

**EFFECTIVENESS OF SODIUM BICARBONATE  
MOUTHWASH VERSUS CHLORHEXIDINE  
MOUTHWASH ON ORAL MUCOSITIS AMONG  
CHILDREN UNDERGOING CHEMOTHERAPY AT  
GRH MADURAI**

**M.Sc (NURSING) DEGREE EXAMINATION  
BRANCH – II CHILD HEALTH NURSING  
COLLEGE OF NURSING  
MADURAI MEDICAL COLLEGE, MADURAI – 20**



*A dissertation submitted to*  
**THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY,  
CHENNAI - 600 032.**

*In partial fulfillment of the requirement for the degree of*  
**MASTER OF SCIENCE IN NURSING**

**OCTOBER 2018**

**EFFECTIVENESS OF SODIUM BICARBONATE  
MOUTH WASH VERSUS CHLORHEXIDINE MOUTH  
WASH ON ORAL MUCOSITIS AMONG CHILDREN  
UNDERGOING CHEMOTHERAPY AT GRH MADURAI**

*Approved by Dissertation committee on*

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## **CERTIFICATE**

This is to certify that this dissertation titled **“EFFECTIVENESS OF SODIUM BICARBONATE MOUTH WASH VERSUS CHLORHEXIDINE MOUTH WASH ON ORAL MUCOSITIS AMONG CHILDREN UNDERGOING CHEMOTHERAPY AT GRH MADURAI”** is a bonafide work done by **Mrs.P.CHITRA**, M.Sc (N) Student, College of Nursing, Madurai Medical College, Madurai - 20, submitted to **THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY, CHENNAI** in partial fulfillment of the university rules and regulations towards the award of the degree of **MASTER OF SCIENCE IN NURSING, Branch II - Child Health Nursing**, under our guidance and supervision during the academic period from 2016-2018.

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## ACKNOWLEDGEMENT

*“Acknowledge him in all your ways and he shall direct your paths”*

Any dissertation work is a corporate endeavor necessitating the assistance of more than one. My attempt to bring out this assignment is therefore teamwork. I the investigator of this study owe deep sense of gratitude to all those who have contributed to the successful completion of this study.

Many helping hands have smoothened every step of this dissertation First of all I praise and thank the **LORD ALMIGHTY** for his abundant grace, Blessing, support, wisdom, and strength throughout this endeavor.

Gratitude calls never expressed in words but this only to deep perceptions, which make words to flow from one’s inner heart. The satisfaction and pleasure that accompany the successful completion of any task would be incomplete without mentioning the people who made it possible, whose constant guidance encouragement, rewards and any effort with success. I consider it is a privilege to express my gratitude and respect to all those who guided and inspired me to complete this study.

I wish to acknowledge my sincere and heartfelt gratitude to **all my well-wishers** for their continuous support, strength and guidance from the beginning to the end of this research study.

I extend my sincere thanks to **Dr.D.MaruthuPandian, M.S., F.I.C.S., F.A.I.S.**, Dean, Madurai Medical College, Madurai for his acceptance and approval for the study.

I wish to extend my heartfelt thanks to **Dr. S. Rajamani, M.Sc (N),M.B.A (HM), M.Sc (Psy), Ph.D.**, Principal Incharge, College of Nursing, Madurai Medical College, Madurai for the guidance , valuable suggestions and constant and affectionate encouragement in each and every steps of the study. It is very essential to mention that her wisdom and helping tendency has made my research a lively and everlasting one.

I wish to express my deep sense of gratitude and heartfelt thanks to **Prof.Mrs. S.Poonguzhali. M.Sc (N), M.A, M.B.A (HM), Ph.D.**, Former Principal, College of Nursing, Madurai Medical College, Madurai for her guidance and suggestions to carry out the study.

I express my heartfelt and earnest thanks to **Mrs. N.Maheswari, M.Sc (N),, M.A., M.B.A.,D.P.H.N., Ph.D.**, Faculty in Nursing, Child Health Nursing, College of Nursing, Madurai Medical College, Madurai for her hard work, effort, interest and sincerity to mould this study in successful way, which had given inspiration , encouragement and laid strong foundation on every stage of research.

My deep sense of gratitude to **Dr.S.Balasankar M.D., DCH.**, Director, Department of Paediatrics, Government Rajaji Hospital, Madurai, for this timely help and guidance.

I owe my special thanks to Librarian **Mr.B.Manikandan,B.Sc., B.L.I.Sc.**, College of Nursing, Madurai Medical College who helped me in literature search to get the references for my topic.

I extend my sincere thanks to **Dr. A. Venkatesan, M.Sc., M.Phil., PGDCA., Ph.D.**, Former Deputy Director of Medical Education ( Statistics), Chennai for his expert advice and guidance in the course of analyzing various data involved in this study.

I extend my thanks to **Mr.K.Balasubramanian, M.A., M.Ed.**, Tamil literature for editing the manuscript in Tamil and for translating the tool in local language (Tamil)

I also thank to **Mr. P. Athiganakumaran, M.A., M.Phil., M.Ed.**, English literature for editing this manuscript in English.

This acknowledgement will not be complete if I fail to offer my special heartfelt thanks, and words are not adequate to express my gratitude to my beloved my son **J. Dhanuspandian** and my daughter **Thaniska** and My Lovable sisters **Mrs. P .Tamilselvi., Mrs.P. Marimuthu, Mrs.P. Backiyalakshmi, Mrs.V.Vanitha, Mrs.V.Selvi** for their love, care, assistance support and constant encouragement throughout this study.

I dedicate this dissertation, to my worldly ever lovable and Dedicated Mother (late) **Mrs.P.Lakshmi** and Father (late) **T.Palsamy.**

I thank all the children participated in the study without them it would have been impossible to complete to this study.

I also thank **Laser Point** Staff for their timely assistance in completion of this study.

I perceive this opportunity as a big milestone in my career development. I will strive to use gained skills and knowledge in the best possible way, and I will continue to work on their improvement, in order to obtain desired career objective.

## ABSTRACT

**Title:** Effectiveness of sodium bicarbonate mouthwash versus chlorhexidine mouthwash on oral mucositis among children undergoing chemotherapy at Government Rajaji hospital, Madurai. **Objectives:** To assess the level of the oral mucositis among children. To evaluate effectiveness and compare sodium bicarbonate mouthwash and chlorhexidine mouthwash among children in group I and group II. To associate the level of oral mucositis among children undergoing chemotherapy and their selected socio demographic and clinical variables. **Hypotheses:** **H<sub>1</sub>:** There is a significant difference between the pretest and posttest level and between the post test level oral mucositis. **H<sub>2</sub>:** There is a significant association between the level of oral mucositis among children and their selected socio demographic and clinical variables. **Methodology:** True experimental design used for 60 subjects by simple random sampling. WHO oral mucositis grading scale was used to assess pre test level of oral mucositis. Intervention was given three times a day for five days. Post test on 6<sup>th</sup> day. **Results:** The result revealed that, there was a significant reduction in the level of oral mucositis confirmed by  $\chi^2=12.52$  at 0.01 level. **Conclusion:** This study statistically proved that sodium bicarbonate mouth wash was more effective than chlorhexidine mouthwash in reducing oral mucositis among children

**Key words:** oral mucositis, sodium bicarbonate mouth wash, chlorhexidine, chemotherapy

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# *Introduction*

# CHAPTER I

## INTRODUCTION

**“Accept the children the way we accept trees-with gratitude, because they are a blessing—but do not have expectations or desires. You don’t expect trees to change, you love them as they are”.**

**— ISABEL ALLENDE**

Children are vital to the nation’s present and its future. Children an important asset to the family and the society and they are the best resources for the nation. Health of the children has historically been of vital important to all societies. Children learn and grow in many ways like physically, socially, emotionally and intellectually. During the childhood period the Common childhood illness are sore throat, ear pain, urinary tract infection ,skin infection ,bronchiolitis, pain, common cold, bacterial sinusitis, cough ,gastroenteritis, conjunctivitis, hand, foot and mouth disease , now cancer also prevalence in India.

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

Cancer is a leading cause of disease worldwide. Approximately 70% of cancer deaths occur in low- and middle-income countries.30% of cancers could be prevented. In India, around 555000 people died of cancer in 2010, according to

estimates published in The *Lancet* today March 28 , 2013. It is estimated that about 9 million new cancer cases are diagnosed every year and over 4.5 million people die from cancer each year in the world. In India the estimated number of new cancers per year is about 7 lakhs and over 3.5 lakhs people die of cancer each year

All over the world, the types of cancer that are seen in children are different from those in adults. Leukemia, lymphoma, and brain tumors are the common cancers in children. Acute lymphoid leukemia (ALL) represents approximately 80% of all leukemias affecting children and young adults, and acute myeloid leukemia (AML) is responsible for approximately 15% of cases. Treatment of choice for this cancer is chemotherapy, which may be used together with other therapies. In the last four decades, there has been major progress in the treatment of leukemia and approximately 80% of children and teenagers with early diagnosis may be cured. However, several studies point to anticancer treatment as inducing oral mucositis. Oral mucositis is characterized by erythema, followed by very painful ulcers in oral mucosa, which interfere with nutritional status and quality of life (QL), and may limit or even interrupt anticancer therapy in severe cases.

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

- Good oral hygiene.
- Avoidance of spicy, acidic, hard, and hot foods and beverages.
- Use of mild-flavored toothpastes.
- Use of mouth washes 3 or 4 times per day such as Listerine, benadryl, salt, magic (lidocaine, Benadryl, and Maalox), sodium bicarbonate, chlorhexidine chamomile mouth washes.

Among these, sodium bicarbonate and chlorhexidine mouth wash are commonly used in India. Sodium bicarbonate (oral rinse) has become almost a cheapest and readily applicable method in reducing the development or decreasing the severity of oral mucositis caused due to cancer treatment, due to its ability to increase salivary pH and suppress the growth of acid uric micro-organisms. Sodium bicarbonate can improve taste and it neutralizes acids and thus prevents erosion. It is bland and will not irritate the oral mucosa in patients with mucositis. The effect of a sodium bicarbonate mouthwash solution is thought to aid in the formation of granulation tissue and to promote healing. Sodium bicarbonate mouthwash solution is safe and economical and has been used in cancer patients.

Chlorhexidine has a broad spectrum of antimicrobial activity including *Candida albicans* and other common non-*albicans* yeast species. The utility of chlorhexidine as an adjunct to conventional antimycotic therapy in the management of oral *Candida* infections.

### **1.1 Need for the study**

As per the WHO meeting at Geneva on 3 April 2003 and The World Cancer Report the most comprehensive global examination of the disease stated that Cancer rates could increase by 50% and 15million, new cases in the year 2020. However, the report also provides clear evidence that healthy lifestyles and public health action by governments and health practitioners could stem this trend, and prevent as many as one third of cancers worldwide.

Of all cancers in childhood (by WHO definition: 0-14 year age group), leukemias constitute one of the most important groups of tumors. Our understanding of the biologic features of the childhood leukemias has increased greatly over the past decade. The ability to discern cytogenetic and molecular differences among

morphologically and immunologically similar populations of leukemic cells has helped to establish the basis for a revised classification of the leukemias. This advance, in turn, has led to new approaches to clinical management. Acute lymphoblastic leukemia (ALL) is diagnosed in approximately 2000 children in the United States each year, whereas acute myeloid leukemia (AML) is diagnosed in only about 500 children and chronic myeloid leukemia (CML) in fewer than 100. Chronic lymphocytic leukemia (CLL), one of the most common leukemias in adults seldom occurs in children. Leukemias and lymphomas followed closely by tumors of central nervous system constitute the vast majority of childhood cancers in India. In different population based cancer registries, leukemias constitute 27% to 52% of childhood cancers in males and 19% to 52% in female. It was estimated that within a population of 882 million, six thousand children would develop acute lymphoblastic leukemia each year in India. With current population rates, this number is likely to increase.

4.8% to 6 of all cancer in India is seen in children below 15 years of age and the overall incidence of 38 to 124 per million children, per year, is lower than that in the developed world.

More than 80% of the 200,000 new cases of childhood cancer annually are from the developing world. In India, cancer is the 9<sup>th</sup> commonest cause for death among children aged 5-14 years. As we progress in reducing infection-related childhood deaths, it is important to care for cancer-affected children who have increasing likelihood of cure with appropriate treatment. Since the fundamental step in this regard is to estimate the current epidemiology and burden of childhood cancer, we provide an updated overview for the years 2012-2014 based on the National Cancer Registry Program (NCRP) report that covered 30 population-based cancer registries (PBCRs). The 5 new PBCRs included in this latest review are Patiala,

Pasighat, Papumpara district, Naharlagun excluding Papumpara and division of Manipur and Mizoram state registries into the state capital-based centers and peripheral centers.

In boys, the relative proportion of childhood cancer was lowest in Nagaland PBCR (North-east region) (0.7%) and highest in Delhi PBCR (North region) (5.4%). In girls, it varied from 0.5% in East Khasi Hill district PBCR (North-east region) to 3.5% in Naharlagun excluding Papumpara PBCR (North-east region). For both sexes, it varied from 0.7% in East Khasi Hill district PBCR to 4.4% in Chennai PBCR (South region). Male pediatric cancer had the highest incidence among 0-4 years age group in North, South and North-East regions and among 10-14 years age group in East, West and Central regions. Female pediatric cancers had the highest incidence among 0-4 years age group in North, West and East regions and among 10-14 years age group in South, Central and North-East regions. The highest incidence of cancer occurred in 0-4 years age group for males and both sexes combined and 10-14 years age group for females separately. Leukemia was the most predominant childhood cancer with highest incidence among 0-4 years for both sexes, 70% being lymphoid leukemia. Both Hodgkin's and Non-Hodgkin's disease had the highest incidence among 10-14 years age group for both sexes. 54% of all lymphomas were Non-Hodgkin's disease. CNS tumours had the highest incidence among 5-9 years of age group for both sexes. Genitourinary, eye and liver tumours had highest incidence among 0-4 years age group while bone and gastrointestinal tumours had highest incidence among 10-14 years age group for both sexes. Childhood cancer incidence (CCI) is generally expressed per million (pm) children. For both boys and girls, CCI as age-adjusted rates for 11 selected broad types of childhood cancers (leukemias, lymphomas, central nervous system (CNS) tumors, sympathetic nervous system

(SNS) tumors, retinoblastoma, renal tumors, hepatic tumors, bone tumors, soft tissue sarcomas, germ cell tumors and others) have be described in this article.

Oral mucositis is an inflammation and ulceration of the oral mucosa with pseudomembrane formation; it is a potential source of infection which may lead to death. This condition is a frequent and painful debilitating effect of radiotherapy and chemotherapy for cancer, affecting over 40% of patients. The initial presentation is erythema followed by white desquamating plaques, which are painful when touched. Epithelial crusting and a fibrin exudate result in a pseudomembrane and ulceration, which is the more pronounced form of mucositis. Exposure of the richly innervated underlying stromal connective tissue due to loss of epithelial cells is found in the most severe form of mucositis; this condition is usually seen 5 to 7 days following medication.

It is associated with significant morbidity characterized by pain, odynodysphagia, dysgeusia, malnutrition, dehydration and it also increases the risk for systemic infections in immune compromised patients.(International cancer of Head and Neck surgery, May- Aug 2010;(2):1-67).

Mucositis can have a negative impact on the overall treatment experience, especially when severe pain or infections occur. In general, mucositis should be treated conservatively to avoid further tissue irritation and damaging the remaining cells from which the epithelium will regenerate. Plaque control and oral hygiene should be maintained. Hence, Nurses have a critical role in all aspects of managing mucositis, including assessing it, teaching oral care, administering pharmacologic interventions, and helping patients cope with symptom distress.

The researcher would like to reduce the mucositis among chemotherapy children for that, the investigator selected Sodium bicarbonate and chlorhexidine mouth wash, which is easily available and also at low cost with good medicinal properties and also the researcher was intended to assess the extent effectiveness of chlorhexidine and Sodium bicarbonate oral wash in reducing oral mucositis among children undergoing chemotherapy.

## **1.2 STATEMENT OF THE PROBLEM**

“A comparative study to evaluate the effectiveness of sodium bicarbonate mouth wash versus chlorhexidine mouth wash on oral mucositis among children undergoing chemotherapy at Government Rajaji hospital Madurai.”

## **1.3 Objectives**

- 1 To assess the level of the oral mucositis among children undergoing chemotherapy at Government Rajaji hospital, Madurai.
- 2 To evaluate effectiveness of sodium bicarbonate mouth wash on oral mucositis among children undergoing chemotherapy in group I.
- 3 To evaluate effectiveness of chlorhexidine mouth wash on oral mucositis among children undergoing chemotherapy in group II.
- 4 To compare the level of oral mucositis among children undergoing chemotherapy in group I and group II.
- 5 To associate the level of oral mucositis among children undergoing chemotherapy in group I and group II and their selected socio demographic and clinical variables.

## **1.4 : Hypotheses**

**H<sub>1</sub>:** There is a significant difference between the pretest and posttest level of oral mucositis among children undergoing chemotherapy in group I.

**H<sub>2</sub>:** There is a significant difference between the pretest and posttest level of oral mucositis among children undergoing chemotherapy in group II.

**H<sub>3</sub>:** There is a significant difference between the posttest level of oral mucositis among children undergoing chemotherapy in group I and group II.

**H<sub>4</sub>:** There is a significant association between the level of oral mucositis among children undergoing chemotherapy in group I, group II and their selected socio demographic variables.

## **1.5 Operational definitions**

### **Effectiveness**

In this study Effectiveness refers to a desired result in oral mucositis among children undergoing chemotherapy and it is measured by WHO Oral Mucositis grading scale.

### **Sodium bicarbonate mouthwash**

In this study, it refers to oral care given to group I who is receiving chemotherapy with 10 ml of Sodium bicarbonate solution for three times a day for 5 days and it is prepared with 250 ml of water and 1.3 grams of Sodium bicarbonate powder

### **Chlorhexidine mouthwash**

In this study Chlorhexidine mouth wash refers to oral care given to group II who is receiving chemotherapy with 10 ml of chlorhexidine and it is readily available solution.

### **Oral mucositis**

In this study oral mucositis refers to redness, swelling, and ulceration that occurs in the oral mucosa as a result of chemotherapy as measured by WHO Oral Mucositis grading scale.

## **Children undergoing chemotherapy**

Children who is in the age group between 5 to 12 years admitted in hematology oncology ward pediatric department diagnosed with all type of cancers and receiving chemotherapy.

### **1.6 Assumption**

1. Cancer Children undergoing chemotherapy develops varying level of Oral mucositis
2. Ability to increase salivary pH and suppress the growth of acid uric micro-organisms property of sodium bicarbonate and antiseptic property of chlorhexidine helps in healing of oral mucositis.

### **1.7 Delimitation**

The study is limited to:

1. Children undergoing chemotherapy at pediatric ward, Government Rajaji Hospital Madurai.
2. Data collection period is limited to 4-6weeks

### **1.8 Projected outcome**

This study will yield the expected outcome to the researcher that chemotherapy induced oral mucositis can be healed by the administration of sodium bicarbonate mouth wash or chlorhexidine mouth wash.

*Review of  
Literature*

## **CHAPTER II**

### **REVIEW OF LITERATURE**

A Literature review is a body of next that aims to review the critical points of knowledge on a particular topic of research. (American nurses association) Review of literature is one of the most important steps in the research process. It is an account of what is already known about a particular phenomenon. The main purpose of literature review is to convey to the readers about the work already done and knowledge and ideas that have been already established on a particular topic of research.

In order to accomplish the goal of present study an attempt has been made to review and discuss the literature which shall cover the following areas. This chapter deals with two parts.

Part – I Review of literature

Part - II Conceptual framework

In this chapter, the researcher presents the review of the literature under the following heading

#### **2.1 Research studies related to oral mucositis**

#### **2.2 Research studies related to effectiveness of sodiumbicarbonate mouthwash**

#### **2.3 Research studies related to effectiveness of chlorhexidine mouthwash**

#### **2.1 Research studies related to oral mucositis**

**Ebtissam, Z.MurshidTahani, A.AzizalrahmanAziza, J.AIJohar., (2017)** conducted a prospective, non-blinded study to determine the incidence and severity of oral mucositis in children newly diagnosed with ALL following chemotherapy at King Fahad National Center for Children’s Cancer , Riyadh. 60 children newly diagnosed with ALL of both genders, aged (6–14 years) were examined. The World

Health Organization's (WHO) oral toxicity scale was used to record oral mucositis . The prevalence of oral mucositis was 23.3% with a mean age of 8.36 (2.98). 92.9% High risk patients had oral mucositis and 7.1% with Low risk patients. The difference in the prevalence of oral mucositis among age and gender was not statistically significant ( $P > .05$ ). However, the difference in the prevalence of oral mucositis among risk categories was little significant difference ( $P = .059$ ).

