(23%) having mild and 4 (14%) having severe oral mucositis.

FIGURE-1

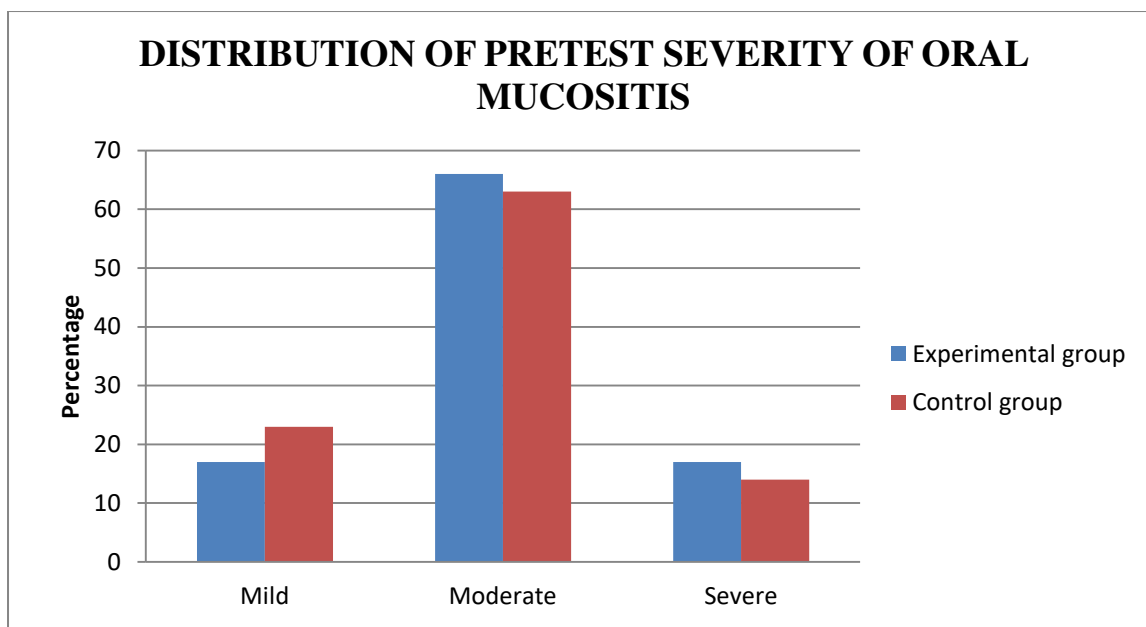


Table: 2.2

FREQUENCY AND PERCENTAGE DISTRIBUTION OF SEVERITY OF ORAL MUCOSITIS IN POST TEST OF EXPERIMENTAL AND CONTROL GROUP

N=60

Level of severity of Muscositis	Experimental group		Control group	
	N Frequency	Percentage %	n Frequency	Percentage %
Mild	20	67%	1	3%
Moderate	10	33%	25	83%
Severe	0	0%	4	14%

The data presented in table 4 (IV) shows that in experimental group majority 20 (67%) were having mild level of oral mucositis after the administration of oral ice cubes, 10(33%) were having moderate oral mucositis and no body reported severe oral mucositis. In control group, 25(83%) reported moderate level oral mucositis and 1(3%) mild and 4 (14%) reported severe oral mucositis.

FIGURE-2

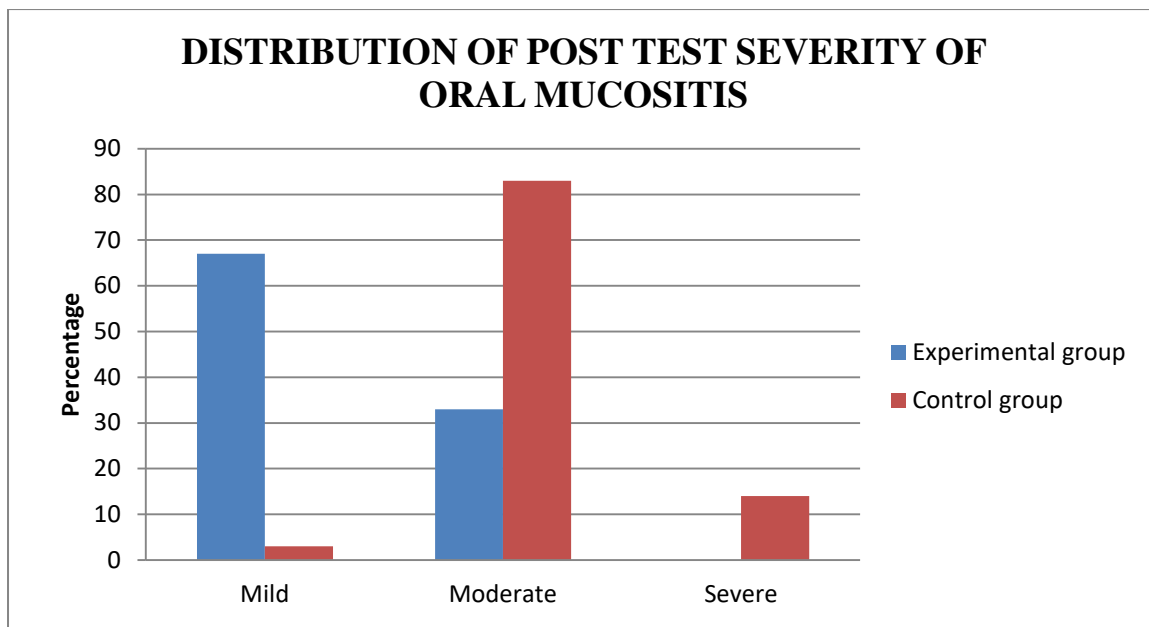


TABLE 2.3

MEAN , STANDARD DEVIATION, T-VALUE OF PRETEST AND POST TEST IN EXPERIMENTAL GROUP

GROUP	TEST	Pretest $X_1$	Post test $X_2$	T Value
Experimental group	MEAN	8	5	17
	STANDARD DEVIATION (SD)	3	2.23	

In experimental group the mean pretest mucositis score was 8 and mean post test mucositis score was 5 . The standard deviation of pretest score is 3 and post test score was 2.23 in experimental group. The T-Value is 17 which is significant at  $P < 0.05$  level. This shows that there is significant difference between the mean pre test and post test score on severity of oral mucositis in experimental group. Hence the hypothesis H1 is accepted.