**Isabella Lima Arrais Ribeiro et al., (2017)** conducted a prospective quantitative and observational study to identify damage on oral cavity and functions that occurs during the induction phase of chemotherapy remission for the treatment of acute lymphoblastic leukemia in pediatric cancer patients, Napoleão Laureano Hospital in João Pessoa, Braziland.. 42 patients aged 0–18 years old were selected .The modified Oral Assessment Guide (OAG) was used, and data were analyzed by Spearman's rank correlation coefficient ( $\alpha = 5\%$ ). Changes to the normal lips and saliva were positively related to an increase in the OAG score during all 10 weeks of evaluation. Of the 42 patients analyzed, 54.8% ( $n = 23$ ) were female, with a mean age of 7.1 ( $\pm 4.7$ ) years (median 5, minimum of 2 and maximum of 18 years of age. Changes in lips and saliva were positively correlated with the total OAG score during all study weeks ( $p \leq 0.05$ ),

**Karthika Nagarajan., (2015)** conducted a quasi experimental study mainly to evaluate the changes in quality and quantity of oral epithelial cells during the course of chemo-radiotherapy in Griffith Health Institute, Australia. 30 study Patients undergoing chemo-radiotherapy were followed through course of treatment. They were compared with a 30 control group of age- and sex-matched healthy individuals. The procedure involved WHO clinical scoring, collection of oral washings and preparation of buccal smears from both study group and control group. Revealed a

significant occurrence of oral mucositis in almost all patients during weekly follow up. There was a significant increase in percentage of viable buccal epithelial cells in study group when compared to normal controls ( $P < 0.005$ ) during and at the end of chemo-radiotherapy.

**Maria Helena Barros., (2015)** conducted a descriptive study to analyze nursing care provided to cancer patients with oral mucositis based on the Nursing Process (NP). 213 patients undergoing chemotherapy and/or radiotherapy in two cancer facilities: one philanthropic and one private service located in Teresina, PI, and Brazil. Nursing Process was established listing the diagnoses, interventions and expected results to establish an ideal, though individualized, standard of nursing care to be provided to these patients. Among the total number of patients, 74.7% reported nurses provided no treatment/orientation, while 25.3% reported orientation was provided at some point during the treatment. When the sample was segmented by degree of severity, only 27.2% of the patients with severe mucositis reported having received specific orientation from nurses.

**Sonis et al., (2014)** conducted a prospective comparative study was designed to determine the effectiveness of a preventive oral care protocol in reducing chemotherapy-induced oral mucositis in children with cancer. During an 8-month period, 42 children aged 6 to 17 years with haematological malignancies or solid tumours were evaluated. The 21 children who were included in the first 4-month period of the study constituted the control group. Another 21 children were enrolled in the subsequent 4 months and were assigned to the experimental group, in which they were given an oral care protocol intervention. The oral care protocol consisted of tooth brushing, 0.2% chlorhexidine mouth rinse and 0.9% saline rinse. Children in both groups were evaluated twice a week for 3 weeks. The incidence of ulcerative

lesions, severity of oral mucositis and the related pain intensity were used as the main outcome variables. A 38% reduction in the incidence of ulcerative mucositis was found in children using the oral care protocol compared with children in the control group. The severity of oral mucositis ( $P=0.000002$ ) and the related pain ( $P=0.0001$ ) were significantly reduced with the intervention. These results support the preventive use of the oral care protocol in paediatric cancer patients who undergo chemotherapy for cancer treatment.

**A Molassiotis., (2007)** conducted a quasi-experimental study on Oral care by nurses can help to reduce patients' mucositis related symptoms arising from stomatotoxic chemotherapy at the Chinese University of Hong Kong, China . Study aimed to provide nurses with education on oral care to prevent mucositis and then to compare patient outcomes for those receiving chemotherapy. 128 subjects receiving their first chemotherapy cycle were included. The oral care protocol emphasized regular oral assessment and frequent mouth rinsing, compare the level of mucositis between experimental patient group (cared for by specially educated nurses) and control patients. Control subjects had a significantly ( $P<0.05$ ) higher prevalence of mucositis (grade  $\geq 1$ ), level of baseline oral symptoms, and longer duration of cancer compared to study patients.

## **2.2 Research studies related to effectiveness of sodium bicarbonate mouthwash**

**Jecin deepa., (2016)** conducted a quasiexperimental study on effectiveness of sodium bicarbonate mouthwash in reducing oral mucositis among oral cancer patients who are receiving radiation therapy at C.S.I Mission Hospital, kanyakumari district. 60 samples were selected by using purposive sampling technique. Sodium bicarbonate mouth wash was given for 3 times for a period of two weeks. After the conduction of the pre-test and post-test, data analysis was done to find out the

effectiveness of sodium bicarbonate mouth wash. In experimental group, the mean post test score was 1.433 with standard deviation 1.145 where as in control group the mean post test was 1.166 with standard deviation of 0.933. The obtained t-test value was 2.52 and the p value was 0.02. The study concluded that sodium bicarbonate mouth was effective in reducing oral mucositis among oral cancer patients who received radiation therapy.

**Sunitha. G., ( 2015)** conducted a Quantitative True experimental-Comparative study to assess Effectiveness of Normal saline mouth wash versus Sodium bicarbonate mouth wash on Oral mucositis among patients undergoing Radiation therapy in oncology ward at Madurai. Sample size was 60 (30 samples in Group I and 30 samples in Group II), assigned by Simple random sampling technique-lottery method. The intervention was administration of Normal saline mouth wash to Group I and Sodium bicarbonate mouth wash to Group II for 1 minute, 3 times a day for about 2 weeks. By using Mann Whitney “u” test, the median difference between the post test score is 2. The obtained “Z” value is 4.445 at p-value 0.000 level of significance. The findings proved that Normal saline mouth wash is very effective than Sodium bicarbonate mouth wash to reduce the level of Oral mucositis.

**Kumar,M., (2012)** conducted a randomized clinical trial on the effectiveness of povidone iodine mouthwash and Soda bicarb mouth wash on stomatitis at University of Lucknow. Eighty patients with Stomatitis were randomly assigned to receive one of the two alcohol-free test mouthwashes (1% povidone-iodine and Soda bicarb). Among the 76 patients who completed the study, patients in the Soda bicarb group had significantly lower scores when compared to the povidone iodine group. When a *post hoc* analysis for repeated measure was used for analysis, a statistically

significant difference was observed between the povidone-iodine group and the control group ( $P = 0.013$ ) at the end of the first week.

**Levy-Polack et al., (2014)** conducted a study preventive protocol for oral complications associated with acute leukemia at Caucasia. A control group of 60 Caucasian children already undergoing chemotherapy who received only palliative treatment for complications was compared with a treatment group of 36 Caucasian children (ages 1 to 16) with newly diagnosed acute lymphoblastic leukemia receiving a daily mouth care protocol for a 13-month period. The protocol consisted of the following: a mouthwash with sodium bicarbonate and water after every meal; a mouthwash with a nonalcoholic solution of chlorhexidine (0.12%) twice a day; cleaning of mucosa with gauze soaked in iodopovidone 4 times a day prior to the use of nystatin. “Post intervention, the control group showed a 68.2% incidence of poor oral hygiene versus 51.6% in the experimental group ( $p < 0.001$ ), a 28.2% incidence of candidiasis versus 16.1% in the experimental group ( $p < 0.009$ ), and a 10.75% incidence of oral bleeding versus 5.1% in the experimental group ( $p = 0.08$ ), respectively. Furthermore, the rate and severity of mucositis were higher in the control group, with 30.2% of the control patients versus 21.9% of the experimental patients exhibiting oral mucositis ( $p = 0.1$ ).

**Suzanne L. Dibble., (2013)** conducted a study to identify the effectiveness of 3 mouthwashes to treat chemotherapy-induced mucositis. The mouthwashes include 0.12% chlorhexidine, 1% povidone-iodine, sodium bicarbonate. A randomized, double-blind clinical trial was implemented among 23 outpatient and office settings. Nurses used the Oral Assessment Guide for initial assessment. Among 142 out of 200 patients, there was a cessation of the signs and symptoms of mucositis within 12 days. No significant differences in time for the cessation of the signs and symptoms were

observed among the 3 groups. Comparatively it was found that the sodium bicarbonate mouth wash is least costly than any other solutions used as mouth wash.

**Hee-SeungKim., (2012)** conducted a repeated measures experimental study to compare the effectiveness of sodium bicarbonate (**SB**) solution with chlorhexidine (**CHX**) mouthwash in oral care of acute leukemia patients under induction chemotherapy admitted to the hematology clinic of a tertiary care hospital in Seoul, South Korea, 48 patients were randomly selected and assigned to an sodium bicarbonate solution group or – chlorhexidine The oral anaerobic bacterial colonization differed significantly between the two groups ( $p = .001$ ). The oral anaerobic bacterial colonization in the SB group was significantly higher than that of the CHX group of chemotherapy ( $p = .001$ ) degrees of Stomatitis. Significant difference also were observed the soda groups ( $p = 0.16$ ).

**Eun Choi .,(2011)** conducted a randomized controlled trial to compare the effectiveness of sodium bicarbonate (SB) solution with chlorhexidine (CHX) mouthwash in oral care of acute leukemia patients under induction chemotherapy at Nambu University, Gwangju, South Korea. Forty-eight patients were randomly selected and assigned to an SB solution group or CHX-based product group according to acute myelogenous leukemia or acute lymphoblastic leukemia. Of all the patients in the SB group, 25.0% developed ulcerative oral mucositis, whereas 62.5% in the CHX group did. As a result of this study, it was found that oral care by SB solution for acute leukemia patients undergoing chemotherapy was an effective intervention to improve oral health. Results showed that chlorhexidine did not significantly reduce incidence of mucositis compared to sodium bicarbonate ( $P = 0.129$ )

### **2.3 Research studies related to effectiveness of chlorhexidine mouthwash**

**Su-Chih Chen, Li-Chueh, WengShu-Chuan Tsai., (2017)** conducted a study on Effectiveness of Oral Rinsing Solutions on Mucositis, Odor, and Plaque , quasi-experimental and pretest–posttest study was conducted in Taiwan. The effectiveness of three types of oral rinsing solutions (normal saline, 0.2% chlorhexidine [CHX], and boiled water) was compared among 120 elderly patients (40 patients per group). The results showed that the oral health condition in terms of mucus, plaque, and odor improved significantly over time. The effect for the oral condition did not differ significantly among the three groups, except for oral odor. The chlorhexidine group experienced higher oral odor than did the boiled water group (Solutions  $\times$  Time interaction,  $F = 3.967$ ,  $p = .002$ ). Boiled water appears to be a safe and effective oral rinsing solution for hospitalized elderly patients.

**Cardona ., (2017)** conducted a systematic review with meta-analyses study on Efficacy of chlorhexidine for the prevention and treatment of oral mucositis in cancer patients. Three databases were searched: MEDLINE (via PubMed), Web of Science, and the Cochrane Library up to May 25, 2016 .Oral mucositis occurs in patients undergoing chemoradiation for cancer treatment. The effect of chlorhexidine on the incidence and severity of oral mucositis in patients with cancer was evaluated in this review. Ninety-eight abstracts were evaluated by three independent reviewers. Twelve studies met the criteria for inclusion. Four of these studies were assessed at unclear risk of bias and eight of them at high risk. Of the 12 studies, nine were included in two meta-analyses. Pooled results showed that chlorhexidine did not significantly reduce incidence of mucositis compared to placebo ( $P = 0.129$ ), nor chlorhexidine did significantly reduce the severity of mucositis ( $P = 0.127$ ), although subgroup analysis in the chemotherapy group showed a trend toward significance ( $P = 0.054$ ).

**Sunila guna sundari.S., (2016)** conducted a Quasiexperimental Study to assess the effectiveness of honey application versus chlorhexidine mouth wash in reducing oral mucositis among children at Institute of child health & hospital, Chennai. 60 samples were selected from Convenient sampling technique.30 children were selected for experimental group and were given honey application and 30 were selected for control group and were given chlorhexidine mouth wash. The findings of the study shows that the calculated 't' value for honey application was 13.730 which was more than the  $p < 0.001$  this shows that honey application is more effective than chlorhexidine mouth wash.

**Narges Gholizadeh., (2016)** conducted a clinical trial on assess the effectiveness of chlorhexidine Mouthwash and palifermin in preventing mucositis in children with acute lymphocytic leukemia (ALL) who undergo chemotherapy in Tabriz University of Medical Sciences, Tabriz, Iran,. 90 children with ALL were randomized to receive chlorhexidine (n=45) or palifermin (n=45). The world health organization (WHO) oral toxicity scale was employed for grading the mucositis. The data were analyzed by using two-way ANOVA. The two groups were matched for age and gender. The study groups were significantly different in terms of mucositis grading (P values after 1 and 2 week therapy were 0.00). Palifermin decreased the incidence and severity of chemotherapy-induced mucositis.

**Cheng et al., (2016)** conducted a study on the effectiveness of an oral care protocol for the prevention of chemotherapy-induced oral mucositis in the United States; the protocol was evaluated over an 8-month period in 42 pediatric cancer patients who ranged in age from 6 to 17 years. The experimental group consisted of 21 children who were instructed in the proper technique of tooth brushing; they were also given a 0.2% chlorhexidine mouth rinse, which was used twice a day, and a 0.9%

saline rinse, which was used in the morning, after each meal, and before going to bed. Another 21 patients made up the control group and did not receive the oral care protocol intervention or information concerning the importance of oral care. The results obtained from this study were significant and demonstrated a 38% reduction in the incidence of ulcerative mucositis in the experimental group ( $p=0.01$ ).

**Cheng and Chang ., (2015)** conducted a randomized 2-period crossover study to compared the efficacy of 0.15% benzydamine and 0.2% chlorhexidine mouthwashes in alleviating the symptoms of oral mucositis in children undergoing chemotherapy at USA . 40 pediatric patients ages 6 to 17 years were randomized into groups receiving 1 of the 2 mouthwashes. Each protocol was started on the first day of chemotherapy and continued for 21 days. Each subject was evaluated at intervals of 3 to 4 days using the WHO scale for mucositis and a 10-cm visual analog scale to evaluate oral symptoms. Of the 34 patients who were evaluated, 26% of the chlorhexidine group compared to 48% of the benzydamine group showed WHO grade II mucositis ( $p<0.05$ ). The results revealed a significant difference in mouth pain ( $p<0.05$ ) and a trend of decreased difficulty in eating/chewing and swallowing in favor of chlorhexidine mouthwash.

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

in a single randomized controlled trial. The severity of oral mucositis ( $P=0.000002$ ) and the related pain ( $P=0.0001$ ) were significantly reduced with the intervention.

**J.Sorensen, T.Skovsgaard .,( 2010)** was conducted a experimental study on effectiveness of three mouth wash in Denmark , 206 (70 patients in chlorhexidine group, 64 patients in normal saline and 63 patients in cryotherapy) patients receiving the chemotherapy were divided into three groups randomly such as chlohexidine 0.1 % 15 ml as mouth rinse for one minute three times a day or another group with normal saline with same dose and frequency or to cryotherapy with crushed ice tips from 10 min before to 35 minutes of initiation of chemotherapy . Mucositis of grade 3 and 4 occurred in 13% of chlorhexidine group, 33% in normal saline and 11% in cryotherapy. Duration of oral mucositis was longer in saline group than other two. So chlorhexidine mouth wash is more effective than normal saline. p-value 0.001 level of significance.

**Neethu chandran., (2009)** A quasi experimental study was conducted in Coimbatore, Ramakrishna hospital. Samples were selected by simple random sampling .24 samples were taken 12 were given honey application with chlorhexidine mouth wash and 12 were given chlorhexidine mouth wash alone for 5 to 7 days. The tool used were WHO oral mucositis assessment scale. Post test was done each day after intervention .The differences between the groups were statistically significant ( $P < 0.001$ ).It was found that honey with chlorhexidine mouth wash was effective than chorhexidine mouth wash.

## PART – II

### CONCEPTUAL FRAMEWORK

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

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

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

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

The following are the major concepts of the theory.

#### **Input**

Input is the matter, energy and transformation that enter the system. In the present study, the input is the characteristics of the children with chemotherapy induced oral mucositis like Age, gender, religion, birth order of the family, No of siblings, type of family, place of residence, income of the family, standard of living, educational status, occupation and family monthly income, weight, height,

educational status of the parents, diagnosis, number of chemotherapy cycles, duration of oral mucositis, oral hygiene followed. In this open system model, the level of chemotherapy induced oral mucositis was assessed and measured by using WHO oral mucositis grading scale. The level of chemotherapy induced oral mucositis can be graded as 0,1,2,3 and 4 based on the severity of children condition.

### **Throughput**

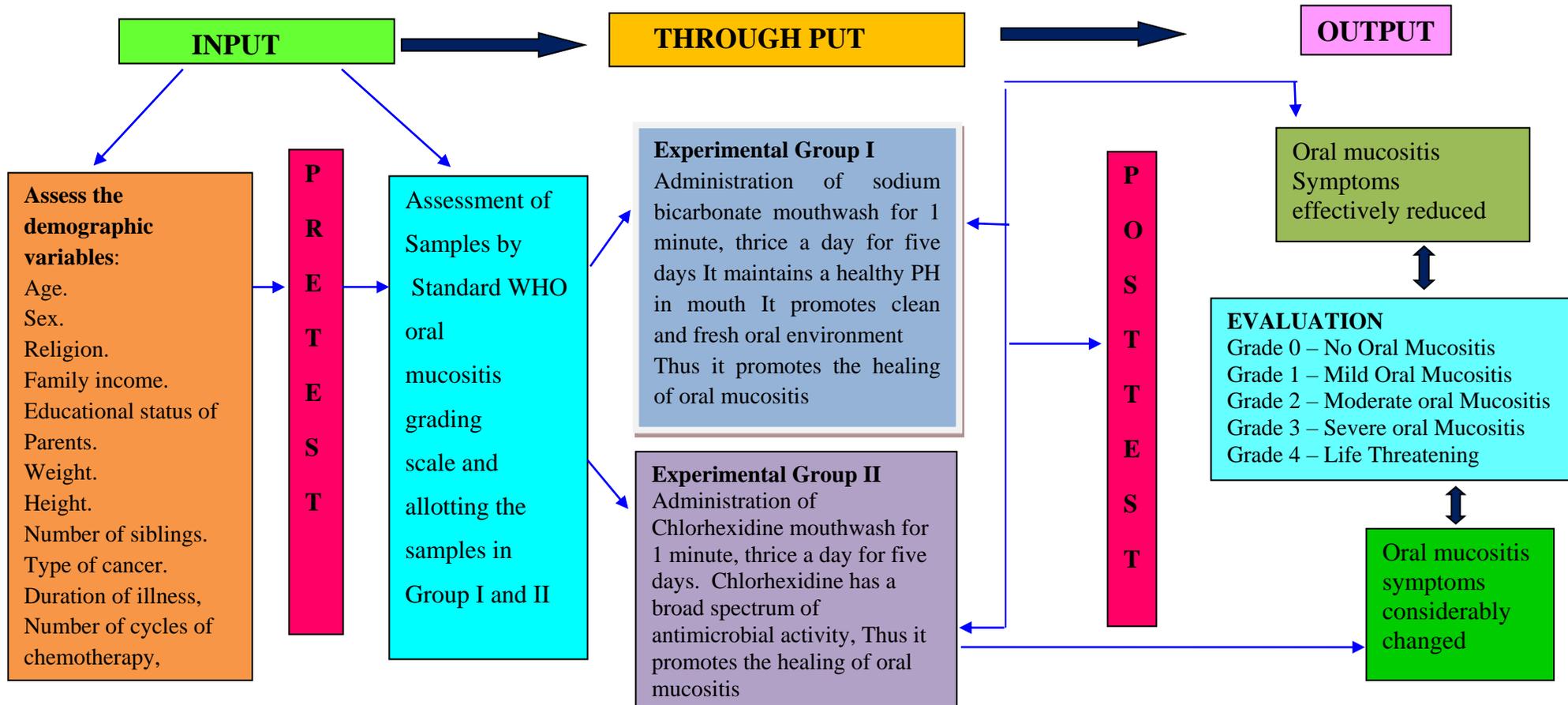
Throughput is the use of biologic, psychologic and socio-cultural sub systems to transform the inputs. The present study considers throughput was the administration of sodium bicarbonate mouthwash and chlorhexidine mouthwash for children with chemotherapy induced oral mucositis.