TABLE 3.1

MEAN , STANDARD DEVIATION, t-VALUE OF PRETEST AND POST TEST IN CONTROL GROUP

GROUP	TEST	Pretest $X_3$	Post test $X_4$	t Value
Control group	MEAN	7	8	2
	STANDARD DEVIATION (SD)	2.7	2	

In control group the mean pretest mucositis score was 7 and mean post test mucositis score was 8 . The standard deviation of pretest score is 2.7 and post test score was 2 in control group. The t-Value is 2 which is not scgnificant at  $P < 0.05$  level This shows that there is no significant difference between the mean pre test and post test score on severity of oral mucositis in control group. Hence the hypothesis H2 is not accepeted.

SECTION III DATA ON EFFECTIVENESS OF ICE CUBE APPLICATION  
ORAL MUCOSITIS AMONG CANCER PATIENTS.

TABLE – 3.2

POST TEST, MEAN DIFFERENCE, MEAN PERCENTAGE, STANDARE DEVIATION, PAIRED ‘t’ TEST OF EXPERIMENTAL AND CONTROL GROUP

Group	Test	Mean difference	Mean %	Standard Deviation	Paired ‘t’ value
Experimental Group	Post Test X <sub>2</sub>	3.13	10.4%	1	6
Control	Post Test X <sub>4</sub>	0.9	3%	2.8	

In section III, the data are subjected to paired ‘t’ test, in order to identify the effectiveness of ice cube application on oral mucositis.

The mean difference of post test score of experimental group is 3.13 and control group is 0.9. The mean percentage in experimental group was 10.4% and control group was 3% standard deviation is 1 in experimental group and 2.8 in control group. The calculated ‘t’ value (paired) of post test of experimental and control group was 6. and it is significant at  $p < 0.05$  level, this inferred that there will be significant difference between the mean and post test score on severity of oral mucositis in experimental and control group. Hence the hypothesis H3 is accepted.

The findings are supported by Epstein et al in (2006) who conducted an experimental study on effectiveness of ice cube application on oral mucositis among cancer patients. She concluded that there is significant difference between the pretest and post severity of oral mucositis after ice cube application.

FIGURE-4.3

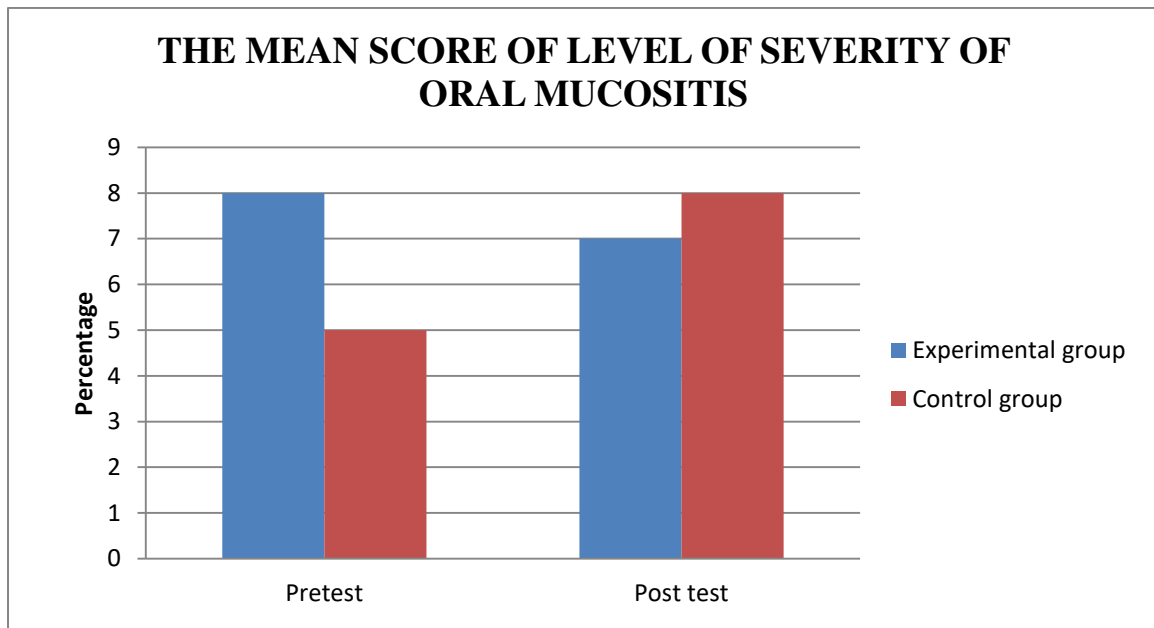


Table 4.1

FREQUENCY, DISTRIBUTION  $\chi^2$  VALUES OF DEMOGRAPHIC VARIABLES  
IN EXPERIMENTAL GROUP

Sl.No	Demographic Variables	Level of severity of oral mucositis			$\chi^2$	df,NS/S
		Mild	Moderate	severe		
1.	Age: a) 16-25 b) 26-35 c) 36-45 d) 46-55 e) 56-65 f) 66-75	5 2 3 4 4 2	3 3 1 1 1 1	0 0 0 0 0 0	6.09	df-3 NS*
5	Gender: a) Male b) Female	11 9	6 4	0 0	11.2	df-5 NS*
3.	Weight In Kg: a) 36-45 b) 46-55 c) 56-65	5 9 5	4 5 2	0 0 0	29.7	df-18 NS*
4.	Educational Status a) Up to 10 <sup>th</sup> std b) Graduate a) Post graduate	8 8 4	4 3 3	0 0 0	8.85	df-3 NS*
5.	Prior Oral Problems a) Yes b) No	7 13	1 9	0 0	5.99	df-2 S**
6.	Habits like smoking a) Yes b) No	5 15	2 8	0 0	7.04	df-3 NS*
7.	Habits like tobacco chewing a) Yes b) No	4 16	1 9	0 0	5	df-2 NS*
8.	Habits of using dentures a) Yes b) No	3 17	0 10	0 0	1.99	df-1 NS*
9.	Type of cancer a) Leukeamia b) Breast cancer c) Lung cancer	7 2 5	3 7 5	0 0 0	38.9	df-26 S**
10.	Duration of chemotherapy a) 1-5 days b) 6-10 days c) 11-15 days d) 16-20 days	1 8 4 6	0 6 3 2	0 0 0 0	31.4	df-20 S**

NS\*-Not Significant S\*\* -Significant

P&lt;0.05

LevelIn experimental group regarding age the calculated  $\chi^2$  was 6.09 and it was not significant at 0.05 level thus it is inferred that there is no significant association between age of the patients and the post test level of severity of oral mucositis.

Regarding gender the calculated  $\chi^2$  was 11.2 and it was not significant at 0.05 level thus it is inferred that there is no significant association between gender of the patients and the post test level of severity of oral mucositis .

Regarding weight the calculated  $\chi^2$  was 29.7 and it was not significant at 0.05 level thus it is inferred that there is no significant association between weight of the patients and the post test level of severity of oral mucositis.

Regarding education the calculated  $\chi^2$  was 8.85 and it was not significant at 0.05 level thus it is inferred that there is no significant association between education of the patients and the post test level of severity of oral mucositis .

Regarding prior problems in the oral cavity the calculated  $\chi^2$  was 5.99 and it was significant at 0.05 level at 2 degrees of freedom, thus it is inferred that there is significant association between prior problems in the oral cavity of the patients and the post test level of severity of oral mucositis .

Regarding smoking habit the calculated  $\chi^2$  was 7.4 and it was not significant at 0.05 level thus it is inferred that there is no significant association between smoking habits of the patients and the post test level of severity of oral mucositis.

Regarding the habit tobacco chewing the calculated  $\chi^2$  was 5 and it was not significant at 0.05 level thus it is inferred that there is no significant association between tobacco chewing habit of the patients and the post test level of severity of oral mucositis .

Regarding dentures used the calculated  $\chi^2$  was 2.99 and it was not significant at 0.05 level thus it is inferred that there is no significant association between dentures used by the patients and the post test level of severity of oral mucositis.

Regarding types of cancer the calculated  $\chi^2$  was 38.9 and it was significant at 0.05 level at 26 degrees of freedom, thus it is inferred that there is significant association between the types of cancer and the post test level of severity of oral mucositis.

Regarding duration of chemotherapy the calculated  $\chi^2$  was 31.4 and it was significant at 0.05 level at 20 degrees of freedom, thus it is inferred that there is significant association between duration of chemotherapy and the post test level of severity of oral mucositis. Hence the hypothesis H4 is accepted .

Table No -4.2

FREQUENCY, DISTRIBUTION  $\chi^2$  VALUES OF DEMOGRAPHIC VARIABLES IN CONTROL GROUP

Sl.No	Demographic Variables	Level of severity of oral mucositis			$\chi^2$	df,NS/S
		Mild	Moderate	severe		
1.	Age: a) 16-25 b) 26-35 c) 36-45 d) 46-55 e) 56-65 f) 66-75	1 0 0 1 1 2	4 4 3 3 3 2	2 2 1 0 0 1	9.30	df-9 NS*
5	Gender: a) Male b) Female	1 1	11 13	3 1	8.30	df-4 NS*
3.	Weight In Kg: a) 36-45 b) 46-55 c) 56-65	1 0 0	8 7 10	1 1 2	41.81	df-23 S**
4.	Educational Status a) Up to 10 <sup>th</sup> std b) Graduate b) Post graduate	1 0 0	12 1 10	3 2 1	13.8	df-7 NS*
5.	Prior Oral Problems a) Yes b) No	1 1	4 20	3 1	6.03	df-3 NS*
6.	Habits like smoking a) Yes b) No	0 1	7 18	1 3	9.45	df-4 NS*
7.	Habits like tobacco chewing a) Yes b) No	0 1	3 22	1 3	0.84	df-1 NS*
8.	Habits of using dentures a) Yes b) No	0 1	2 23	2 2	2.3	df-1 NS*
9.	Type of cancer a) Leukeamia b) Breast cancer c) Lung cancer	1 0 0	9 8 8	4 0 0	33.9	df-22 S**
10.	Duration of chemotherapy a) 1-5 days b) 6-10 days c) 11-15 days d) 16-20 days	0 1 0 0	2 10 10 3	0 1 3 0	28.9	df-18 S**

NS\*-Not Significant S\*\*-Significant

P&lt;0.05 Level

In control group regarding age the calculated  $\chi^2$  was 8.6 and it was not significant at 0.05 level thus it is inferred that there is no significant association between age of the patients and the post test level of severity of oral mucositis .

Regarding gender the calculated  $\chi^2$  was 9.3 and it was not significant at 0.05 level thus it is inferred that there is no significant association between gender of the patients and the post test level of severity of oral mucositis.

Regarding weight the calculated  $\chi^2$  was 41.81 and it is significant at 0.05 level at 23 degrees of freedom thus it is inferred that there is significant association between weight of the patients and the post test level of severity of oral mucositis.

Regarding education the calculated  $\chi^2$  was 13.8 and it was not significant at 0.05 level thus it is inferred that there is no significant association between education of the patients and the post test level of severity of oral mucositis .

Regarding prior problems in the oral cavity the calculated  $\chi^2$  was 6.03 and it was significant at 0.05 level at 3 degrees of freedom, thus it is inferred that there is significant association between prior problems in the oral cavity of the patients and the post test level of severity of oral mucositis.

Regarding smoking habit the calculated  $\chi^2$  was 9.45 and it was not significant at 0.05 level thus it is inferred that there is no significant association between smoking habits of the patients and the post test level of severity of oral mucositis.