### **Output**

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

### **Feedback**

Differences in pre and post test scores were observed from the subjects by using WHO oral mucositis grading scale. . In the present study, the feedback was considered as a process of effectiveness of sodium bicarbonate mouth wash and chlorhexidine mouthwash on chemotherapy induced oral mucositis . It was assessed by comparing the pre and post test scores, through McNemar's test. The effectiveness between both interventions was assessed through McNemar's test and the association between the level of chemotherapy induced oral mucositis with their demographic variables were assessed through chi-square test.



**FIGURE 1. MODIFIED J.W.KENNY'S OPEN SYSTEM MODEL (1991)**

# *Methodology*

## **CHAPTER III**

### **METHODOLOGY**

Research methodology is the systemic way of doing a research to solve a problem. This chapter deals with the brief description of the different steps for the study. It includes the research approach, research design, variables, setting of the study, population, sample and sampling techniques, development of tool, description of tool, data collection procedure and plan for data analysis.

#### **3.1 Research approach**

The research approach is the most essential part of any research. The entire study is based on it. A research approach tells the researcher about the collection of data that is what to collect, when to collect, how to collect and how to analyze. It also helps the researcher with suggestions of possible conclusions to be drawn from the data.

**According to Polit and Hungler (1999)** evaluative research is an applied formate research that involves finding out how well a program, practice, procedure or policy is working. It involves the collection and analysis of information relating to the functioning of a program or procedure. With the aim of assessing its effectiveness.

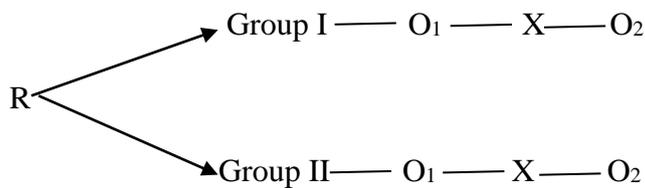
A quantitative approach was adopted in the present study as the investigation is aimed at evaluating the effectiveness of sodium bicarbonate mouth wash versus chlorhexidine mouth wash on oral mucositis among children undergoing chemotherapy.

### 3.2 Study design

According to Kothari.C.R.(2003) “A research design is defined as the overall plan for collecting and analyzing data, including a specification for enhancing the internal and external validity of the study.”

The research design is the plan, structure and strategy of investigations of answering the research question. It is the overall plan or blueprint the researcher select to carry out the study.

The research design selected for the present study is **true experimental pretest - posttest design**



Group I: Subjects receiving Sodium bicarbonate mouth wash

Group II: Subjects receiving chlorhexidine mouth wash

O<sub>1</sub>: Observation before intervention

X: Intervention

Group I- Sodium bicarbonate mouth wash for three times a day for five consecutive days

Group II - chlorhexidine mouth wash for three times a day for five consecutive days

O<sub>2</sub>: Observation after intervention

R- Randomization

### **3.3 Research variables**

The variable is “an attribute of a person or object that varies, that is taken different values”.

**Polit and Hunger**

#### **Dependent variable**

In this study the dependent variable is oral mucositis among children undergoing chemotherapy.

#### **Independent variable**

In this study the independent variable is sodium bicarbonate mouth wash for group I and chlorhexidine mouth wash for group II.

#### **Sociodemographic variables**

Age, gender, religion, birth order of the family, No of siblings, type of family, place of residence, income of the family, standard of living, educational status, occupation and family monthly income, weight, height, educational status of the parents, diagnosis, number of chemotherapy cycles, duration of oral mucositis, oral hygiene followed.

### **3.4 Study setting**

The setting is the physical location and condition in which data collection takes place in the study.

**- Polit and Hunger**

The study was conducted in pediatric hematology oncology ward in the Institute of Child Health & research center, government rajaji hospital , Madurai .Institute of Child Health & research center for children is the second biggest hospital in South Tamil nadu providing excellent care to children .The institute is rendering meritorious care and has been contributing to various research in the field of Child health.

### **3.5 Population of the study**

#### **Target population**

Target population is cancer children with chemotherapy induced oral mucositis.

#### **Accessible population**

The study populations are children with chemotherapy induced oral mucositis admitted in pediatric hematology oncology ward at Government Raja Hospital Madurai.

### **3.6 Sample**

Cancer Children with chemotherapy induced oral mucositis who are admitted in pediatric hematology oncology ward at Government Raja Hospital Madurai and those who fulfill the inclusion criteria.

### **3.7 Sample size**

The sample size is  $N = 60$

Group I = 30

Group II = 30

### **3.8 Sampling technique**

The sampling technique was used simple Random sampling technique – lottery method.

### **3.9 Criteria for sample selection**

#### **Inclusion criteria**

- ✓ Parents of Children who is willing to participate in this study.
- ✓ Children who is conscious, oriented to follow the instructions.
- ✓ Cancer children age group between 5 -12 years for both sexes.

### **Exclusion criteria**

- ✓ Children who have bleeding from gum.
- ✓ Clinically ill children.
- ✓ Parents who are taking home remedies for oral mucositis.

### **3.10. Development of the tool**

The investigator developed the data collection tool based on review of literature and obtained expert opinion and content validity from medical, nursing department and tool was constructed. Pre testing of the tool was done during pilot study. Direct assessment of the client was performed during the data collection.

### **3.11 Description of the tool**

#### **Section I**

1. **Socio demographic variables** - age, gender, religion, place of residence, educational status of the parents, occupation status of the parents, monthly income. weight, height, number of siblings.
2. **Clinical variables** – type of cancer, duration of illness, type of chemotherapy, number of chemotherapy cycles, occurrence of oral mucositis and oral hygiene.

#### **Section II**

WHO oral mucositis grading Scale

**Section II** - This section includes standard WHO grading system for oral mucositis

It provides parameters to assess oral mucositis like soreness, erythema, type of food taken.

<b>GRADE</b>	<b>ORAL MUCOSITIS WHO GRADING</b>	<b>BEFORE INTERVENTION</b>	<b>AFTER INTERVENTION 6<sup>th</sup> day</b>
0	None		
1	Soreness + erythema		
2	Erythema, ulcer, and patient can swallow solid food		
3	Ulcers with extensive erythema and patient cannot swallow solid food		
4	Mucositis to the extent that alimentation is not possible		

The oral mucositis was assessed with Standard WHO grading system for oral mucositis which implies that

### **Score interpretation**

#### **WHO Oral Mucositis Grading Scale**

<b>Grade</b>	<b>Description</b>
0 (none)	None
I (mild)	Oral soreness, erythema
II (moderate)	Oral erythema, ulcers, solid diet tolerated
III (severe)	Oral ulcers, liquid diet only
IV (life-threatening)	Oral alimentation impossible

This scale was administered to the children before and after the intervention.

### **3.12 CONTENT VALIDITY**

The tools used for this study was given to five experts in the field of nursing and medical department for content validity. Suggestions were considered and appropriate changes were made and found valid. Tool was translated in Tamil and retranslated by experts to confirm language validity. For measuring the level of Oral mucositis - WHO Oral mucositis grading scale was used. It is a standardized tool.

### **3.13 RELIABILITY**

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

### **3.14 Ethical consideration**

This study was conducted after the approval from the ethical committee, Madurai Medical College, Madurai – 20. All respondents were carefully informed about the purpose of the study and their part during the study and how the privacy was guarded. Ensured confidentiality of the study result. Written permission was obtained from all participants.

### **3.15 Pilot study**

The pilot study was conducted after getting formal administrative permission and ethical clearance. The pilot study was conducted in hematology ward institute of child health & research center for children, Madurai. A self-introduction was given by the investigator. Children with oral mucositis who met the inclusion criteria were selected sociodemographic variables was assessed. After the explanation oral and written consent was obtained from the parents. Samples were selected by simple

random method (lottery) . Among 10 children, 5 group I and get sodium bicarbonate mouth wash remaining 5 in group II and get chlorhexidine mouth wash. Intervention was given three times a day for five consecutive days daily. posttest was assessed 6<sup>th</sup> day using WHO oral mucositis scale. Through pilot study the instrument was found reliable for proceeding with the main study.

### **3.16 Data collection procedure**

The data collection done for 4-6 weeks from 04/06/2018 to 13/07/2018 A self-introduction was given by the investigator. Children with oral mucositis who met the inclusion criteria were selected socio.demographic variables was assessed. After the explanation oral and written consent was obtained from the parents. Samples were selected by simple random method (lottery). Among 60 children, 30 group I and get sodium bicarbonate mouth wash remaining 30 in group II and get chlorhexidine mouth wash. Intervention was given three times a day for five consecutive days daily. Posttest was assessed 6<sup>th</sup> day.

#### **The steps were divided into three parts**

**Part 1:** Assessing the sociodemographic variables, anthropometric measurement and disease condition.

**Part 2:** Assess the level of oral mucositis using standard WHO oral mucositis assessment scale.

#### **Part 3**

##### **For group I**

##### **Steps in sodium bicarbonate mouth wash**

1. Explain the procedure to the parent and the child.
2. Assess the oral mucositis.
3. Place the child in comfortable position.

4. Provide 10 ml of sodium bicarbonate mouth wash to the child for rinsing the mouth for 1 minute.
5. Then ask the child to spit it out.
6. Provide sodium bicarbonate three times a day for five consecutive days.
7. Assess the healing of oral mucositis on the 6th day by using standard WHO oral mucositis scale.

### **For group II**

#### **Steps in chlorhexidine mouth wash**

1. Explain the procedure to the mother and the child.
2. Assess the oral mucositis.
3. Place the child in comfortable position.
4. Provide 10 ml of chlorhexidine mouth wash to the child for rinsing the mouth for 1 minute
5. Then ask the child to spit it out.
6. Provide chlorhexidine three times a day for five consecutive days.
7. Assess the healing of oral mucositis on 6th day by using standard WHO oral mucositis scale.

### **3.17 Plan for Data analysis**

The data analysis involves the translation of information collected during the course of research project into an interpretable and managerial form. It involves the use of statistical procedures to give an organization and meaning to the data. Descriptive and inferential statistics use for data analysis. To compute the data, a master sheet was prepare by the investigator. The data obtained were analyzed using both descriptive and inferential statistics. Data was presented in frequency table to

compare the pre test and post test assessment differences between group I (sodium bicarbonate mouth wash) and group II (chlorhexidine).

#### **Descriptive statistics include**

1. Analysis of socio demographic and clinical variables by using Frequency and percentage .
2. The level of oral mucositis was analysed by compute frequency and percentage.

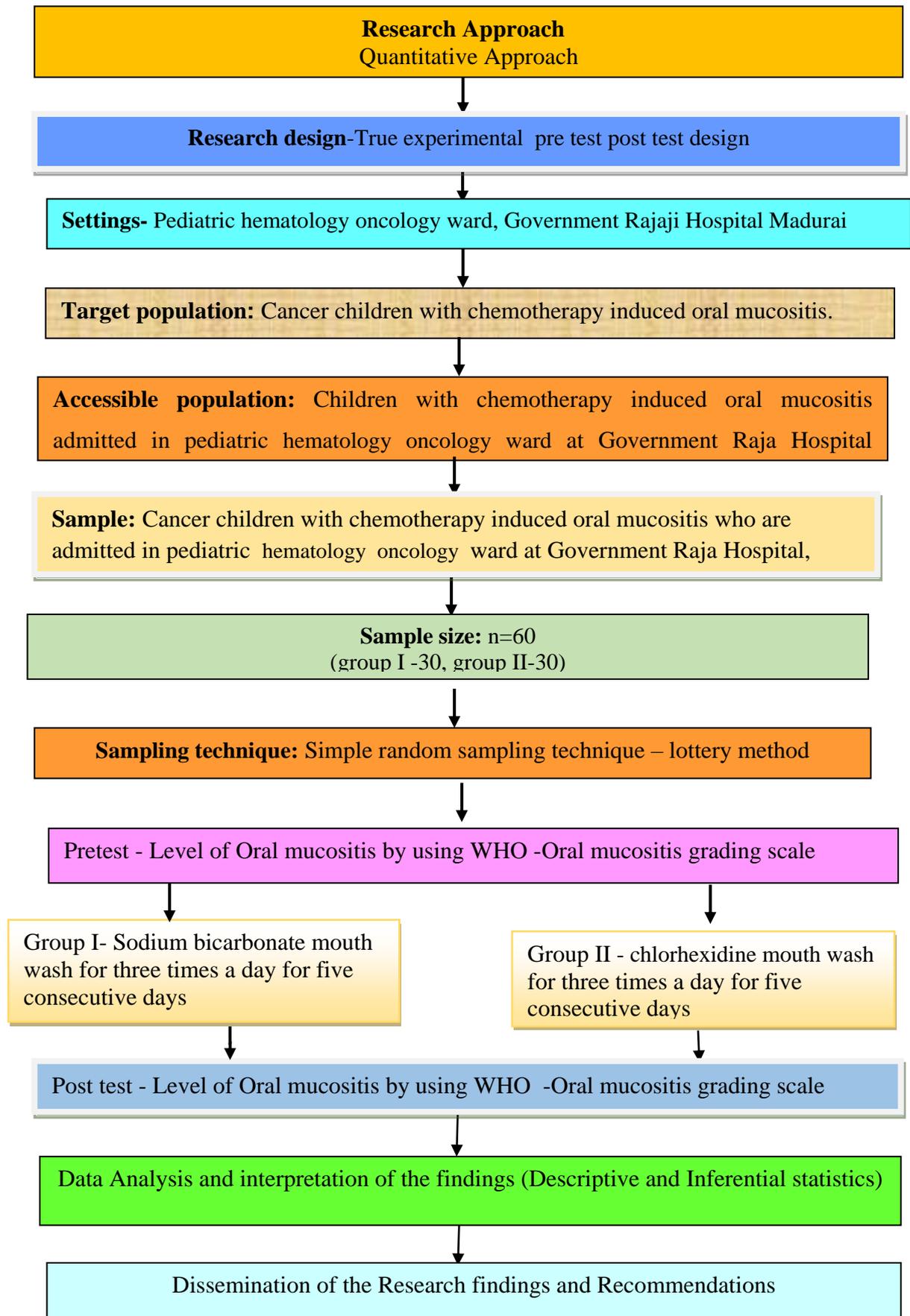
#### **Inferential statistics include**

1. Wilcoxon signed rank test was used to test was used to evaluate the effectiveness of sodiumbicarbonatemouth wash in group I and chlorhexidine mouth wash in group II
2. Chi- square test was used to compare the post test level of oral mucositis in group I and group II.
3. Chi square analysis was used to find out the association between the post test level of oral mucositis among group I and group II with their selected socio demographic and clinical variables

### **3.18 Protection of human rights**

Research proposal was approved by the dissertation committee of College Of Nursing, Madurai Medical College, Madurai and Head of the Department of Pediatrics, Institute of Child Health and Research Centre at Government Rajaji Hospital, Madurai. An oral and written consent of each study samples can be obtained before starting the data collection. Positive benefits were explained to all the study subjects. They were explained that they may withdraw from the study at any time without any penalty. Assurance has given to the subjects that confidentiality will be maintained throughout the study.

## SCHEMATIC REPRESENTATION OF RESEARCH METHODOLOGY



*Data Analysis  
And  
Interpretation*

## CHAPTER – IV

### DATA ANALYSIS AND INTERPRETATION

Analysis is the process of categorizing, ordering, manipulating and summarizing of data to obtain an answer to the research question. The purpose of the analysis is to reduce the data intelligible and interpretable form, so that relation for the research problem can be studied and tested. In this chapter the data collected were edited, tabulated, analyzed and interpreted.

**The analysis and interpretation of the data was organized under the following sections**

**Section 1:** Distribution of socio demographic and clinical variables among children undergoing Chemotherapy both in group I and group II.

**Section II:** Distribution of pre test level of oral mucositis among children undergoing Chemotherapy in group I and group II.

**Section III:** Effectiveness of sodium bicarbonate mouthwash and chlorhexidine mouthwash on oral mucositis among children undergoing Chemotherapy in group I and group II.

**Section IV:** Comparison on post test level of oral mucositis among children undergoing chemotherapy in group I and group II.

**Section V:** Association between the post test level of oral mucositis with their selected socio demographic and clinical variables among children undergoing chemotherapy in group I and group II.

## Section I

### Distribution of socio demographic and clinical variables among children undergoing Chemotherapy both in group I and group II

**Table - 1**

**Frequency and percentage distribution of children undergoing Chemotherapy  
according to their selected socio demographic variables**

**n = 60**

<b>Socio demographic variables</b>		<b>Group</b>				<b><math>\chi^2</math></b>
		<b>Group I(n=30)</b>		<b>Group II(n=30)</b>		
		<b>f</b>	<b>%</b>	<b>f</b>	<b>%</b>	
<b>Age</b>	5 to 7 years	14	46.67%	13	43.33%	$\chi^2=0.10$ P=0.95 (NS)
	8 to 9 years	9	30.00%	9	30.00%	
	10 to 12 years	7	23.33%	8	26.67%	
<b>Sex</b>	Male child	17	56.67%	15	50.00%	$\chi^2=0.26$ P=0.60 (NS)
	Female child	13	43.33%	15	50.00%	
<b>Religion</b>	Hindu	25	83.33%	29	96.67%	$\chi^2=3.29$ P=0.19 (NS)
	Christian	3	10.00%	1	3.33%	
	Muslim	2	6.67%	0	0.00%	
<b>Residential area</b>	Rural	6	20.00%	5	16.67%	$\chi^2=0.37$ P=0.83 (NS)
	Urban	7	23.33%	9	30.00%	
	Semi urban	17	56.67%	16	53.33%	
<b>Type of family</b>	nuclear family	24	80.00%	24	80.00%	$\chi^2=4.00$ P=0.13 (NS)
	joint family	3	10.00%	6	20.00%	
	extended family	3	10.00%	0	0.00%	
<b>Family income</b>	Rs.1000 to 3000	3	10.00%	3	10.00%	$\chi^2=5.52$ P=0.14 (NS)
	Rs.3001 to 5000	16	53.33%	20	66.67%	
	Rs. 5001 to 7000	6	20.00%	7	23.33%	
	Rs. 7001 to 10000	5	16.67%	0	0.00%	
<b>Mother's educational status</b>	No - formal education	5	16.67%	4	13.33%	$\chi^2=0.74$ P=0.98 (NS)
	Primary school	9	30.00%	8	26.67%	
	Middle school	9	30.00%	12	40.00%	
	High school	4	13.33%	3	10.00%	
	Higher secondary school	3	10.00%	3	10.00%	
	Graduate	0	0.00%	0	0.00%	

<b>Father's educational status</b>	No - formal education	5	16.67%	5	16.67%	$\chi^2=0.95$ P=0.96 (NS)
	Primary school	8	26.67%	11	36.67%	
	Middle school	8	26.67%	6	20.00%	
	High school	5	16.66%	5	16.66%	
	Higher secondary school	4	13.33%	3	10.00%	
	Graduate	0	0.00%	0	0.00%	
<b>Father's occupation</b>	Unemployed	3	10.00%	2	6.67%	$\chi^2=0.43$ P=0.93 (NS)
	Coolie	20	66.67%	22	73.33%	
	Self-employee	4	13.33%	3	10.00%	
	Business	3	10.00%	3	10.00%	
	Profession	0	0.00%	0	0.00%	
<b>Mother's occupation</b>	House wife	20	66.66%	21	70.00%	$\chi^2=2.89$ P=0.40 (NS)
	Coolie	6	20.00%	2	6.67%	
	Self-employee	2	6.67%	3	10.00%	
	Business	2	6.67%	4	13.33%	
	Profession	0	0.00%	0	0.00%	
<b>No of sibilings</b>	None	6	20.00%	9	30.00%	$\chi^2=0.80$ P=0.66 (NS)
	One	23	76.67%	20	66.67%	
	Two	1	3.33%	1	3.33%	
	more than 2	0	0.00%	0	0.00%	
<b>Height of the child</b>	95 - 105 cms	11	36.67%	6	20.00%	$\chi^2=2.05$ P=0.36 (NS)
	106 -125 cms	11	36.67%	14	46.67%	
	126- 150 cms	8	26.66%	10	33.33%	
<b>Weight of the child</b>	10 - 20 kgs	16	53.33%	17	56.67%	$\chi^2=0.41$ P=0.81 (NS)
	21 - 30 kgs	12	40.00%	10	33.33%	
	31 - 40 kgs.	2	6.67%	3	10.00%	

Above table 1 reveals the distribution of children undergoing chemotherapy according to their selected socio demographic variables in Group I and Group II.