Regarding the habit tobacco chewing the calculated  $\chi^2$  was 0.84 and it was not significant at 0.05 level thus it is inferred that there is no significant association between tobacco chewing habit of the patients and the post test level of severity of oral mucositis.



Regarding dentures used the calculated  $\chi^2$  was 2.3 and it was not significant at 0.05 level thus it is inferred that there is no significant association between dentures used by the patients and the post test level of severity of oral mucositis.

Regarding types of cancer the calculated  $\chi^2$  was 33.9 and it was significant at 0.05 level at 22 degrees of freedom, thus it is inferred that there is significant association between the types of cancer and the post test level of severity of oral mucositis.

Regarding duration of chemotherapy the calculated  $\chi^2$  was 28.9 and it was significant at 0.05 level at 18 degrees of freedom, thus it is inferred that there is significant association between duration of chemotherapy and the post test level of severity of oral mucositis. Hence the hypothesis H5 is accepted.

This findings are supported by Epstein et al. (2006) who conducted an experimental study to evaluate the effectiveness of ice cube application on oral mucositis among cancer patients. He concluded that there is significant association between demographic variables and the level of severity of oral mucositis among cancer patients.

# *CHAPTER - V*

## CHAPTER – V

### DISCUSSION

This chapter deals with the findings of the study as per the objectives and hypothesis.

#### Demographic Data

The findings of the study demonstrated that, among control group, subjects, majority of cancer patients with oral mucositis belongs to the age group of 16-25 years, gender male, weight was between 56-65 kg, and in a category of education up to 10<sup>th</sup> standard. Majority has no prior oral problems, no habit of smoking tobacco chewing and not using any dentures. Majority was leukemia patients, and was in 11-15 days of chemotherapy.

In experimental group majority belongs to the age group of 16-25 yrs, gender male, and weight belongs to 46-55 kg and education in a category of up to 10<sup>th</sup> standard. Majority has no prior oral problems, and no habit of smoking and tobacco chewing. Majority were leukemia patients and were in a duration of chemotherapy of 6-10 days.

The first objective of the study was to assess the severity of oral, mucositis associated with injection 5 fluorouracil among cancer patients in experimental and control group.

In pretest, majority 20 (66%) were having moderate level mucositis 5(17%) were having mild and 5 (17%) were reported severe oral mucositis, in experimental group.

In control group majority 19(63%) were having moderate level oral mucositis and 7 (23%) having mild oral mucositis and 4 (14%) having severe oral mucositis.

In control group majority 25(83%) experienced moderate level of oral mucositis 4 (14%) experienced severe mucositis 1(3%) experienced mild oral mucositis, where in

experimental group majority 20(67%) were having mild level of oral mucositis after the administration of oral ice cubes, 10 (33%) were having moderate level and nobody reported severe oral mucositis.

The second objective was to evaluate the effectiveness of ice cube application on oral mucositis associated with injection 5-fluorouracil in experimental and control group.

In experimental group the mean pretest mucositis score was 8 and mean post test mucositis score was 5 . The standard deviation of pretest score is 3 and post test score was 2.23 in experimental group. The t-Value is 17 which is significant at  $P < 0.05$  level This shows that there is significant difference between the mean pre test and post test score on severity of oral mucositis in experimental group. Hence the hypothesis H1 is accepted

In control group the mean pretest mucositis score was 7 and mean post test mucositis score was 8 . The standard deviation of pretest score is 2.7 and post test score was 2 in control group. The t-Value is 2 which is not significant at  $P < 0.05$  level This shows that there is no significant difference between the mean pre test and post test score on severity of oral mucositis in control group. Hence the hypothesis H2 is not accepted.

.The mean difference of post test score of experimental group is 3.13 and control group is 0.9. The mean percentage in experimental group was 10.4% and control group was 3% standard deviation is 1 in experimental group and 2.8 in control group. The calculated 't' value (paired) of post test of experimental and control group was 6. and it is significant at  $p < 0.05$  level, this inferred that there will be significant difference between the mean and post test score on severity of oral mucositis in experimental and control group. Hence the hypothesis H3 is accepted.

The third objective of the study was to determine the association between the post level severity of oral mucositis associated with injection 5 fluororacil among cancer patients with their selected demographic variables in experimental and control group.

H4: There will be a significant association between the post -test, score on severity of oral mucositis among cancer patients in experimental group with their selected demographic variables.

The table 4( ) shows that in experimental group regarding age the calculated  $\chi^2$  was 6.09 and it was not significant at 0.05 level thus it is inferred that there is no significant association between age of the patients and the post test level of severity of oral mucositis.

Regarding gender the calculated  $\chi^2$  was 11.2 and it was not significant at 0.05 level thus it is inferred that there is no significant association between gender of the patients and the post test level of severity of oral mucositis .

Regarding weight the calculated  $\chi^2$  was 29.7 and it was not significant at 0.05 level thus it is inferred that there is no significant association between weight of the patients and the post test level of severity of oral mucositis.

Regarding education the calculated  $\chi^2$  was 8.85 and it was not significant at 0.05 level thus it is inferred that there is no significant association between education of the patients and the post test level of severity of oral mucositis .

Regarding prior problems in the oral cavity the calculated  $\chi^2$  was 5.99 and it was significant at 0.05 level at 2 degrees of freedom, thus it is inferred that there is significant association between prior problems in the oral cavity of the patients and the post test level of severity of oral mucositis .

Regarding smoking habit the calculated  $\chi^2$  was 7.4 and it was not significant at 0.05 level thus it is inferred that there is no significant association between smoking habits of the patients and the post test level of severity of oral mucositis.

Regarding the habit tobacco chewing the calculated  $\chi^2$  was 5 and it was not significant at 0.05 level thus it is inferred that there is no significant association between tobacco chewing habit of the patients and the post test level of severity of oral mucositis .

Regarding dentures used the calculated  $\chi^2$  was 2.99 and it was not significant at 0.05 level thus it is inferred that there is no significant association between dentures used by the patients and the post test level of severity of oral mucositis.

Regarding types of cancer the calculated  $\chi^2$  was 38.9 and it was significant at 0.05 level at 26 degrees of freedom, thus it is inferred that there is significant association between the types of cancer and the post test level of severity of oral mucositis.

Regarding duration of chemotherapy the calculated  $\chi^2$  was 31.4 and it was significant at 0.05 level at 20 degrees of freedom, thus it is inferred that there is significant association between duration of chemotherapy and the post test level of severity of oral mucositis. Hence the hypothesis H4 is accepted .

In control group regarding age the calculated  $\chi^2$  was 8.6 and it was not significant at 0.05 level thus it is inferred that there is no significant association between age of the patients and the post test level of severity of oral mucositis .

Regarding gender the calculated  $\chi^2$  was 9.3 and it was not significant at 0.05 level thus it is inferred that there is no significant association between gender of the patients and the post test level of severity of oral mucositis.

Regarding weight the calculated  $\chi^2$  was 41.81 and it is significant at 0.05 level at 23 degrees of freedom thus it is inferred that there is significant association between weight of the patients and the post test level of severity of oral mucositis.

Regarding education the calculated  $\chi^2$  was 13.8 and it was not significant at 0.05 level thus it is inferred that there is no significant association between education of the patients and the post test level of severity of oral mucositis .

Regarding prior problems in the oral cavity the calculated  $\chi^2$  was 6.03 and it was significant at 0.05 level at 3 degrees of freedom, thus it is inferred that there is significant association between prior problems in the oral cavity of the patients and the post test level of severity of oral mucositis.

Regarding smoking habit the calculated  $\chi^2$  was 9.45 and it was not significant at 0.05 level thus it is inferred that there is no significant association between smoking habits of the patients and the post test level of severity of oral mucositis.

Regarding the habit tobacco chewing the calculated  $\chi^2$  was 0.84 and it was not significant at 0.05 level thus it is inferred that there is no significant association between tobacco chewing habit of the patients and the post test level of severity of oral mucositis.

Regarding dentures used the calculated  $\chi^2$  was 2.3 and it was not significant at 0.05 level thus it is inferred that there is no significant association between dentures used by the patients and the post test level of severity of oral mucositis.

Regarding types of cancer the calculated  $\chi^2$  was 33.9 and it was significant at 0.05 level at 22 degrees of freedom, thus it is inferred that there is significant association between the types of cancer and the post test level of severity of oral mucositis.

Regarding duration of chemotherapy the calculated  $\chi^2$  was 28.9 and it was significant at 0.05 level at 18 degrees of freedom, thus it is inferred that there is significant association between duration of chemotherapy and the post test level of severity of oral mucositis. Hence the hypothesis H5 is accepted.

The table 4( ) shows that there is no significant association between age ( $\chi^2$ - 66.09) at 3 degrees of freedom, gender ( $\chi^2$ - 11.2), weight ( $\chi^2$ - 21.26), education ( $\chi^2$ - 21.84), prior oral problems ( $\chi^2$ - 8.64), smoking habits ( $\chi^2$ -7.045), tobacco chewing ( $\chi^2$ -5), dentures used ( $\chi^2$ -2.99), type of cancer ( $\chi^2$ -39), duration of chemotherapy ( $\chi^2$ -31.3) in experimental group.

In control group there is no significant association between age ( $\chi^2$ - 63) ,gender ( $\chi^2$ - 9.3), weight ( $\chi^2$ - 29.7), education ( $\chi^2$ - 13.8), prior oral problems ( $\chi^2$ - 6.03), smoking habits ( $\chi^2$ -9.45), tobacco chewing ( $\chi^2$ -0.84), dentures used ( $\chi^2$ -2.3), type of cancer ( $\chi^2$ - 33), duration of chemotherapy ( $\chi^2$ -29.3)



# *CHAPTER - VI*

## CHAPTER VI

### SUMMARY, CONCLUSION AND RECOMMENDATIONS

This chapter presents a brief amount of the present study. Conclusions are drawn from the findings and the implications of the results are stated. It also includes recommendations, implications for the nursing practice, nursing education, nursing administration and nursing research.

#### SUMMARY OF THE STUDY

The present study statement is “A study to assess the effectiveness of ice cube application on oral mucositis, associated with injection 5-fluorouracil among cancer patients in Amala Cancer Centre And Research Institute at Trichur District.

The objectives of the study were:

- ➔ To assess the severity of oral mucositis associated with injection 5- fluorouracil. among cancer patients experimental and control group.
- ➔ To evaluate the effectiveness of ice cube application on oral mucositis associated with injection 5-Fluorouracil in experimental and control group.
- ➔ To determine the association between the post level severity of oral mucositis associated with injection 5-Fluorouracil among cancer patients with their selected demographic variables in experimental and control group.

A purposive sampling technique was adopted to select the subjects with inclusion criteria sample size was 30. The data collection tool consists of two parts

#### SECTION -A

Section –A consists of demographic data with questions regarding age, gender, weight, educational status, any prior problems in oral cavity, any habits like smoking and tobacco chewing, using dentures by the patients, type of cancer and duration of chemotherapy.

## SECTION-B

Section –B consists of two scales to assess the severity of oral mucositis. It includes Oral Mucositis Assessment Scale and Visual Analogue Pain Scale.

### II. ORAL MUCOSITIS ASSESSMENT SCALE (OMAS) :

This scale was developed and tested by Sonis, Eilers, Epstein et al (1999) for the purpose of investigative applications by a panel of experts including physicians, nurses, dental hygienists, dentists, statisticians and representatives of pharmaceutical and bio technology industries. The OMAS is an objective scale suitable for research purposes , that measure, erythema and ulceration at 9 different sites in the oral cavity.

It ranges from : 0-3 Grades on oral ulceration.

0-2 Grades on erythema

### II. VISUAL ANALOGUE PAIN SCALE :

This scale is a unidimensional measure of pain intensity which was developed and tested by Wewers and Lowe in (1990) and is widely used in diverse adult population and consists of a linear line with marks spaced 1cm apart ranging from '0' (no pain) to '10' (worst possible pain) and the samples are asked to mark a point of line indicating the intensity of pain. It is widely preferred by national and international investigators for its applicability and clarity in determining pain intensity.