Considering the age in group I, majority of the subjects 14 (46.67%) belongs to the age group between 5 to 7 years, 9 (30.00%) belongs to the age group between 8 to 9 years, 7 (16.67%) belongs to the age group between 10 to 12 years. In group II, majority of the subjects 13 (43.33%) belongs to the age group between 5 -7 years, 9

(30.00%) belongs to the age group between 8 to 9 years, 8 (26.67%) belongs to the age group between 10 to 12 years.

According to the gender in Group I, majority of the subjects 17 (56.67%) were male child and 13 (43.3%) were female child. In group II, 15 (50.00%) were male and female child.

While stating the religion in group I, majority of the subjects 25 (83.33%) were hindu, 3 (10.00%) were christian, 2 (6.67%) were muslim and none of them in other religion. In group II, 29 (90.67%) were hindu, 1 (3.33%) were christian, none of them in muslim and other religion.

As far as residential area in group I, majority of the subjects 17 (56.67%) hailed from semi urban area, 7 (23.33%) hailed from urban, 6 (20.00%) hailed from rural, In group II, 16 (53.33%) hailed from semi urban area, 9 (30.00%) hailed from rural, 5 (16.67%) hailed from urban.

With respect of type of family in group I children, majority of the subjects 24 (80.00%) belongs to nuclear family, 3 (10.00%) belongs to joint family, 3 (10.00%) belongs to extended family. In group II, 24 (80.00%) belongs to nuclear family, 6 (20.00%) belongs to joint family and none of them had extended family.

While comparing the family income in group I, majority of the subjects 16 (53.33%) were earned between Rs.3000-5000, 6(20%) were earned between Rs.5001- 7000, 5 (16.67) were earned between Rs.7001 -10000, 3 (10.00%) were earned between Rs.1000 to 3000. In group II, 20 (80%) were earned between Rs.3001 -5000, 7 (23.33%) were earned between Rs.5001- 7000, 3 (10.00%) were earned between income of Rs.1000 -3000 and none of them were earned between Rs.7001 -10000.

When discussing mother's educational status in group I, majority of the subjects, 9 (30%) studied up to primary school and middle school, 5 (16.67%) had no formal education, 4 (13.33) studied up to High school, 3(10.00%) studied up to higher secondary and none of them had graduates. In group II, 12 (40.00. %) studied up to middle school, 8 (26.67%) studied up to primary school, 4 (13.33%) had no formal education, 3 (10.00%) studied up to High school, 3 (10.00%) studied up to higher secondary and none of them had graduates.

When discussing father's educational status in group I, majority of the subjects 8 (26.67%) studied up to primary school, 8 (26.67%) studied up to middle school, 5 (16.67%) had no formal education, 5 (16.67%) had studied up to high school, 4 (13.33%) studied up to higher secondary and none of them had graduates. In group II, 11 (36.67%) studied up to primary school, 6 (20.00%) studied up to middle school education, 5(16.67%) no formal education, 5 (16.67%) studied up to high school, 3 (10.00%) studied up to higher secondary and none of them had graduates.

While stating father's occupation in group I, majority 20 (66.67%) were coolie, 4 (13.33%) were self-employee, 3 (10.00%) were unemployee, 3 (10.00%) father were business and none of them were in professional job. In group II, 22 (73.33%) were coolie, 3 (10.00%) were self-employee, 2 (6.67%) were unemployee, 3 (10.00%) were business and none of them were in professional job.

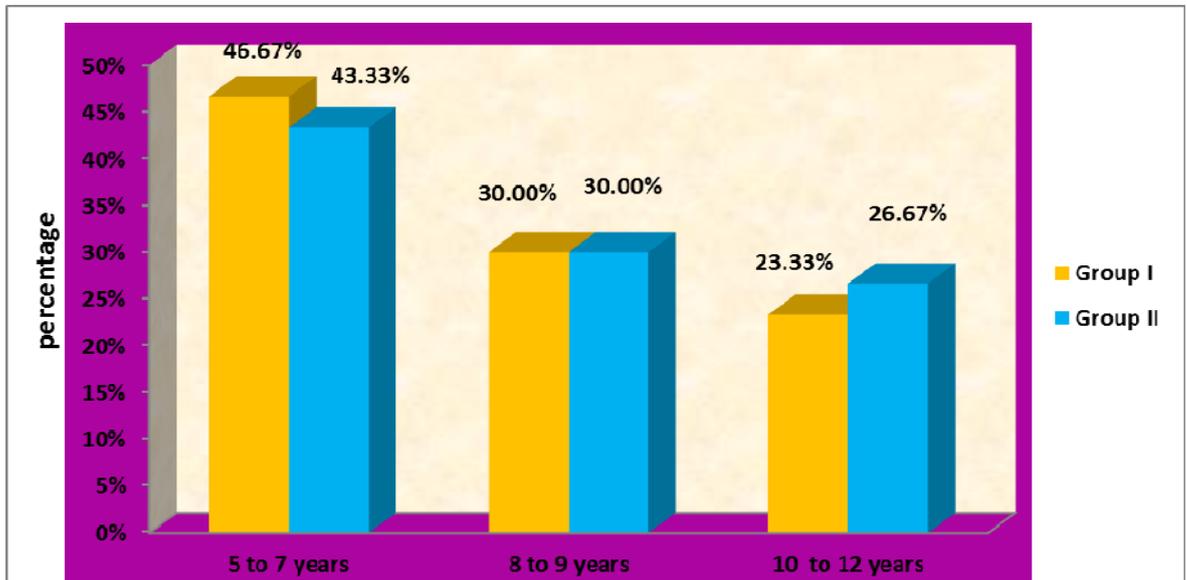
While stating mother's occupation in group I, majority 20 (66.66%) were house wife, 6 (20.00%) were coolie, 2(6.67%) were self-employee, 2 (6.67%) mother were business and none of them were in professional job. In group II, 21 (70.00%) were house wife, 2 (6.67%) were coolie, 3 (10.00%) were self-employee, 4 (13.33%) mother were business and none of them were in professional work.

Considering the number of siblings in group I, majority of the subjects, 23 (76.67%) had 1 sibling, 6 (20.00%) had no siblings, 1 (3.33%) had 2 siblings and no one had more than 2 siblings. In group II, 20 (66.67%) had 1 sibling, 9 (30%) had no siblings, 1 (3.33%) had 2 siblings and no one of had more than 2 siblings

In the aspect of height of the child in group I, majority of the subjects 11 (36.67%) were had between 95 -105 cms, 11 (36.67%) were had between 106 -125 cms, 8 (26.66%) were had between 126 -150 cms. In group II, 14 (46.67%) were had between 106 -125 cms, 10 (33.33%) were had between 126 -150 cms , 6 (20.00%) were had between 95 -105 cms.

In the aspect of weight of the child in group I, majority of the subjects 16 (53.33%) were had 10 -20 kgs, 12 (40%) were had 21 -30 kgs , 2 (6.67%) were had 31- 40 kgs. In group II, 17 (56.67%) were had 10 -20 kgs, 10 (33.33%) were had 21 -30 kgs, 3 (10.00%) were had 31 -40 kgs.

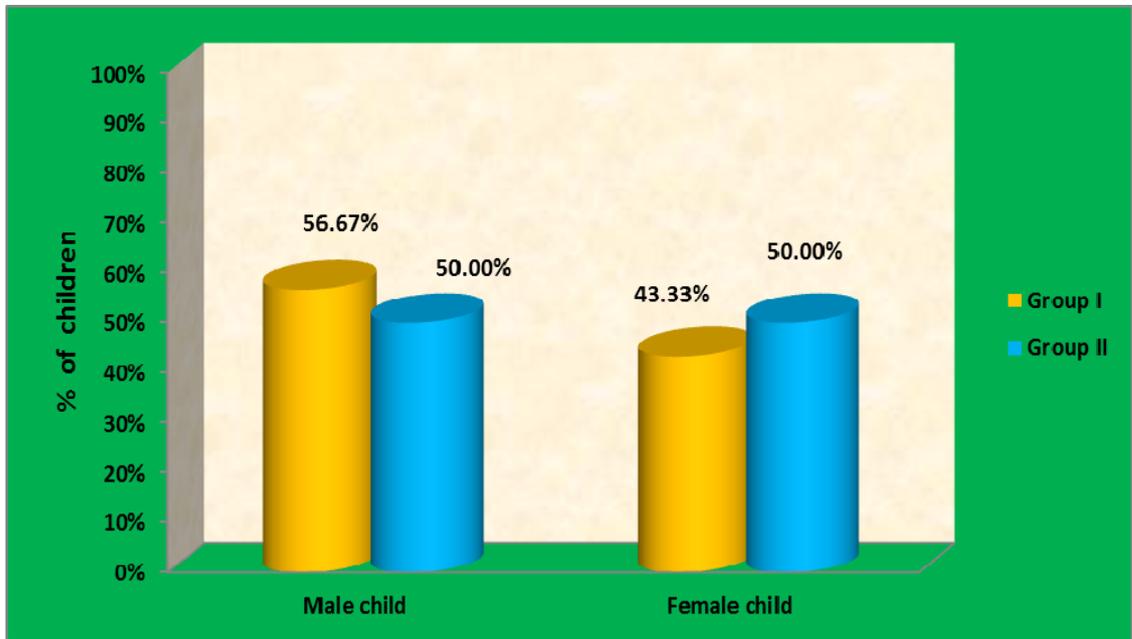
### Distribution of subjects according to age



**Figure 2 : Multiple Bar diagram quotes that distribution of children undergoing chemotherapy according to their age**

The above bar diagram shows that in group I, majority of the subjects 14 (46.67%) belongs to the age group between 5 to 7 years, 9 (30.00%) belongs to the age group between 8 to 9 years, 7 (16.67%) belongs to the age group between 10 to 12 years. Whereas in group II, 13 (43.33%) belongs to the age group between 5 -7 years, 9 (30.00%) belongs to the age group between 8 to 9 years, 8 (26.67%) belongs to the age group between 10 to 12 years.

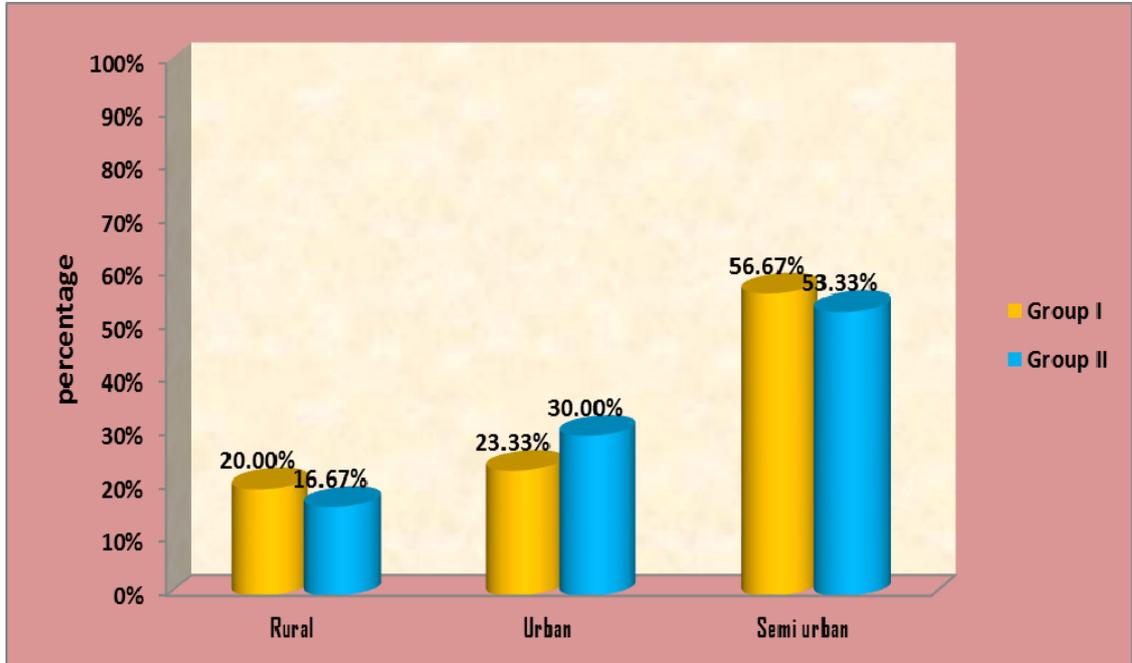
### Distribution of subjects according to gender



**Figure 3: Multiple cylinder diagram depicts that distribution of children undergoing chemotherapy according to their gender**

Above multiple bar diagram shows that in Group I, majority of the subjects 17 (56.67%) were male child, 13(43.3%) were female child. In group II, 15(50.00%) were male and female child.

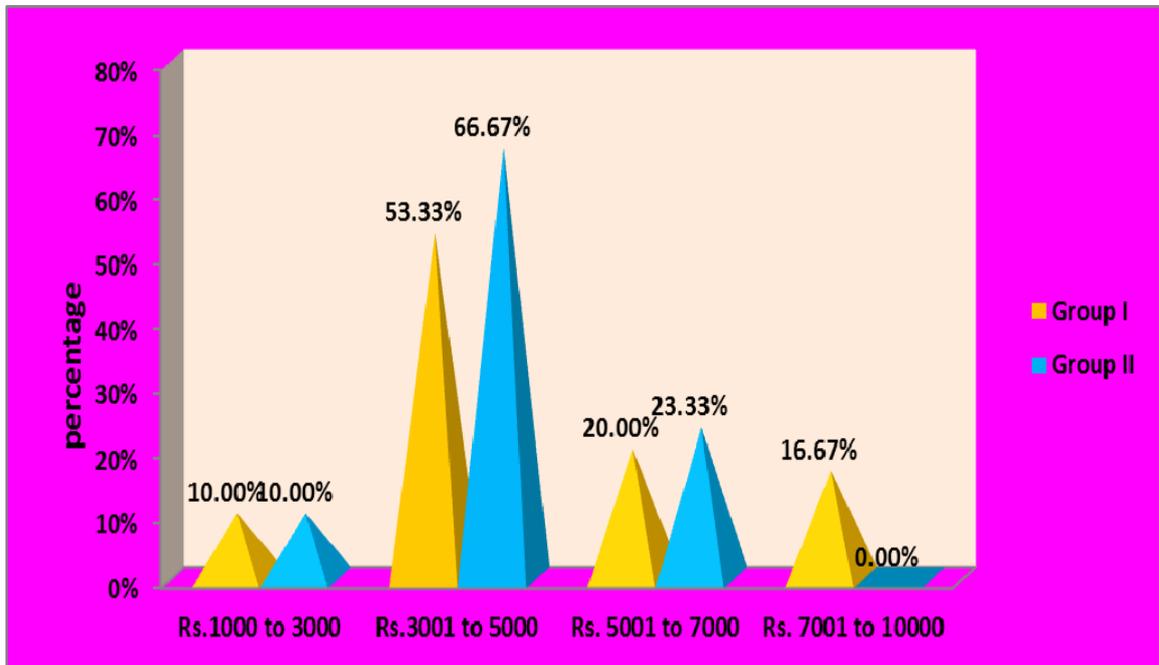
### Distribution of subject according to residential area



**Figure 4: Multiple cylinder diagram depicts that distribution of children undergoing chemotherapy according to their residential area**

The above cylinder diagram shows that in group I, majority of the subjects 17 (56.67%) hailed from semi urban area, 7 (23.33%) hailed from urban, 6 (20.00%) hailed from rural, In group II, 16 (53.33%) hailed from semi urban area ,9 (30.00%) hailed from rural, 5 (16.67%) hailed from urban.

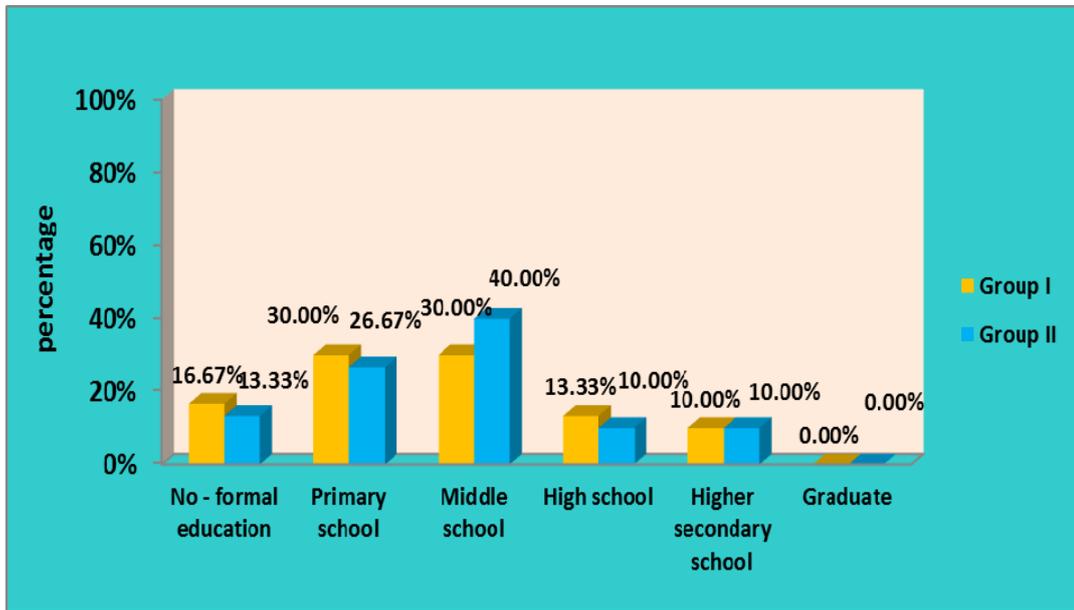
### Distribution of subjects according to family income



**Figure 5: multiple pyramid diagram comparing that distribution of children undergoing chemotherapy according to their family income**

Above pyramid diagram shows that in group I, majority of the subjects 16 (53.33%) were earned between Rs.3000 -5000, 6 (20%) were earned between Rs.5001- 7000, 5 (16.67) were earned between Rs.7001 -10000, 3 (10.00%) were earned between Rs.1000 to 3000. In group II, 20 (80%) were earned between Rs.3001 -5000, 7 (23.33%) were earned between Rs.5001- 7000, 3 (10.00%) were earned between income of Rs.1000 -3000 and none of them were earned between Rs.7001 -10000.

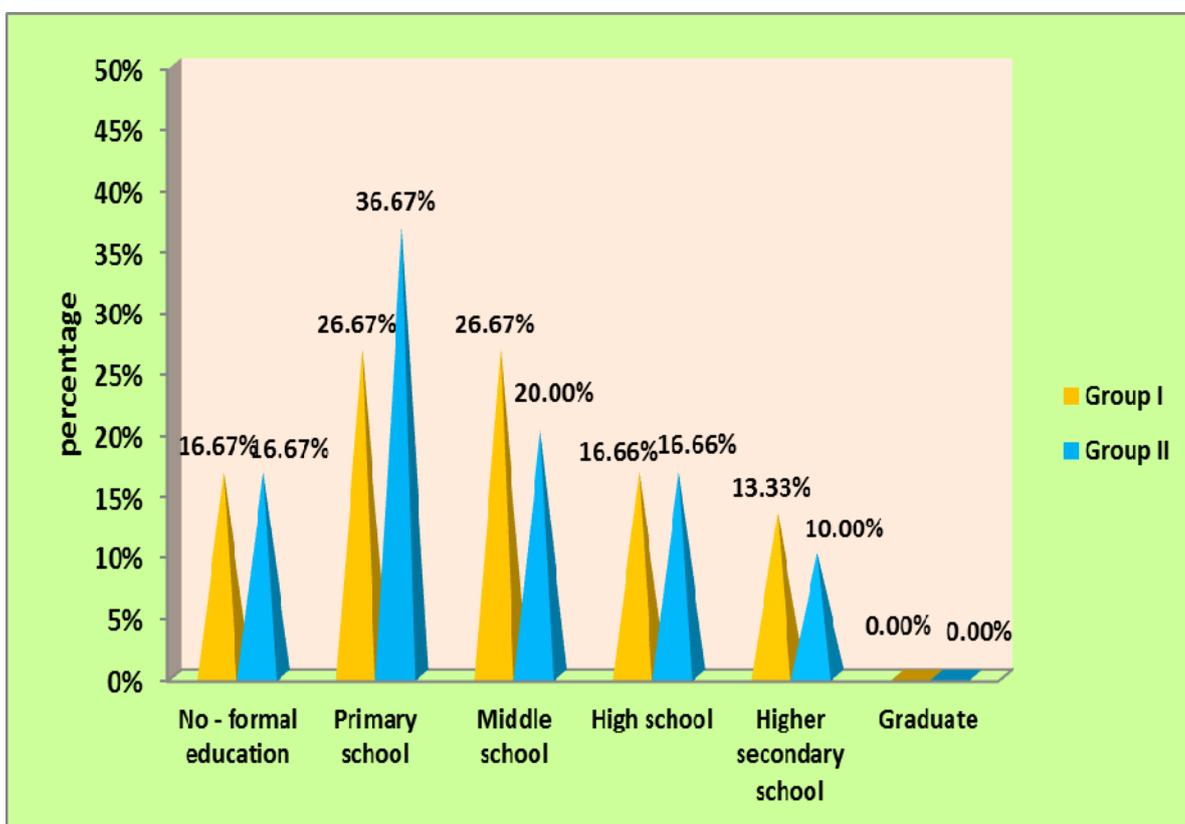
### Distribution of subjects according to mother's educational status



**Figure 6: Multiple bar diagram discussing that distribution of children undergoing chemotherapy according to their mother's educational status**

The above bar diagram shows that in group I, majority of the subjects, 9 (30%) studied up to primary school and middle school, 5 (16.67%) had no formal education, 4 (13.33) studied up to High school, 3(10.00%) studied up to higher secondary and none of them had graduates. In group II, 12 (40.00. %) studied up to middle school, 8 (26.67%) studied up to primary school, 4 (13.33%) had no formal education, 3 (10.00%) studied up to High school, 3 (10.00%) studied up to higher secondary and none of them had graduates.

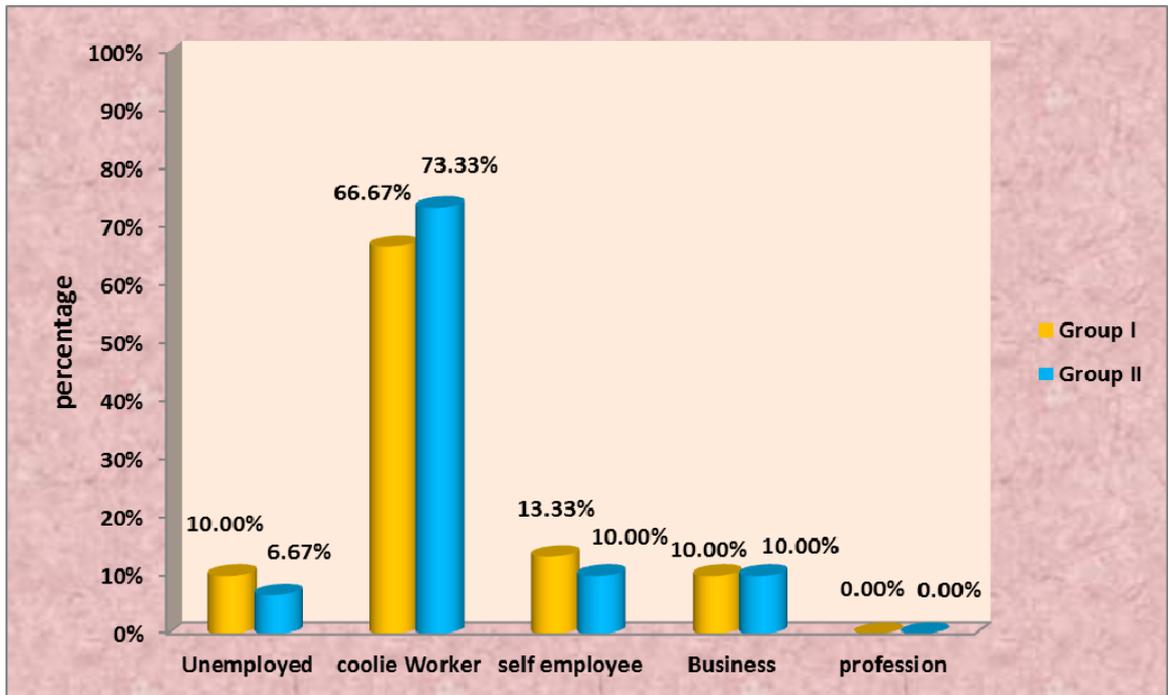
### Distribution of subjects according to father's educational status



**Figure 7: Pyramid diagram discussing that distribution of children undergoing chemotherapy according to their father's educational status.**

The above pyramid diagram shows that in in group I, majority of the subjects 8 (26.67%) studied up to primary school, 8 (26.67%) studied up to middle school, 5 (16.67%) had no formal education, 5 (16.67%) had studied up to high school, 4 (13.33%) studied up to higher secondary and none of them had graduates. In group II, 11 (36.67%) studied up to primary school, 6 (20.00%) studied up to middle school education, 5(16.67%) no formal education, 5 (16.67%) studied up to high school, 3 (10.00%) studied up to higher secondary and none of them had graduates.

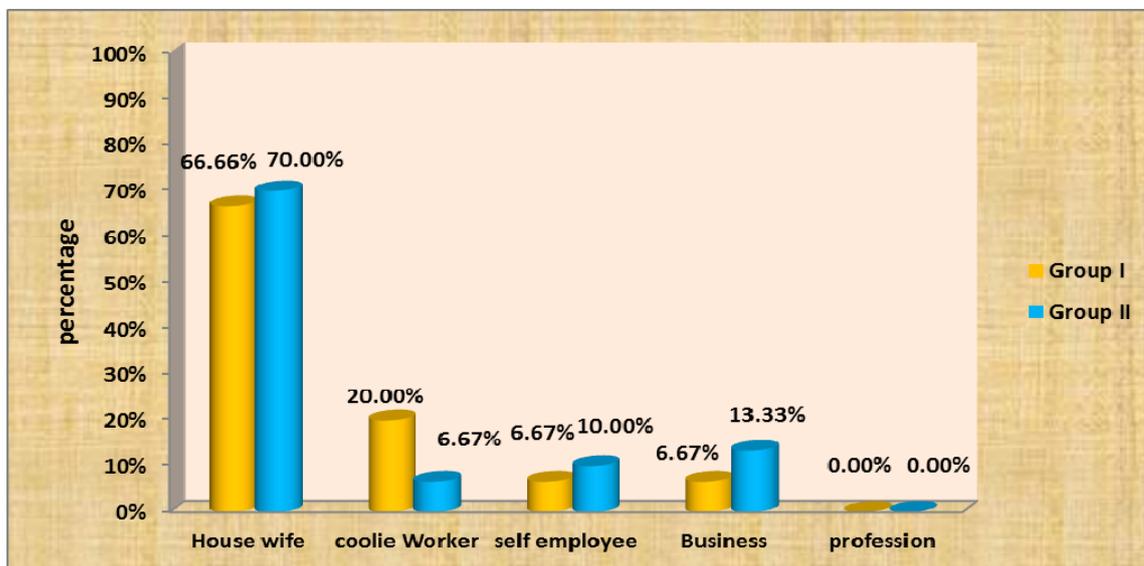
### Distribution of subjects according to father's occupation



**Figure 8: multiple cylindrical diagram stating that distribution of children undergoing chemotherapy according to their father's occupation**

The above Cylindrical diagram shows that in group I, majority 20 (66.67%) were coolie, 4 (13.33%) were self-employee, 3 (10.00%) were unemployed, 3 (10.00%) father were business and none of them were in professional job. In group II, 22 (73.33%) were coolie, 3 (10.00%) were self-employee, 2 (6.67%) were unemployed, 3 (10.00%) were business and none of them were in professional job.

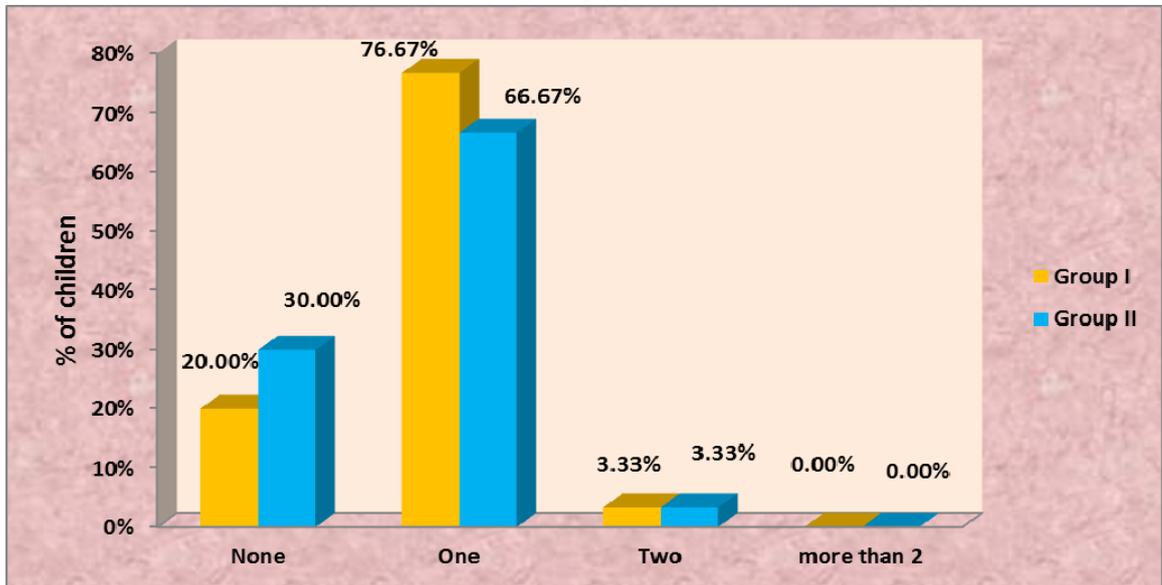
### Distribution of subjects according to mother's occupation



**Figure 9: multiple cylindrical diagram stating that distribution of children undergoing chemotherapy according to their mother's occupation**

The above Cylindrical diagram shows that in group I, majority 20 (66.66%) were house wife, 6 (20.00%) were coolie, 2(6.67%) were self-employee, 2 (6.67%) mother were business and none of them were in professional job. In group II, 21 (70.00%) were house wife, 2 (6.67%) were coolie, 3 (10.00%) were self-employee, 4 (13.33%) mother were business and none of them were in professional work.

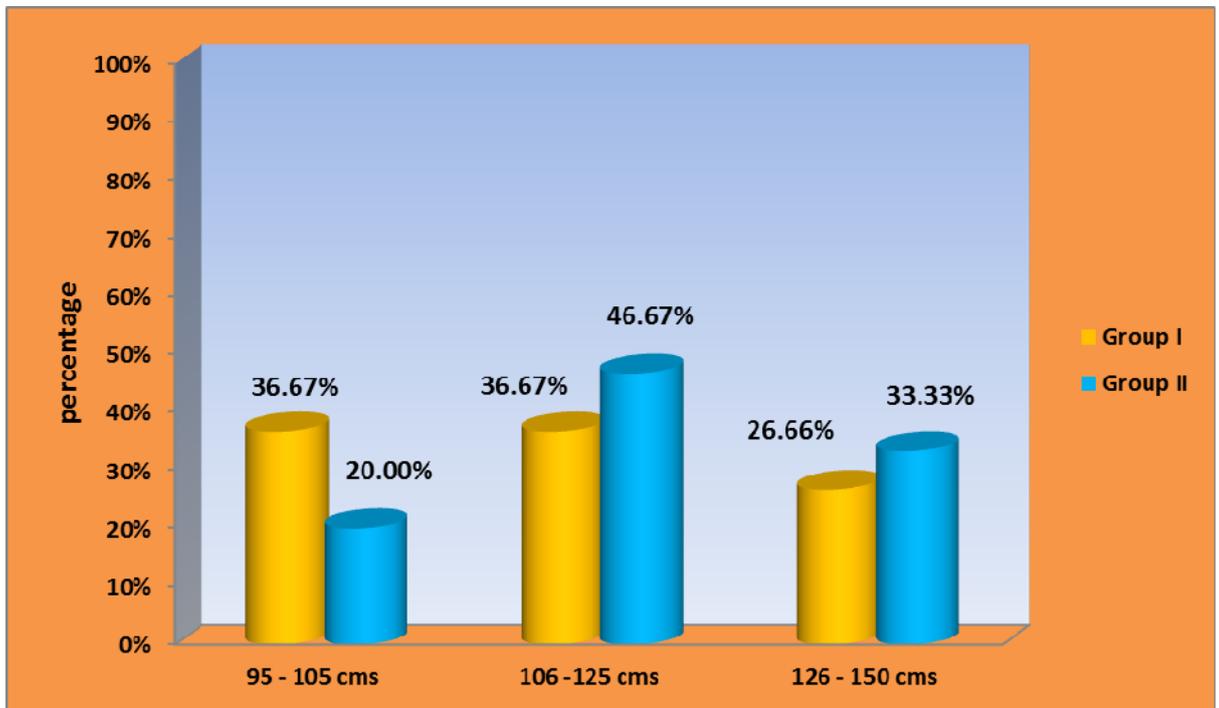
### Distribution of subjects according to number of siblings



**Figure 10: multiple bar diagram considering that distribution of children undergoing chemotherapy according to their number of siblings**

Above multiple bar shows that in group I, majority of the subjects, 23 (76.67%) had 1 sibling, 6 (20.00%) had no siblings, 1 (3.33%) had 2 siblings and no one had more than 2 siblings. In group II, 20 (66.67%) had 1 sibling, 9 (30%) had no siblings, 1 (3.33%) had 2 siblings and no one had more than 2 siblings.

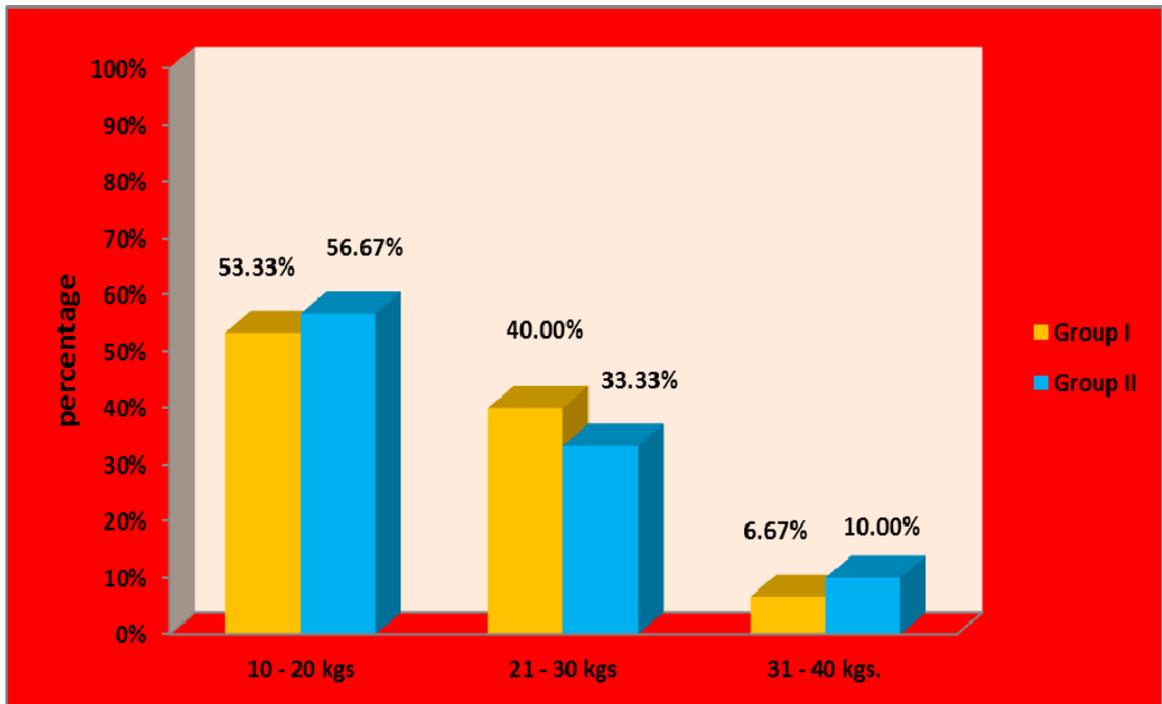
### Distribution of subjects according to height



**Figure 11: multiple cylindrical diagram explains that distribution of children undergoing chemotherapy according to their height**

Above Cylindrical diagram shows that in group I, majority of the subjects 11 (36.67%) were had between 95 -105 cms, 11 (36.67%) were had between 106 -125 cms, 8 (26.66%) were had between 126 -150 cms. In group II, 14 (46.67%) were had between 106 -125 cms, 10 (33.33%) were had between 126 -150 cms, 6 (20.00%) were had between 95 -105 cms.

### Distribution of subjects according to weight



**Figure 12: multiple bar diagram explains that distribution of children undergoing chemotherapy according to their weight**

Above multiple bar diagram shows that in group I, majority of the subjects 16 (53.33%) were had 10 -20 kgs, 12 (40%) were had 21 -30 kgs , 2 (6.67%) were had 31- 40 kgs. In group II, 17 (56.67%) were had 10 -20 kgs, 10 (33.33%) were had 21 - 30 kgs , 3 (10.00%) were had 31 -40 kgs.

**Table 2: Frequency and percentage distribution of children undergoing Chemotherapy according to their selected clinical variables**

**n=60**

Clinical variables		Group				$\chi^2$
		Group I(n=30)		Group II(n=30)		
		f	%	f	%	
<b>Type of cancer</b>	ALL/CLL	27	90.00%	29	96.67%	$\chi^2=1.40$ P=0.49 NS
	AML /CML	2	6.67%	1	3.33%	
	NHL/ HL	1	3.33%	0	0.00%	
	Other type of cancer	0	0.00%	0	0.00%	
<b>Duration of illness</b>	Below 6 months	7	23.33%	7	23.33%	$\chi^2=1.51$ P=0.46 (NS)
	1 to 2 years	18	60.00%	21	70.00%	
	2 to 3 years	5	16.67%	2	6.67%	
	more than 3 years	0	0.00%	0	0.00%	
<b>Type of chemotherapy</b>	Single drug regimen	0	0.00%	0	0.00%	$\chi^2=0.00$ P=1.00 (NS)
	Two drug regimen	1	3.33%	1	3.33%	
	More than two drug regimen	29	96.67%	29	96.67%	
<b>Number of cycles for chemotherapy</b>	1st Cycle	7	23.33%	7	23.33%	$\chi^2=0.00$ P=1.00 (NS)
	2nd Cycle	15	50.00%	15	50.00%	
	3rd Cycle	8	26.67%	8	26.67%	
	more than 3 cycle.	0	0.00%	0	0.00%	
<b>Occurrence of mucositis</b>	Newly occurred	8	26.67%	9	30.00%	$\chi^2=0.73$ P=0.69 (NS)
	occured once and treated	18	60.00%	15	50.00%	
	occured twice and treated	4	13.33%	6	20.00%	
	occured but not treated	0	0.00%	0	0.00%	
<b>Oral hygiene followed by the child</b>	Brushes once daily	28	93.33%	27	90.00%	$\chi^2=0.21$ P=0.64 (NS)
	Brushes twice daily	2	6.67%	3	10.00%	
	Brushes with mouth wash	0	0.00%	0	0.00%	

Table 2 explains the distribution of children according to their clinical variables. While mentioning the type of cancer in group I children, majority of subjects 27 (90.00%) were had ALL/CLL, 2 (6.67%) were had AML/CML, 1 (3.33%)

were had NHL/HL. In group II, 29 (96.67%) were had ALL/CLL, 1 (3.33%) were had AML/CML, none of them were had in NHL/HL.