It includes: 0- No pain.

1-3 Mild pain.

4-6 Moderate pain.

7-9 Severe pain.

10 - Worst possible pain.

## Major Study Findings

- The findings of the study demonstrated that in control group
- The findings of the study demonstrated that, among control group, subjects, majority of cancer patients with oral mucositis belongs to the age group of 16-25 years, gender male, weight was between 56-65 kg, and in a category of education up to 10<sup>th</sup> standard. Majority has no prior oral problems, no habit of smoking tobacco chewing and not using any dentures. Majority was leukemia patients, and was in 11-15 days of chemotherapy.
- In experimental group majority belongs to the age group of 16-25 yrs, gender male, and weight belongs to 46-55 kg and education in a category of up to 10<sup>th</sup> standard. Majority has no prior oral problems, and no habit of smoking and tobacco chewing. Majority were leukemia patients and were in a duration of chemotherapy of 6-10 days.
- The study findings showed that in pretest, majority 20 (66%) were having moderate level mucositis 5(17%) were having mild and 5 (17%) were reported severe oral mucositis, in experimental group.
- In control group majority 19(63%) were having moderate level oral mucositis and 7 (23%) having mild oral mucositis and 4 (14%) having severe oral mucositis.
- In control group majority 25(83%) experienced moderate level of oral mucositis 4 (14%) experienced severe mucositis 1(3%) experienced mild oral mucositis, where in experimental group majority 20(67%) were having mild level of oral mucositis after the administration of oral ice cubes, 10 (33%) were having moderate level and nobody reported severe oral mucositis.

- In experimental group the mean pretest mucositis score was 8 and mean post test mucositis score was 5 . The standard deviation of pretest score is 3 and post test score was 2.23 in experimental group. The T-Value is 17 which is significant at  $P < 0.05$  level This shows that there is significant difference between the mean pre test and post test score on severity of oral mucositis in experimental group. Hence the hypothesis H1 is accepted
- In control group the mean pretest mucositis score was 7 and mean post test mucositis score was 8 . The standard deviation of pretest score is 2.7 and post test score was 2 in control group. The T-Value is 2 which is not significant at  $P < 0.05$  level This shows that there is significant difference between the mean pre test and post test score on severity of oral mucositis in control group. Hence the hypothesis H2 is not accepted.
- .The mean difference of post test score of experimental group is 3.13 and control group is 0.9. The mean percentage in experimental group was 10.4% and control group was 3% standard deviation is 1 in experimental group and 2.8 in control group. The calculated 't' value (paired) of post test of experimental and control group was 6. and it is significant at  $p < 0.05$  level, this inferred that there will be significant difference between the mean and post test score on severity of oral mucositis in experimental and control group. Hence the hypothesis H3 is accepted.
- The study findings showed that there is significant association between age ( $\chi^2$ -66.09) at 3 degrees of freedom, gender ( $\chi^2$ - 11.2), weight ( $\chi^2$ - 21.26), education ( $\chi^2$ - 21.84), prior oral problems ( $\chi^2$ - 8.64), smoking habits ( $\chi^2$ -7.045), tobacco chewing ( $\chi^2$ -5), dentures used ( $\chi^2$ -2.99), type of cancer ( $\chi^2$ -39), duration of chemotherapy ( $\chi^2$ -31.3) in experimental group.

- In control group there is no significant association between age ( $\chi^2$ - 63) ,gender ( $\chi^2$ - 9.3),weight ( $\chi^2$ - 29.7), education ( $\chi^2$ - 13.8), prior oral problems ( $\chi^2$ - 6.03), smoking habits ( $\chi^2$ -9.45), tobacco chewing ( $\chi^2$ -0.84), dentures used ( $\chi^2$ -2.3), type of cancer ( $\chi^2$ -33), duration of chemotherapy ( $\chi^2$ -29.3)
- The table 4( ) shows that in control group regarding age the calculated  $\chi^2$  was 8.6 and it was not significant at 0.05 level thus it is inferred that there is no significant association between age of the patients and the post test level of severity of oral mucositis .
- Regarding gender the calculated  $\chi^2$  was 9.3 and it was not significant at 0.05 level thus it is inferred that there is no significant association between gender of the patients and the post test level of severity of oral mucositis.
- Regarding weight the calculated  $\chi^2$  was 41.81 and it is significant at 0.05 level at 23 degrees of freedom thus it is inferred that there is significant association between weight of the patients and the post test level of severity of oral mucositis.
- Regarding education the calculated  $\chi^2$  was 13.8 and it was not significant at 0.05 level thus it is inferred that there is no significant association between education of the patients and the post test level of severity of oral mucositis .
- Regarding prior problems in the oral cavity the calculated  $\chi^2$  was 6.03 and it was significant at 0.05 level at 3 degrees of freedom, thus it is inferred that there is significant association between prior problems in the oral cavity of the patients and the post test level of severity of oral mucositis.
- Regarding smoking habit the calculated  $\chi^2$  was 9.45 and it was not significant at 0.05 level thus it is inferred that there is no significant association between

smoking habits of the patients and the post test level of severity of oral mucositis.

- Regarding the habit tobacco chewing the calculated  $\chi^2$  was 0.84 and it was not significant at 0.05 level thus it is inferred that there is no significant association between tobacco chewing habit of the patients and the post test level of severity of oral mucositis.
- Regarding dentures used the calculated  $\chi^2$  was 2.3 and it was not significant at 0.05 level thus it is inferred that there is no significant association between dentures used by the patients and the post test level of severity of oral mucositis
- Regarding types of cancer the calculated  $\chi^2$  was 33.9 and it was significant at 0.05 level at 22 degrees of freedom, thus it is inferred that there is significant association between the types of cancer and the post test level of severity of oral mucositis.
- Regarding duration of chemotherapy the calculated  $\chi^2$  was 28.9 and it was significant at 0.05 level at 18 degrees of freedom, thus it is inferred that there is significant association between duration of chemotherapy and the post test level of severity of oral mucositis. Hence the hypothesis H5 is accepted.
- There is significant association between age ( $\chi^2$ - 6.09), gender ( $\chi^2$ - 11.2), weight ( $\chi^2$ - 29.7), education ( $\chi^2$ - 28.85), prior oral problems ( $\chi^2$ - 5.99), smoking habits ( $\chi^2$ -7.04), tobacco chewing ( $\chi^2$ -5), dentures used ( $\chi^2$ -2.99), type of cancer ( $\chi^2$ - 38.9), duration of chemotherapy ( $\chi^2$ -31.4) in experimental group .Hence the hypothesis H4 is accepted.
- In control group there is significant association between age ( $\chi^2$ - 8.76) ,gender ( $\chi^2$ - 9.3),weight ( $\chi^2$ - 41.81), education ( $\chi^2$ - 13.8), prior oral problems ( $\chi^2$ - 6.03),

smoking habits ( $\chi^2-9.45$ ), tobacco chewing ( $\chi^2-0.84$ ), dentures used ( $\chi^2-2.3$ ), type of cancer ( $\chi^2-33$ ), duration of chemotherapy ( $\chi^2-28.9$ ). Hence the hypothesis H5 is accepted.

## CONCLUSION

The main conclusion drawn from the study was the practice of oral ice cube application is helpful in reducing the severity of oral mucositis. This result can potentially employed as one of the complementary therapy in the reduction of severity of oral mucositis associated with chemotherapy with inj-5 flurouracil. After the application of ice cubes orally, the subjects found themselves comfort and expressed satisfaction.

### Implications of the study

According to Monica Flidner 2009), this section of research report that focuses on nursing implications usually includes specific suggestions for nursing practice, nursing education and nursing administration and nursing research.

### Nursing Practice

- Nursing are key persons of the health team who plays a major role in health promotion, maintenance and prevention of complications.

- ➔ The study findings will help the community health nurse to know the importance of oral ice cube application in reducing severity of oral mucositis.
- ➔ The nurse can plan for complementary and alternative therapies like this as health programmes.



### Nursing Education

- ➔ The nursing students will learn this technique of ice cube application.
- ➔ The student nurses can update this, versatile complementary therapy of ice cube application on oral mucositis reduction.
- ➔ The student nurses will get an idea of improvisation in reducing mucositis by using cheap materials like ice cubes.
- ➔ The student nurses can understand that this new method can replace the analgesics used for oral mucositis.

### Nursing Administration

- ➔ The nurse can organize an in service education programme on ice cube application on oral mucositis.
- ➔ The nurses working in the oncology set up can conduct demonstrations of this method in order to reduce oral mucositis.
- ➔ The present study purposes to help the nurse to plan complementary therapy for reducing oral mucositis.

### Nursing research

- ➔ Research can be conducted as a complementary and alternative therapy for reducing oral mucositis.
- ➔ The study finding can be added to the research review regarding the effectiveness of ice cube application on oral mucositis.
- ➔ The study findings can be kept as baseline data and further research can be conducted in same setting, and expand the study in different fields.

## Limitations

- ➔ This study is limited to the cancer patients with oral mucositis associated with injection 5-fluorouracil in Amala Cancer Centre and Research Institute, Trichur.
- ➔ This study was conducted only in a selected hospital in Trichur. Hence generalization is possible only to the selected settings.

## Recommendations

- ➔ The same study can be replicated on a large sample to generalize the findings.
- ➔ Effectiveness of ice cube application can be compared with other complementary therapies to find its effectiveness.
- ➔ The same study can be conducted with different demographic variables.
- ➔ The same study can be conducted in different settings.
- ➔ The same study can be conducted with different demographic variables.
- ➔ The comparative study can be conducted between different age groups.

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## APPENDIX - D

### Name List Of Experts Who Validated The Tool

MR.SENTHIL KUMAR.T., M.Sc.,(N)

Professor ,

Hod.Medical Surgical Nursing,

Aswini College Of Nursing,

Thrissur.

Mr.Purushothaman.R.,M.Sc.,(N)

Assistant Professor,

Aswini College Of Nursing,

Thrissur.

Mrs.Christal.A.,M.Sc.,(N)

Assistant Professor,

Westfort College Of Nursing,

Thrissur.

Mrs.Neeta.V.M.,M.Sc.,(N)

Assistant Professor,

Westfort College Of Nursing,

Thrissur.

Mrs.Elizabeth.A.J.,M.Sc.,(N)

Professor,

Medical Trust College of Nursing,

Kochi.

Dr.Anil Jose.MD.,  
Consultant Medical Oncologist,  
Amala Cancer Center And Research Institute,  
Thrissur.

Dr,Deyin Antony,MD.,  
Consultant Physician,  
Sacred Heart Mission Hospital,  
Pullur, Irinjalakuda.

## APPENDIX-E

### TOOLS

**Sample number**

### SECTION – A

#### DEMOGRAPHIC DATA

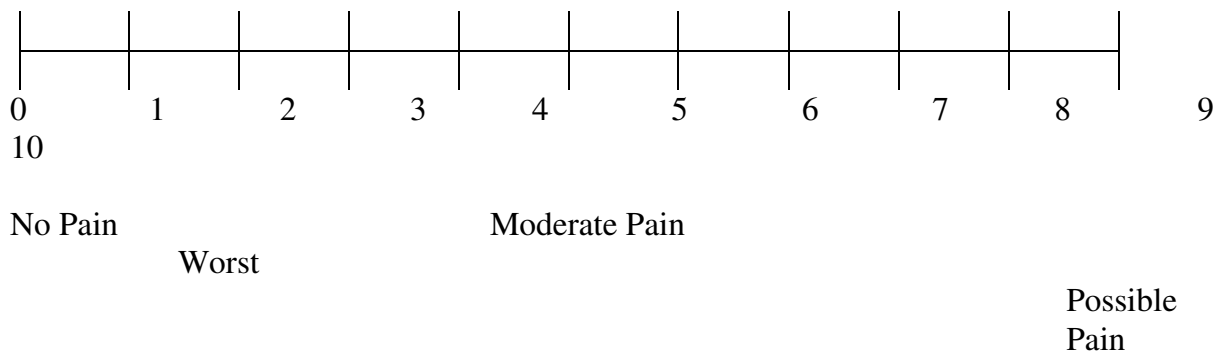
1. Age :
2. Gender :
3. Weight :
4. Educational status
5. Do you have any prior problems in oral cavity : Yes/ No
6. Do you have any habits like smoking? : Yes/No
7. Do you have any habits like tobacco chewing?: Yes/No
8. Are you using any dentures : Yes/No
9. Type of cancer
10. Duration of chemotherapy :