While depicting the duration of illness in group I, majority of subjects 18 (60.00%) had 1 to 2 years ,7 (23.33%) had less than 6 months, 5 (16.67%) had 2 to 3 years and none of them had more than 3 years of duration. In group II, 21 (70.00%) had 1 to 2 years, 7 (23.33%) had less than 6 months, 2 (6.67%) had 2 to 3 years and none of them had more than 3 years of duration.

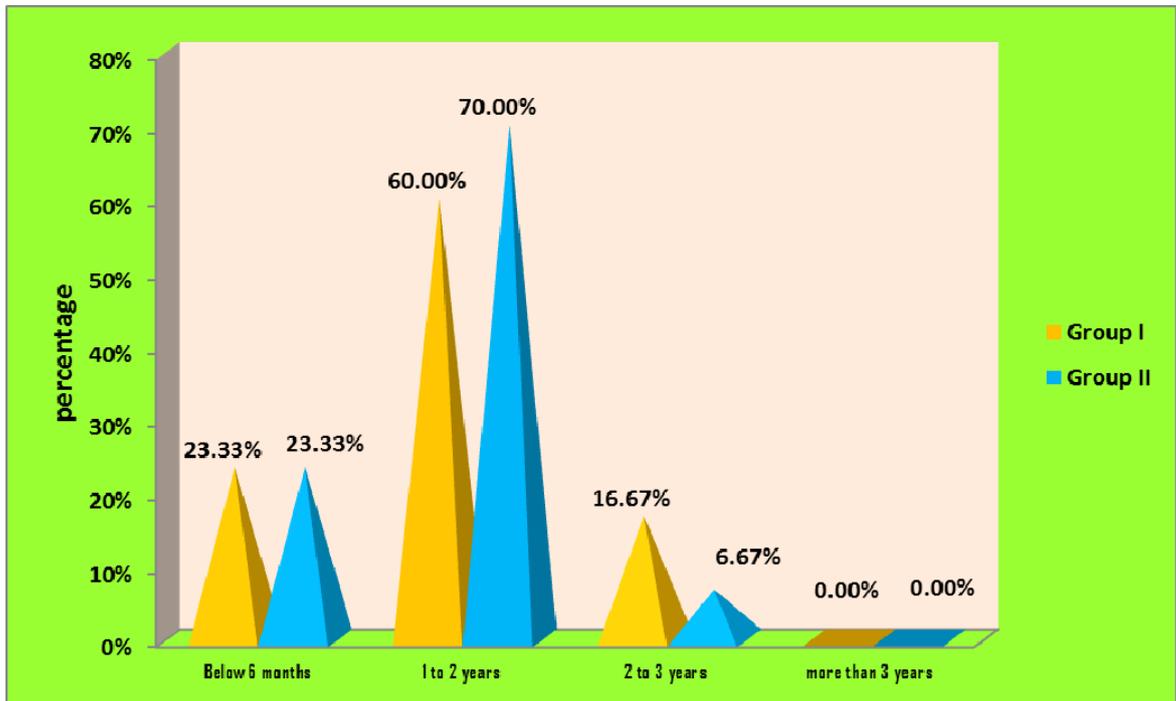
While denoting the type of chemotherapy in group I, majority 29 (96.67%) had more than two drug regimen, 1 (3.33%) had two drug regimen and none of them had single drug regimen. In group II, 29 (96.67%) had more than two drug regimen, 1 (3.33%) had two drug regimen and none of them had single drug regimen.

Regarding Number of cycles for chemotherapy in group I, majority 15 (50%) were in 2nd cycle, 8 (26.67) were in 3rd cycle, 7 (23.33%) were in 1st cycle and none of them were in more than 3 cycle. In group II, 15 (50%) were in 2nd cycle, 8 (26.67) were in 3rd cycle, 7 (23.33%) were in 1st cycle and none of them were in more than 3 cycle.

While stating the occurrence of oral mucositis in group I, majority of subjects 18 (60.00%) were occurred once and treated, 8 (26.67) were newly occurred mucositis, 4 (13.33%) were occurred twice and treated and none of them were occurred but not treated. In group II, 15 (50%) were occurred once and treated, 9 (30.00%) were newly occurred, 6 (20.00%) were occurred twice and treated and none of them had and treated.

On the basis of oral hygiene in group I, majority of subjects 28 (93.33%) were doing brushes once a day, 2 (6.67%) were doing brushes twice daily and none of them were doing brushes with mouthwash. In group II, 27 (90%) were doing brushes once a day, 3(10.00%) were doing brushes twice daily and none of them were doing brushes with mouthwash.

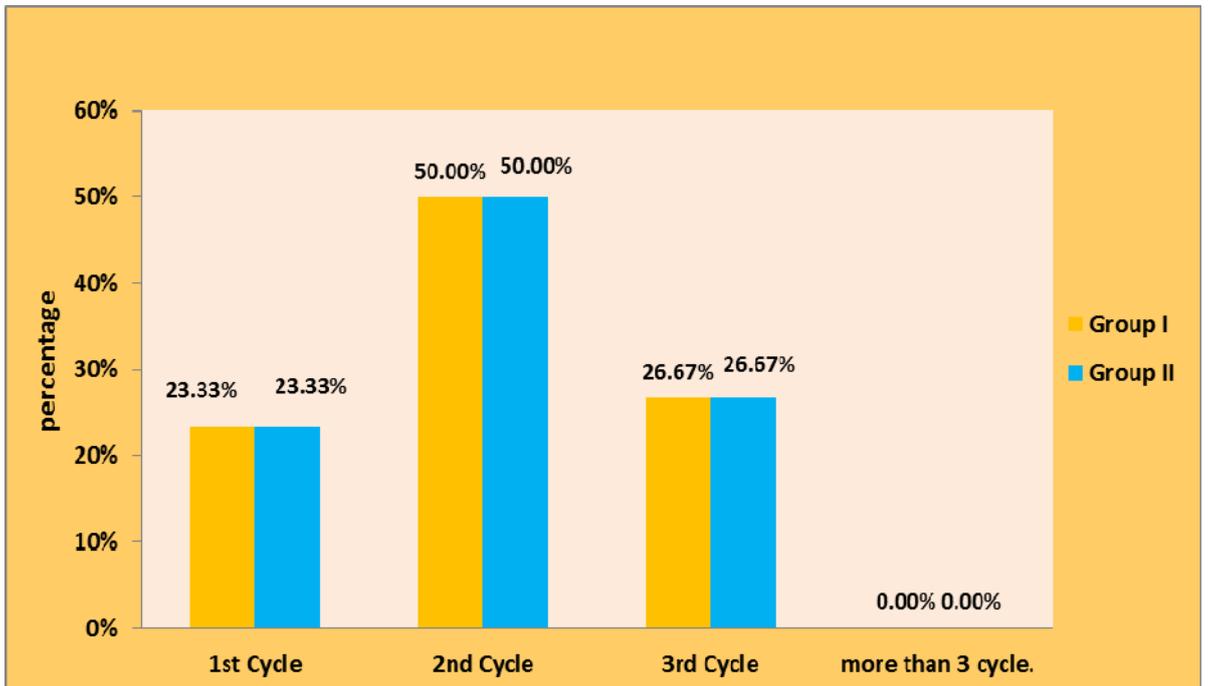
### Distribution of subjects according to duration of illness



**Figure 13: pyramid diagram depicts that distribution of children undergoing chemotherapy according to their duration of illness**

Above multiple pyramid diagram shows that in group I, majority of subjects 18 (60.00%) had 1 to 2 years, 7 (23.33%) had less than 6 months, 5 (16.67%) had 2 to 3 years and none of them had more than 3 years of duration. In group II, 21 (70.00%) had 1 to 2 years, 7 (23.33%) had less than 6 months, 2 (6.67%) had 2 to 3 years and none of them had more than 3 years of duration.

### Distribution of children according to number of cycles for chemotherapy



**Figure 14: Multiple bar diagram regarding that distribution of children undergoing chemotherapy according to their number of cycles for chemotherapy**

Above multiple bar diagram shows that in group I, majority 15 (50%) were in 2nd cycle, 8 (26.67) were in 3rd cycle, 7 (23.33%) were in 1st cycle and none of them were in more than 3 cycle. In group II, 15 (50%) were in 2nd cycle, 8 (26.67) were in 3rd cycle, 7 (23.33%) were in 1st cycle and none of them were in more than 3 cycle.

## SECTION II

### Distribution of pre test level of oral mucositis among children undergoing chemotherapy in group I and group II

**Table - 3**

**Frequency and percentage distribution of pre test level of oral mucositis among children undergoing chemotherapy in Group I and Group II**

n=60

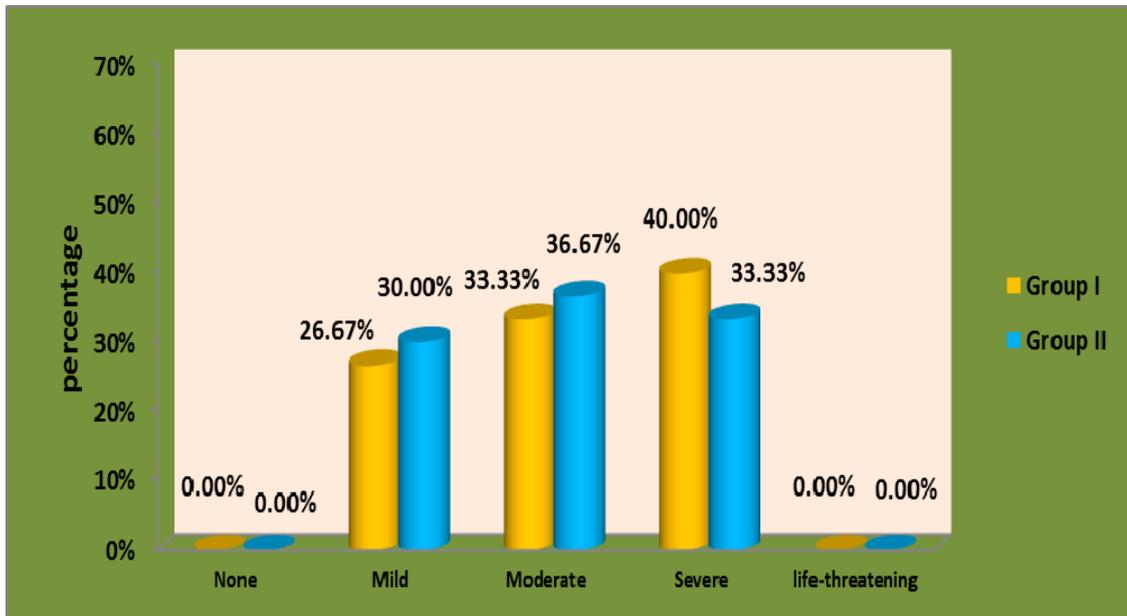
Level of oral mucositis	Group				$\chi^2$
	Group I		Group II		
	f	%	f	%	
None	0	0.00%	0	0.00%	$\chi^2=0.28$ P=0.87(NS)
Mild	8	26.67%	9	30.00%	
Moderate	10	33.33%	11	36.67%	
Severe	12	40.00%	10	33.33%	
life-threatening	0	0.00%	0	0.00%	
<b>Total</b>	<b>30</b>	<b>100.00%</b>	<b>30</b>	<b>100.00%</b>	

The above table 3 reveals distribution of children according to the pre test level of oral mucositis in Group I and group II.

In Group I, majority 12 (40.00%) had severe level of oral mucositis, 10 (33.33%) had moderate level of oral mucositis, remaining 8 (26.67%) had mild level of oral mucositis and none of them had no or life-threatening oral mucositis. Whereas in the Group II, majority 11(36.67%) had moderate level of oral mucositis, 10 (33.33%) had severe level of oral mucositis, remaining 9 (30.00%) had mild level of oral mucositis and none of them had no or life-threatening level of oral mucositis.

Chi- square test reveals that, there is no significant difference between Group I and Group II.

### Pre test level of oral mucositis in group I and group II



**Figure 15: cylindrical diagram shows that pre test level of oral mucositis among Children undergoing chemotherapy in Group I and Group II**

Above Cylindrical diagram denoting the pre test level of oral mucositis among Children undergoing chemotherapy in Group I, majority 12 (40.00%) had severe level of oral mucositis, 10 (33.33%) had moderate level of oral mucositis, remaining 8 (26.67%) had mild level of oral mucositis and none of them had no or life-threatening oral mucositis. Whereas in the Group II, majority 11(36.67%) had moderate level of oral mucositis, 10 (33.33%) had severe level of oral mucositis, remaining 9 (30.00%) had mild level of oral mucositis and none of them had no or life-threatening oral mucositis.

Chi- square test reveals that, there is no significant difference between Group I and Group II.

### SECTION III

**Effectiveness of sodium bicarbonate mouthwash and chlorhexidine mouthwash on oral mucositis among children undergoing chemotherapy in group I and group II.**

**Table-4**

**Pre test and post test level of oral mucositis among children undergoing chemotherapy in group I**

**n = 30**

Level of oral mucositis	Group I				$\chi^2$
	Pre test		Post test		
	f	%	f	%	
None	0	0.00%	20	66.67%	$\chi^2=27.22$ P=0.001*** (S)
Mild	8	26.67%	10	33.33%	
Moderate	10	33.33%	0	0.00%	
Severe	12	40.00%	0	0.00%	
life-threatening	0	0.00%	0	0.00%	
Total	30	100.00%	30	100.00%	

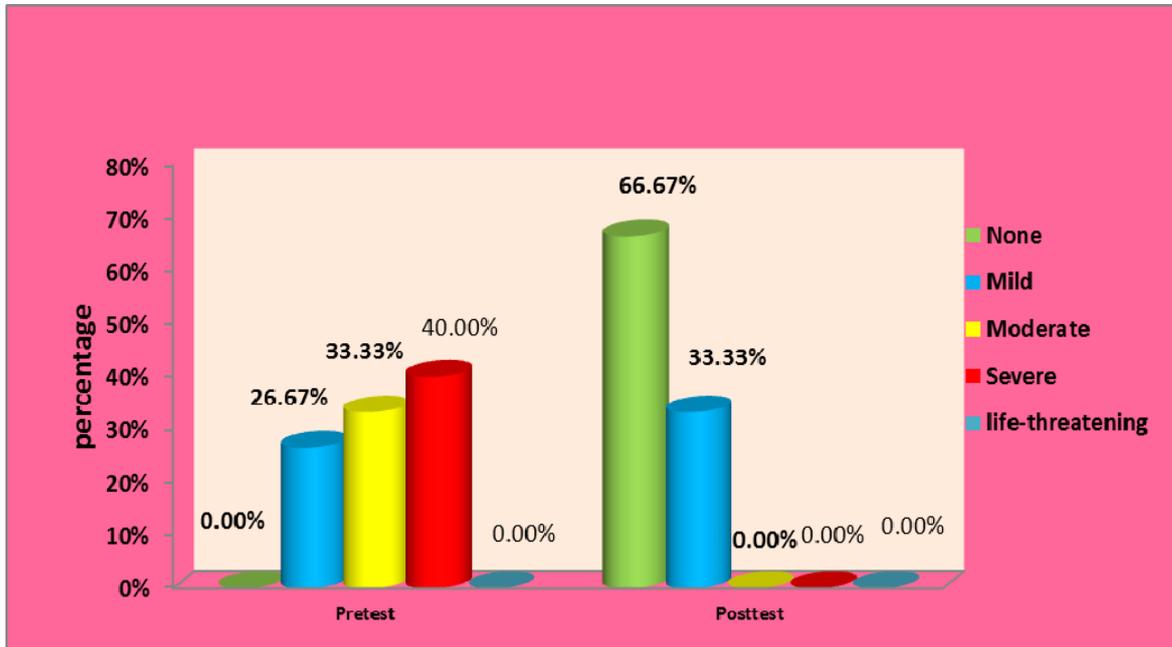
S= significant \*\*\* P<0.001 very high significant

Above table 4 reveals the comparison of pre test and post test level oral mucositis score among children undergoing chemotherapy in group I.

In Pre test, majority 12 (40.00%) had severe level of oral mucositis, 10 (33.33%) had moderate level of oral mucositis , remaining 8 (26.67%) had mild level of oral mucositis and none of them had no or life-threatening oral mucositis.. Whereas in the post test majority 20 (66.67%) had no oral mucositis, remaining 10 (33.33%) had mild level of oral mucositis and none of them had moderate or severe or life-threatening level of oral mucositis

Generalized McNemar's test was done to find out difference between pre test and post test level of oral mucositis in group I. The  $\chi^2= 27.22$  was greater than table value, which was significant at 0.001 level.

### Pre test and post test level of oral mucositis in Group I



**Figure 16:** cylindrical diagram shows that Pre test and Post test level of oral mucositis in Group I

Above Cylindrical diagram shows that, in pre test, majority 12 (40.00%) had severe level of oral mucositis, 10 (33.33%) had moderate level of oral mucositis, remaining 8 (26.67%) had mild level of oral mucositis and none of them had no or life-threatening oral mucositis. Whereas in the post test majority 20 (66.67%) had no oral mucositis, remaining 10 (33.33%) had mild level of oral mucositis and none of them had moderate or severe or life-threatening level of oral mucositis

Generalized McNemar's test was done to find out difference between pre test and post test level of oral mucositis in group I. The  $\chi^2 = 27.22$  was greater than table value, which was significant at 0.001 level.

**Table 5: Pre test and post test level of oral mucositis among children undergoing chemotherapy in group II**

**n = 30**

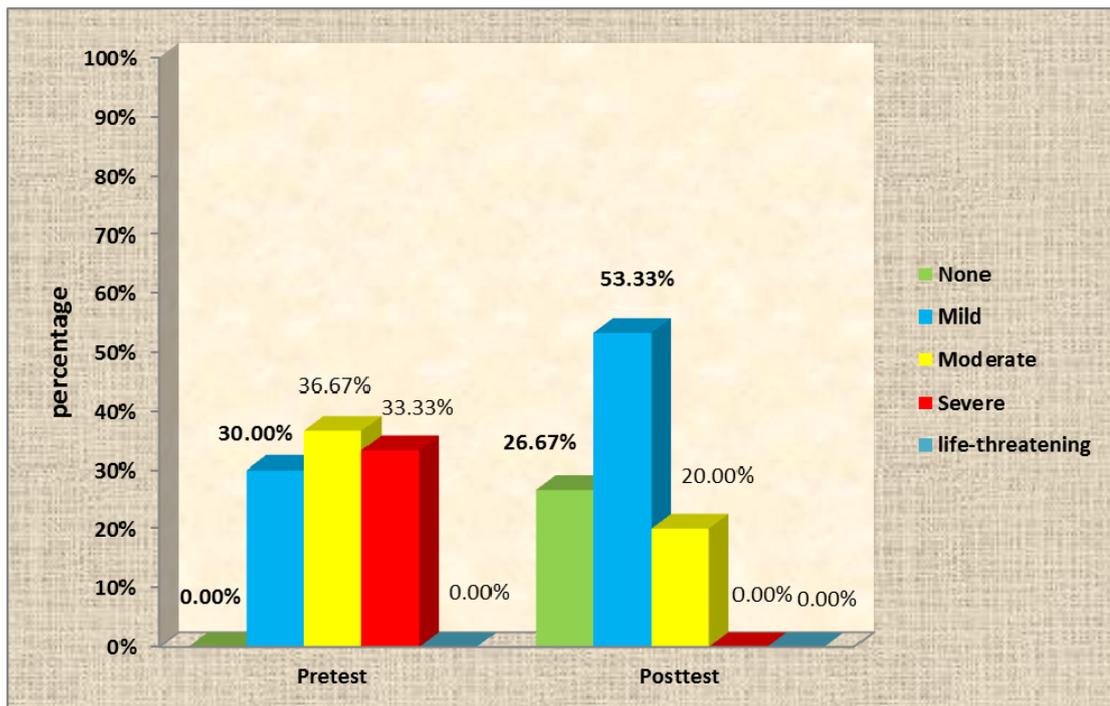
Level of oral mucositis	Group II				$\chi^2$
	Pre test		Post test		
	f	%	f	%	
None	0	0.00%	8	26.67%	$\chi^2=19.09$ P=0.001***(S)
Mild	9	30.00%	16	53.33%	
Moderate	11	36.67%	6	20.00%	
Severe	10	33.33%	0	0.00%	
life-threatening	0	0.00%	0	0.00%	
Total	30	100.00%	30	100.00%	

S= significant \*\*\* P<0.001 very high significant

Above table 5 shows the comparison of pre test and post test level of oral mucositis among children undergoing chemotherapy in group II.

In pre test, majority 11(36.67%) had moderate level of oral mucositis, 10 (33.33%) had severe level of oral mucositis, remaining 9 (30.00%) had mild level of oral mucositis and none of them had no or life-threatening oral mucositis. Whereas in the post test 16 (53.33%) had mild level of oral mucositis, 8 (26.67%) had no oral mucositis, 6 (20.00%) had moderate level of oral mucositis and none of them had severe or life-threatening level of oral mucositis. Generalized McNemar's test was done to find out difference between pre test and post test level of oral mucositis. The  $\chi^2 = 19.09$  was greater than table value, which was significant at 0.001 level.

### Pre test and Post test level of oral mucositis in Group II



**Figure 17: multiple bar diagram shows that pre test and post test level of oral mucositis in Group II**

Above multiple bar diagram shows that, In pre test, majority 11(36.67%) had moderate level of oral mucositis, 10 (33.33%) had severe level of oral mucositis, remaining 9 (30.00%) had mild level of oral mucositis and none of them had no or life-threatening oral mucositis. Whereas in the post test 16 (53.33%) had mild level of oral mucositis, 8 (26.67%) had no oral mucositis, 6 (20.00%) had moderate level of oral mucositis and none of them had severe or life-threatening level of oral mucositis

Generalized McNemar's test was done to find out difference between pre test and post test level of oral mucositis. The  $\chi^2 = 19.09$  was greater than table value, which was significant at 0.001 level.

## SECTION IV

**Comparison on post test level of oral mucositis among children undergoing chemotherapy in group I and group II.**

**Table -6**

**Distribution of subjects according to their post level of oral mucositis in group I and group II.**

**n=60**

Level of oral mucositiis	Group				$\chi^2$
	Group I		Group II		
	f	%	f	%	
None	20	66.67%	8	26.67%	$\chi^2=12.52$ P=0.01**(S)
Mild	10	33.33%	16	53.33%	
Moderate	0	0.00%	6	20.00%	
Severe	0	0.00%	0	0.00%	
life-threatening	0	0.00%	0	0.00%	
Total	30	100.00%	30	100.00%	

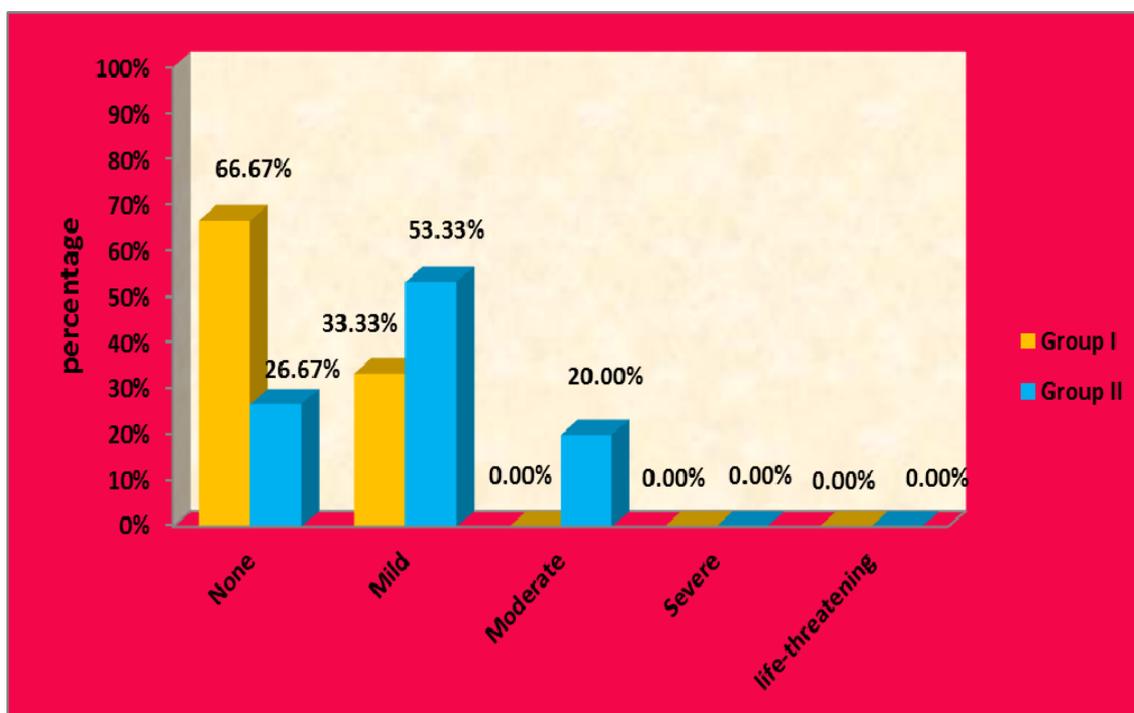
S= significant \*\* P=0.01\*\*(S)

Above table 6 reveals that, post test level of oral mucositis among children undergoing chemotherapy in group I and group II.

In group I, majority 20 (66.67%) had no oral mucositis, remaining 10 (33.33%) had mild level of oral mucositis and none of them had moderate or severe or life-threatening level of oral mucositis after the intervention of sodium bicarbonate mouthwash. Whereas in the group II, after the intervention of chlorhexidine mouthwash, the post test 16 (53.33%) had mild level of oral mucositis, 8 (26.67%) had no oral mucositis, 6 (20.00%) had moderate level of oral mucositis and none of them had severe or life-threatening level of oral mucositis.

Generalized McNemar's test was done to find out difference between post test level of oral mucositis between group I and group II. The  $\chi^2 = 12.52$  was greater than table value, which was significant at 0.01 level.

### Post test level of oral mucositis in Group I and Group II



**Figure 18: multiple bar diagram shows that Post test level of oral mucositis in Group I and Group II**

Above multiple bar diagram shows that in group I, majority 20 (66.67%) had no oral mucositis, remaining 10 (33.33%) had mild level of oral mucositis and none of them had moderate or severe or life-threatening level of oral mucositis after the intervention of sodium bicarbonate mouthwash. Whereas in the group II, after the intervention of chlorhexidine mouthwash, the post test 16 (53.33%) had mild level of oral mucositis, 8 (26.67%) had no oral mucositis, 6 (20.00%) had moderate level of oral mucositis and none of them had severe or life-threatening level of oral mucositis.

Generalized McNemar's test was done to find out difference between post test level of oral mucositis between group I and group II. The  $\chi^2 = 12.52$  was greater than table value, which was significant at 0.01 level.

**Table 7: Pre test post test Mean, Standard deviation, Mean difference among children undergoing chemotherapy in group I and group II**

<b>Group</b>		<b>n</b>	<b>Mean</b>	<b>SD</b>	<b>Mean difference</b>	<b>% of Mean score</b>	<b>Percentage of mean reduction score</b>	<b>Wilcoxon signed rank test</b>
<b>Group I</b>	<b>Pretest</b>	30	2.13	0.81	1.8	53.3	45.0%	<b>Z= 4.89</b> <b>P=0.001(s)</b>
	<b>Post test</b>		0.33	0.47		8.3		
<b>Group II</b>	<b>Pretest</b>	30	2.03	0.80	1.1	50.8	27.5%	<b>Z= 3.33</b> <b>P=0.001(s)</b>
	<b>Post test</b>		0.93	0.69		23.3		

The above table 7 shows the comparison of Pre test post test Mean on level of oral mucositis among children undergoing chemotherapy in group I and group II.

Considering Group I, the pre test mean score was 2.13 (53.3%) with Standard deviation 0.81 whereas in post test the mean score was 0.33 (8.3%) with Standard deviation 0.47 and the mean difference 1.8 and the calculated Z value 4.89 at 0.001 level.

When comparing in group II, the pre test mean score was 2.03 (50.8%) with standard deviation 0.8 whereas in post test the mean score was 0.93 (23.3%) with standard deviation 0.69 and the mean difference 1.1 and the calculated Z value 3.33 at 0.001 level.

Considering percentage of mean reduction score, Group I were had 45% (Z= 4.89 II) whereas in group II, 27.5 (Z= 3.33). The calculated Z value shows difference between group I and group.

## SECTION V

**Association between the post test level of oral mucositis with their selected socio demographic and clinical variables among children undergoing chemotherapy in group I and group II**

**Table -8**

**Association between the post test level of oral mucositis in group I with their selected socio demographic variables**

n=30

Socio demographic variables		Post test level of oral mucositis						n	$\chi^2$
		Mild		Moderate		Severe			
		f	%	f	%	f	%		
<b>Age</b>	5 to 7 years	6	85.7%	8	14.3%	0	0.0%	14	$\chi^2=6.71$ P=0.03*(S)
	8 to 9 years	8	88.9%	1	11.1%	0	0.0%	9	
	10 to 12 years	6	85.7%	1	14.3%	0	0.0%	7	
<b>Sex</b>	Male child	11	64.7%	6	35.3%	0	0.0%	17	$\chi^2=0.07$ P=0.79 (NS)
	Female child	9	69.2%	4	30.8%	0	0.0%	13	
<b>Religion</b>	Hindu	17	68.0%	8	32.0%	0	0.0%	25	$\chi^2=2.52$ P=0.28 (NS)
	Christian	1	33.3%	2	66.7%	0	0.0%	3	
	Muslim	2	100.0%	0	0.0%	0	0.0%	2	
<b>Residential area</b>	Rural	5	83.3%	1	16.7%	0	0.0%	6	$\chi^2=6.05$ P=0.05*(S)
	Urban	2	28.6%	5	71.4%	0	0.0%	7	
	Semi urban	13	76.5%	4	23.5%	0	0.0%	17	
<b>Type of family</b>	nuclear family	16	66.7%	8	33.3%	0	0.0%	24	$\chi^2=3.00$ P=0.22 (NS)
	joint family	1	33.3%	2	66.7%	0	0.0%	3	
	extended family	3	100.0%	0	0.0%	0	0.0%	3	
<b>Family income</b>	1000 to 3000	1	33.3%	2	66.7%	0	0.0%	3	$\chi^2=2.10$ P=0.55 (NS)
	3001 to 5000	12	75.0%	4	25.0%	0	0.0%	16	
	5001 to 7000	4	66.7%	2	33.3%	0	0.0%	6	
	7001 to 10000	3	60.0%	2	40.0%	0	0.0%	5	

<b>Mother's educational status</b>	No - formal education	4	80.0%	1	20.0%	0	0.0%	5	$\chi^2=3.02$ P=0.55 (NS)
	Primary school	7	77.8%	2	22.2%	0	0.0%	9	
	Middle school	4	44.4%	5	55.6%	0	0.0%	9	
	High school	3	75.0%	1	25.0%	0	0.0%	4	
	Higher secondary school	2	66.7%	1	33.3%	0	0.0%	3	
	Graduate	0	0.0%	0	0.0%	0	0.0%	0	
<b>Father's educational status</b>	No - formal education	4	80.0%	1	20.0%	0	0.0%	5	$\chi^2=3.56$ P=0.46 (NS)
	Primary school	5	62.5%	3	37.5%	0	0.0%	8	
	Middle school	4	50.0%	4	50.0%	0	0.0%	8	
	High school	3	60.0%	2	40.0%	0	0.0%	5	
	Higher secondary school	4	100.0%	0	0.0%	0	0.0%	4	
	Graduate	0	0.0%	0	0.0%	0	0.0%	0	
<b>Father's occupation</b>	Unemployed	3	100.0%	0	0.0%	0	0.0%	3	$\chi^2=2.02$ P=0.56 (NS)
	Coolie	13	65.0%	7	35.0%	0	0.0%	20	
	Self employee	2	50.0%	2	50.0%	0	0.0%	4	
	Business	2	66.7%	1	33.3%	0	0.0%	3	
	Profession	0	0.0%	0	0.0%	0	0.0%	0	
<b>Mother's occupation</b>	House wife	14	70.0%	6	30.0%	0	0.0%	20	$\chi^2=5.10$ P=0.16 (NS)
	Coolie	4	66.7%	2	33.3%	0	0.0%	6	
	Self-employee	0	0.0%	2	100.0%	0	0.0%	2	
	Business	2	100.0%	0	0.0%	0	0.0%	2	
	Profession	0	0.0%	0	0.0%	0	0.0%	0	
<b>No of siblings</b>	None	3	50.0%	3	50.0%	0	0.0%	6	$\chi^2=3.29$ P=0.19 (NS)
	One	17	73.9%	6	26.1%	0	0.0%	23	
	Two	0	0.0%	1	100.0%	0	0.0%	1	
	more than 2	0	0.0%	0	0.0%	0	0.0%	0	
<b>Height of the child</b>	95 - 105 cms	6	54.5%	5	45.5%	0	0.0%	11	$\chi^2=4.61$ P=0.09 (NS)
	106 -125 cms	10	90.9%	1	9.1%	0	0.0%	11	
	126 - 150 cms	4	50.0%	4	50.0%	0	0.0%	8	
<b>Weight of the child</b>	10 - 20 kgs	11	68.8%	5	31.3%	0	0.0%	16	$\chi^2=1.40$ P=0.49 (NS)
	21 - 30 kgs	7	58.3%	5	41.7%	0	0.0%	12	
	31 - 40 kgs.	2	100.0%	0	0.0%	0	0.0%	2	

The above table 8 depicts that there is a significant association between the post test level of oral mucositis with their selected socio demographical variables among children undergoing chemotherapy in group I. Chi square test reveals that, there was a significant association between the level of oral mucositis and the age of the children ( $\chi^2=6.71$ ) (P=0.03), Residential area ( $\chi^2=6.05$ ) (P=0.05) at 0.05 level (i-e) 5 to 7 years of children and rural children. All other socio demographic variables were not statistically associated with post test level of oral mucositis.

**Table 9: Association between the post test level of oral mucositis in Group I with their selected clinical variables**

Clinical variables		Level of oral mucositis						n	$\chi^2$
		None		Mild		Moderate			
		f	%	f	%	f	%		
<b>Type of cancer</b>	ALL/CLL	19	70.4%	8	29.6%	0	0.0%	27	$\chi^2=2.41$ P=0.30 (NS)
	AML /CML	1	50.0%	1	50.0%	0	0.0%		
	NHL/ HL	0	0.0%	1	100.0%	0	0.0%		
	Other type of cancer	0	0.0%	0	0.0%	0	0.0%		
<b>Duration of illness</b>	Below 6 months	2	28.6%	5	71.4%	0	0.0%	7	$\chi^2=6.92$ P=0.03 (S)
	1 to 2 years	15	83.3%	3	16.7%	0	0.0%		
	2 to 3 years	3	60.0%	2	40.0%	0	0.0%		
	more than 3 years	0	0.0%	0	0.0%	0	0.0%		
<b>Type of chemotherapy</b>	Single drug regimen	0	0.0%	0	0.0%	0	0.0%	0	$\chi^2=2.06$ P=0.15 (NS)
	Two drug regimen	0	0.0%	1	100.0%	0	0.0%		
	More than two drug regimen	20	69.0%	9	31.0%	0	0.0%		
<b>Number of cycles for chemotherapy</b>	1st Cycle	4	57.1%	3	42.9%	0	0.0%	7	$\chi^2=6.04$ P=0.04*(S)
	2nd Cycle	13	86.7%	2	13.3%	0	0.0%		
	3rd Cycle	3	37.5%	5	62.5%	0	0.0%		
	more than 3 cycle.	0	0.0%	0	0.0%	0	0.0%		
<b>Occurrence of mucositis</b>	freshly occurred	6	75.0%	2	25.0%	0	0.0%	8	$\chi^2=9.25$ P=0.01**(S)
	occurred once and treated	14	77.8%	4	22.2%	0	0.0%		
	occured twice and treated	0	0.0%	4	100.0%	0	0.0%		
	occured but not treated	0	0.0%	0	c0.0%	0	0.0%		
<b>Oral hygiene followed by the child</b>	Brushes once daily	19	67.9%	9	32.1%	0	0.0%	28	$\chi^2=0.26$ P=0.60 (NS)
	Brushes twice daily	1	50.0%	1	50.0%	0	0.0%		
	Brushes with mouth wash	0	0.0%	0	0.0%	0	0.0%		
		0	0.0%	0	0.0%	0	0.0%		

The above table 9 denotes association between post test level of oral mucositis with their selected clinical variables among children undergoing chemotherapy in group I. Chi square test reveals that, there was a significant association between the

level of oral mucositis and the duration of illness ( $\chi^2=6.92$ ) ( $P=0.03$ ), Number of cycles for chemotherapy children ( $\chi^2=6.04$ ) ( $P=0.04$ ), Occurrence of mucositis ( $\chi^2=9.25$ ) ( $P=0.01$ ) at 0.05 level (i-e) **1-2 years duration of illness, children had two cycles of chemotherapy and occurrence of mucositis only once and treated.** All other variables were not statistically associated with post test level of oral mucositis.

**Table 10: Association between the post test level of oral mucositis with their selected socio demographic variables in group II**

**n=30**

Socio demographic variables		Level of oral mucositis						n	$\chi^2$
		None		Mild		Moderate			
		F	%	f	%	f	%		
<b>Age</b>	5 to 7 years	1	7.7%	7	53.8%	5	38.5%	13	$\chi^2=10.52$ <b>P=0.05*(S)</b>
	8 to 9 years	2	22.2%	6	66.7%	1	11.1%	9	
	10 to 12 years	5	62.5%	3	37.5%	0	25.0%	8	
<b>Sex</b>	Male child	5	33.3%	7	46.7%	3	20.0%	15	$\chi^2=0.75$ P=0.68 (NS)
	Female child	3	20.0%	9	60.0%	3	20.0%	15	
<b>Religion</b>	Hindu	8	27.6%	15	51.7%	6	20.7%	29	$\chi^2=0.90$ P=0.63 (NS)
	Christian	0	0.0%	1	100.0%	0	0.0%	1	
	Muslim	0	0.0%	0	0.0%	0	0.0%	0	
<b>Residential area</b>	Rural	4	80.0%	1	20.0%	0	60.0%	5	$\chi^2=9.23$ <b>P=0.05*(S)</b>
	Urban	2	22.2%	5	55.6%	2	22.2%	9	
	Semi urban	2	12.5%	10	62.5%	4	25.0%	16	
<b>Type of family</b>	nuclear family	7	29.2%	12	50.0%	5	20.8%	24	$\chi^2=0.57$ P=0.75 (NS)
	joint family	1	16.7%	4	66.7%	1	16.7%	6	
	extended family	0	0.0%	0	0.0%	0	0.0%	0	
<b>Family income</b>	1000 to 3000	2	66.7%	1	33.3%	0	0.0%	3	$\chi^2=3.53$ P=0.47 (NS)
	3001 to 5000	4	20.0%	12	60.0%	4	20.0%	20	
	5001 to 7000	2	28.6%	3	42.9%	2	28.6%	7	
	7001 to 10000	0	0.0%	0	0.0%	0	0.0%	0	
<b>Mother's educational status</b>	No - formal education	0	0.0%	4	100.0%	0	0.0%	4	$\chi^2=11.38$ P=0.18 (NS)
	Primary school	3	37.5%	3	37.5%	2	25.0%	8	
	Middle school	3	25.0%	7	58.3%	2	16.7%	12	
	High school	0	0.0%	1	33.3%	2	66.7%	3	
	Higher secondary school	2	66.7%	1	33.3%	0	0.0%	3	
	Graduate	0	0.0%	0	0.0%	0	0.0%	0	

<b>Father's educational status</b>	No - formal education	1	20.0%	4	80.0%	0	0.0%	5	$\chi^2=8.38$ P=0.39 (NS)
	Primary school	3	27.3%	6	54.5%	2	18.2%	11	
	Middle school	2	33.3%	1	16.7%	3	50.0%	6	
	High school	1	20.0%	4	80.0%	0	0.0%	5	
	Higher secondary school	1	33.3%	1	33.3%	1	33.3%	3	
Graduate	0	0.0%	0	0.0%	0	0.0%	0		
<b>Father's occupation</b>	Unemployed	0	0.0%	2	100.0%	0	0.0%	2	$\chi^2=7.46$ P=0.28 (NS)
	Coolie	6	27.3%	12	54.5%	4	18.2%	22	
	self-employee	1	33.3%	0	0.0%	2	66.7%	3	
	Business	1	33.3%	2	66.7%	0	0.0%	3	
	Profession	0	0.0%	0	0.0%	0	0.0%	0	
<b>Mother's occupation</b>	House wife	6	28.6%	12	57.1%	3	14.3%	21	$\chi^2=7.93$ P=0.24 (NS)
	Coolie	0	0.0%	1	50.0%	1	50.0%	2	
	self-employee	1	33.3%	0	0.0%	2	66.7%	3	
	Business	1	25.0%	3	75.0%	0	0.0%	4	
	Profession	0	0.0%	0	0.0%	0	0.0%	0	
<b>No of siblings</b>	None	3	33.3%	4	44.4%	2	22.2%	9	$\chi^2=1.21$ P=0.87 (NS)
	One	5	25.0%	11	55.0%	4	20.0%	20	
	Two	0	0.0%	1	100.0%	0	0.0%	1	
	more than 2	0	0.0%	0	0.0%	0	0.0%	0	
<b>Height of the child</b>	95 - 105 cms	2	33.3%	4	66.7%	0	0.0%	6	$\chi^2=2.57$ P=0.63 (NS)
	106 - 125 cms	4	28.6%	6	42.9%	4	28.6%	14	
	126 - 150 cms	2	20.0%	6	60.0%	2	20.0%	10	
<b>Weight of the child</b>	10 - 20 kgs	5	29.4%	9	52.9%	3	17.6%	17	$\chi^2=5.01$ P=0.28 (NS)
	21 - 30 kgs	3	30.0%	6	60.0%	1	10.0%	10	
	31 - 40 kgs.	0	0.0%	1	33.3%	2	66.7%	3	

The above table 10 depicts, association between post test level of oral mucositis with their selected socio demographical variables among children undergoing chemotherapy in group II. Chi square test reveals that, there was a significant association between the level of oral mucositis and the age of the children ( $\chi^2=10.52$ ), (P=0.05), Residential area ( $\chi^2=9.03$ ) (P=0.05) at 0.05 level (i-e) **5 to 7 years of children and children from rural area.** All other variables were not statistically associated with post test level of oral mucositis.