**SECTION - B**

**I ORAL MUCOSITIS ASSESSMENT SCALE. (OMAS)**

ORAL CAVITY FOR ULCERATION		ORAL CAVITY FOR ERYTHEMA	
Grade - 0	No lesion	Grade - 0	None
Grade - I	Lesion < 1 cm <sup>2</sup>	Grade - I	Not severe
Grade - II	Lesion 1-3 cm <sup>2</sup>	Grade - II	Severe
Grade - III	Lesion > 3 cm <sup>2</sup>		

**II VISUAL ANALOGUE PAIN SCALE**





APPENDIX-F  
CONCENT FORM

Respected Sir/Madam,

I am JIPSITHA.K.MEERAN, doing my second year Msc.,(N) in Ellen College of Nursing. I am doing a research on a A Study To Assess The Effectiveness Of Ice Cube Application On Oral Mucositis, Associated With Injection 5 -Flurouracil Among Cancer Patients In Amala Cancer Centre And Research Institute At Trichur District. I request your cooperation to complete my research. I assure you that you won't get any harm due to my research.

I am Mr./Mrs..... I heard about The Effectiveness Of Ice Cube Application On Oral Mucositis, Associated With Injection 5 - Flurouracil Among Cancer Patients from JIPSITHA.K.MEERAN. She explained me about the benefits of this intervention. I agree with this intervention of Ice Cube application and its benefits and study project whole heartedly.

Yours sincerely,

Place:

Date:

L

**CONCEPTUAL FRAMEWORK BASED ON WIDEN BACH'S CLINICAL NURSING THEORY, (1964)**

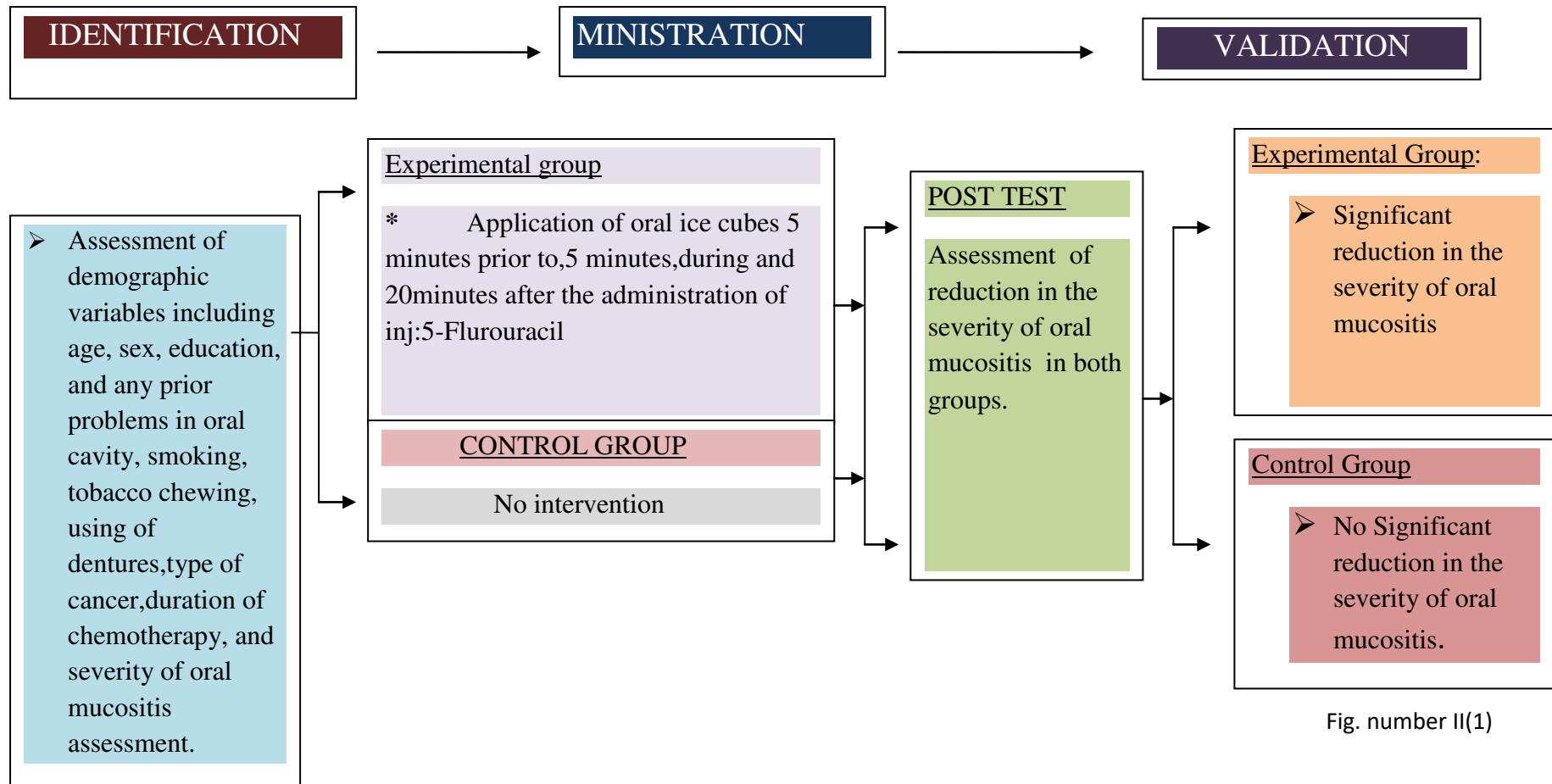


Fig. number II(1)