**Table 11: Association between post test level of oral mucositis with their clinical variables in Group II**

Clinical variables		Level of oral mucositis						n	$\chi^2$
		None		Mild		Moderate			
		f	%	f	%	f	%		
<b>Type of cancer</b>	ALL/CLL	8	27.6%	15	51.7%	6	20.7%	9 1 0 0	$\chi^2=0.90$ P=0.64 (NS)
	AML /CML	0	0.0%	1	100.0%	0	0.0%		
	NHL/ HL	0	0.0%	0	0.0%	0	0.0%		
	Other type of cancer	0	0.0%	0	0.0%	0	0.0%		
<b>Duration of illness</b>	Below 6 months	1	14.2%	3	42.8%	3	42.8%	7 21 2 0	$\chi^2=10.23$ P=0.05*(S)
	1 to 2 years	7	33.3%	12	57.1%	2	9.6%		
	2 to 3 years	0	0.0%	1	50.0%	1	50.0%		
	more than 3 years	0	0.0%	0	0.0%	0	0.0%		
<b>Type of chemotherapy</b>	Single drug regimen	0	0.0%	0	0.0%	0	0.0%	0 1 29	$\chi^2=2.84$ P=0.24 (NS)
	Two drug regimen	1	100.0%	0	0.0%	0	0.0%		
	More than two drug regimen	7	24.1%	16	55.2%	6	20.7%		
<b>Number of cycles for chemotherapy</b>	1st Cycle	1	14.3%	4	57.1%	2	28.6%	7 15 8 0	$\chi^2=11.67$ P=0.01** (S)
	2nd Cycle	7	46.7%	8	53.3%	0	20.0%		
	3rd Cycle	0	0.0%	4	50.0%	4	50.0%		
	more than 3 cycle.	0	0.0%	0	0.0%	0	0.0%		
<b>Occurrence of mucosits</b>	Newly occurred	1	11.1%	5	55.6%	3	33.3%	9 15 6 0	$\chi^2=11.18$ P=0.02** (S)
	occured once and treated	7	46.7%	8	53.3%	0	0.0%		
	occured twice and treated	0	0.0%	3	50.0%	3	50.0%		
	occured but not treated	0	0.0%	0	0.0%	0	0.0%		
<b>Oral hygiene followed by the child</b>	Brushes once daily	7	25.9%	15	55.6%	5	18.5%	27 3 0	$\chi^2=0.60$ P=0.74 (NS)
	Brushes twice daily	1	33.3%	1	33.3%	1	33.3%		
	Brushes with mouth wash	0	0.0%	0	0.0%	0	0.0%		

The above table 11 denotes, association between post test level of oral mucositis with their selected clinical variables among children undergoing chemotherapy in group II. Chi square test reveals that, there was a significant association between the level of oral mucositis and the duration of illness ( $\chi^2= 10.23$ ) ( $P=0.05$ ), Number of cycles for chemotherapy children ( $\chi^2= 11.67$ ) ( $P=0.01$ ), Occurrence of mucositis ( $\chi^2= 11.18$ ) ( $P=0.02$ ) at 0.05 level (i-e) **1-2 years duration of illness and had Two cycles of chemotherapy with occurrence of mucositis only once and treated.** All other variables were not statistically associated with post test level of oral mucositis.

# *Discussion*

## CHAPTER – V

### DISCUSSION

The chapter deals to find meaningful answers to research questions, the collected data must be processed, analyzed in an order and coherent fashion, so that patterns and relationship can be discussed.

Based on the objectives of the study and hypotheses, this chapter deals with detailed discussion of the results of the data interpreted from the statistical analysis. The present study was focused to evaluate the effectiveness of sodium bicarbonate mouth wash versus chlorhexidine mouth wash on oral mucositis among children undergoing chemotherapy in hematology oncology ward, Institute of child health and Research center, Govt Rjaji hospital, Madurai.

#### **The objectives of the Study were**

1. To assess the level of the oral mucositis among children undergoing chemotherapy at Government Rajaji hospital, Madurai.
2. To evaluate effectiveness of sodium bicarbonate mouth wash on oral mucositis among children undergoing chemotherapy in group I.
3. To evaluate effectiveness of chlorhexidine mouth wash on oral mucositis among children undergoing chemotherapy in group II.
4. To compare the level of oral mucositis among children undergoing chemotherapy in group I and group II.
5. To associate the level of oral mucositis among children undergoing chemotherapy in group I and group II and their selected socio demographic and clinical variables.

### **The following hypotheses were set for the study**

All the hypotheses were tested at 0.05 level of significance

**H<sub>1</sub>:** There is a significant difference between the pre test and posttest level of oral mucositis among children undergoing chemotherapy in group I.

**H<sub>2</sub>:** There is a significant difference between the pre test and post test level of oral mucositis among children undergoing chemotherapy in group II

**H<sub>3</sub>:** There is a significant difference between the post test level of oral mucositis among children undergoing chemotherapy in group I and group II.

**H<sub>4</sub>:** There is a significant association between the level of oral mucositis among children undergoing chemotherapy in group I, group II and their selected socio demographic variables.

### **The findings of the study were discussed under the following headings**

- Distribution of socio demographic and clinical variables among children undergoing Chemotherapy both in group I and group II.
- Description of pre test level of oral mucositis among children undergoing Chemotherapy in group I and group II.
- Effectiveness of sodium bicarbonate mouthwash and chlorhexidine mouthwash on oral mucositis among children undergoing Chemotherapy in group I and group II.
- Comparison on post test level of oral mucositis among children undergoing chemotherapy in group I and group II.
- Association between the post test level of oral mucositis with their selected socio demographic and clinical variables among children undergoing chemotherapy in group I and group II.

All over the world, the types of cancer that are seen in children are different from those in adults. Leukemia, lymphoma, and brain tumors are the common cancers in children. Acute lymphoid leukemia (ALL) represents approximately 80% of all leukemias affecting children and young adults, and acute myeloid leukemia (AML) is responsible for approximately 15% of cases. Treatment of choice for this cancer is chemotherapy, which may be used together with other therapies. In the last four decades, there has been major progress in the treatment of leukemia and approximately 80% of children and teenagers with early diagnosis may be cured. However, several studies point to anticancer treatment as inducing oral mucositis. Oral mucositis is characterized by erythema, followed by very painful ulcers in oral mucosa, which interfere with nutritional status and quality of life (QL), and may limit or even interrupt anticancer therapy in severe cases.

### **5.1 Discussion based on the socio demographic and clinical variables among children undergoing chemotherapy**

- It is interesting to note that while considering the age in group I, majority of the subjects 14 (46.67%) belongs to the age group between 5 - 7 years. In group II, 13 (43.33%) belongs to the age group between 5 -7 years.
- According to the gender in Group I, majority 17 (56.67%) were male child. In group II, 15(50.00%) were male and female child.
- While stating the religion in group I, majority 25 (83.33%) were Hindu. In group II, 29 (90.67%) were Hindu.
- As far as place of residential area in group I, majority 17 (56.67%) hailed from semi urban area. In group II, 16 (53.33%) hailed from semi urban area.

- With respect of type of family in group I, majority of the subjects 24 (80.00%) belongs to nuclear family. In group II, 24 (80.00%) belongs to nuclear family.
- While comparing the family income in group I, majority 16 (53.33%) were earned between Rs.3000 -5000. In group II, 20 (80%) were earned between Rs.3001 -5000.
- When discussing mother's educational status in group I, majority 9 (30%) studied up to primary school and middle school. In group II, 12 (40.00. %) studied up to middle school.
- When discussing father's educational status in group I, majority 8 (26.67%) studied up to primary school and middle school. In group II, 11 (36.67%) studied up to primary school.
- While stating father's occupation in group I, majority 20 (66.67%) were coolie. In group II, 22 (73.33%) were coolie.
- While stating mother's occupation in group I, majority 20 (66.66%) were house wife. In group II, 21 (70.00%) were house wife.
- Considering the number of siblings in group I, majority 23 (76.67%) had 1 sibling. In group II, 20 (66.67%) had 1 sibling.
- In the aspect of height of the child in group I, majority 11 (36.67%) were had between 95 -105 cms, 11 (36.67%) were had between 106 -125 cms. In group II, 14 (46.67%) were had between 106 -125 cms.
- In the aspect of weight of the child in group I, majority 16 (53.33%) were had 10 -20 kgs. In group II, 17 (56.67%) were had 10 -20 kgs.

- In the aspect of Height in group I, majority 11 (36.67%) were between 95 -105 cms, 11 (36.67%) were between 106 -125 cms. In group II, 14 (46.6%) were between 106 -125 cms .
- In the aspect of weight in group I, majority 16 (53.33%) were 10 -20 kgs, 12 (40%) were 21 -30 kgs. In group II, 17 (56.67%) were 10 -20 kgs, 10 (33.33%) were 21 -30 kgs.
- While mentioning the type of cancer in group I children, majority 27 (90.00%) were had ALL/CLL. In group II, 29 (96.67%) were had ALL/CLL.
- While depicting the duration of illness in group I, majority 18 (60.00%) had 1 to 2 years. In group II, 21 (70.00%) had 1 to 2 years.
- While denoting the type of chemotherapy in group I, majority 29 (96.67%) had more than two drug regimen. In group II, 29 (96.67%) had more than two drug regimen.
- Regarding Number of cycles for chemotherapy in group I, majority 15 (50%) were in 2nd cycle. In group II, 15 (50%) were in 2nd cycle.
- While stating the occurrence of oral mucositis in group I, majority 18 (60.00%) were occurred once and treated. In group II, 15 (50%) were occurred once and treated.
- On the basis of oral hygiene in group I, majority 28 (93.33%) were doing brushes once a day. In group II, 27 (90%) were doing brushes once a day.

## **5.2 Discussion of the study based on its objectives**

**The first objective was to assess the level of the oral mucositis among children undergoing chemotherapy at Government Rajaji hospital, Madurai.**

WHO oral mucositis grading scale was used to assess the level of oral mucositis among children undergoing chemotherapy. In Group I, majority 12 (40.00%) had severe level of oral mucositis, 10 (33.33%) had moderate level of oral mucositis, remaining 8 (26.67%) had mild level of oral mucositis and none of them had no or life-threatening oral mucositis. Whereas in the Group II, majority 11(36.67%) had moderate level of oral mucositis, 10 (33.33%) had severe level of oral mucositis, remaining 9 (30.00%) had mild level of oral mucositis and none of them had no or life-threatening level of oral mucositis.

The study was supported by **ShanthiAppavu, (2007)** conducted a descriptive study about oral complications related to cancer treatment. Out of 118 patients 9 had developed complications. The overall prevalence rate was found to be higher in oncology ward (13.6%) as compared to medical ward (4.2%). The findings revealed that the majority of staff (67.5%) reported they give more importance to oral mucositis. More than one third of the nurses had also reported that they inspect for local infection ( 37.5% ), Xerostomia ( 37.55 ), functional disabilities ( 15.0% ), taste alteration ( 20.0% ) and abnormal dental development ( 10.0% ). As a conclusion there is a great need to educate not only nurses but relatives and the patients to adopt certain preventive strategies to reduce the prevalence of oral complications related to cancer treatment.

**The second objective was to evaluate effectiveness of sodium bicarbonate mouth wash on oral mucositis among children undergoing chemotherapy in group I.**

The intervention sodium bicarbonate mouth wash create a vast difference between the pre test and post test score obtained by children in group I (sodium bicarbonate mouth wash)

In the Pre test, majority 12 (40.00%) had severe level of oral mucositis, 10 (33.33%) had moderate level of oral mucositis, remaining 8 (26.67%) had mild level of oral mucositis and none of them had no or life-threatening oral mucositis. Whereas in the post test majority 20 (66.67%) had no oral mucositis, remaining 10 (33.33%) had mild level of oral mucositis and none of them had moderate or severe or life-threatening level of oral mucositis. Generalized McNemar's test was done to find out difference between pre test and post test level of oral mucositis in group I. The  $\chi^2=27.22$  was greater than table value, which was significant at 0.001 level.

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

study yields the conclusion that given the comparable effectiveness of the mouthwashes, the least costly was salt and soda mouthwash.

**Thus the Hypotheses H<sub>1</sub> - There is a significant difference between the pretest and post test level of oral mucositis among children undergoing chemotherapy in group I was accepted.**

**Third objective was to evaluate effectiveness of chlorhexidine mouth wash on oral mucositis among children undergoing chemotherapy in group II**

The intervention chlorhexidine mouth wash create a vast difference between the pre test and post test score obtained by children in group II (chlorhexidine mouth wash).

In the pre test, majority 11(36.67%) had moderate level of oral mucositis, 10 (33.33%) had severe level of oral mucositis, remaining 9 (30.00%) had mild level of oral mucositis and none of them had no or life-threatening oral mucositis. Whereas in the post test 16 (53.33%) had mild level of oral mucositis, 8 (26.67%) had no oral mucositis, 6 (20.00%) had moderate level of oral mucositis and none of them had severe or life-threatening level of oral mucositis. Generalized McNemar's test was done to find out difference between pre test and post test level of oral mucositis. The  $\chi^2 = 19.09$  was greater than table value, which was significant at 0.001 level.

This study was supported by **Cheng and Chang., (2015)** conducted a randomized 2-period crossover study to compared the efficacy of 0.15% benzydamine and 0.2% chlorhexidine mouthwashes in alleviating the symptoms of oral mucositis in children undergoing chemotherapy at USA . 40 pediatric patients ages 6 to 17 years were randomized into groups receiving 1 of the 2 mouthwashes. Each protocol was started on the first day of chemotherapy and continued for 21 days. Each subject was evaluated at intervals of 3 to 4 days using the WHO scale for mucositis and a 10-cm

visual analog scale to evaluate oral symptoms. Of the 34 patients who were evaluated, 26% of the chlorhexidine group compared to 48% of the benzydamine group showed WHO grade II mucositis ( $p < 0.05$ ). The results revealed a significant difference in mouth pain ( $p < 0.05$ ) and a trend of decreased difficulty in eating/chewing and swallowing in favor of chlorhexidine mouthwash.

**Thus the Hypotheses H<sub>2</sub> - There is a significant difference between the pretest and post test level of oral mucositis among children undergoing chemotherapy in group II was accepted.**

**Fourth objective was to compare the level of oral mucositis among children undergoing chemotherapy in group I and group II.**

The intervention sodium bicarbonate mouthwash and chlorhexidine mouth wash create a vast difference between the post test level among children in group I and group II. In the post test majority 20 (66.67%) had no oral mucositis, remaining 10 (33.33%) had mild level of oral mucositis and none of them had moderate or severe or life-threatening level of oral mucositis in group I. Whereas, in the group II the post test 16 (53.33%) had mild level of oral mucositis, 8 (26.67%) had no oral mucositis, 6 (20.00%) had moderate level of oral mucositis and none of them had severe or life-threatening level of oral mucositis. Generalized McNemar's test was done to find out difference between post test level of oral mucositis between group I and group II. The  $\chi^2 = 12.52$  was greater than table value, which was significant at 0.01 level.

Pre test and post test level of oral mucositis mean score shows in Considering Group I, the pre test mean score was 2.13 (53.3%) with standard deviation 0.81 whereas in post test the mean score was 0.33 (8.3%) with standard deviation 0.47 and the mean difference 1.8 and the calculated Z value 4.89 at 0.001 level.

When comparing in group II, the pre test mean score was 2.03 (50.8%) with standard deviation 0.80 whereas in post test the mean score was 0.93 (23.3%) with standard deviation 0.69 and the mean difference 1.1 and the calculated Z value 3.33 at 0.001 level.

Considering percentage of mean reduction score, Group I were had 45% (Z= 4.89 II) whereas in group II, 27.5 (Z= 3.33). The calculated Z value shows difference between group I and group.

Similar study was done by **Eun Choi .,(2011)** conducted a randomized controlled trial to compare the effectiveness of sodium bicarbonate (SB) solution with chlorhexidine (CHX) mouthwash in oral care of acute leukemia patients under induction chemotherapy at Nambu University, Gwangju, South Korea. Forty-eight patients were randomly selected and assigned to an SB solution group or CHX-based product group according to acute myelogenous leukemia or acute lymphoblastic leukemia. Of all the patients in the SB group, 25.0% developed ulcerative oral mucositis, whereas 62.5% in the CHX group did. As a result of this study, it was found that oral care by SB solution for acute leukemia patients undergoing chemotherapy was an effective intervention to improve oral health. Results showed that chlorhexidine did not significantly reduce incidence of mucositis compared to sodium bicarbonate (P = 0.129).

**Thus the Hypotheses H<sub>3</sub> - There is a significant difference between the post test level of oral mucositis among children undergoing chemotherapy in group I and group II was accepted.**

**Fifth objective was to associate the level of oral mucositis among children undergoing chemotherapy in group I and group II and their selected socio demographic and clinical variables.**

Chi square analysis reveals that there is a significant association between the post test level of oral mucositis and socio demographic variables among children, in group I there was a significant association between the level of oral mucositis and the age of the children ( $\chi^2=6.71$ ) ( $P=0.03$ ), Residential area ( $\chi^2=6.05$ ) ( $P=0.05$ ) at 0.05 level (i-e) 5 to 7 years of children and rural children. Whereas, in group II chi square test reveals that there was a significant association between the level of oral mucositis and the age of the children ( $\chi^2=10.52$ ), ( $P=0.05$ ), Residential area ( $\chi^2=9.03$ ) ( $P=0.05$ ) at 0.05 level (i-e) 5 to 7 years of children and children from rural area.

Chi square analysis reveals that there is a significant association between the post test level of oral mucositis and clinical variables among children in group I, there was a significant association between the level of oral mucositis and the duration of illness ( $\chi^2=6.92$ ) ( $P=0.03$ ), Number of cycles for chemotherapy children ( $\chi^2=6.04$ ) ( $P=0.04$ ), Occurrence of mucositis ( $\chi^2=9.25$ ) ( $P=0.01$ ) at 0.05 level (i-e) 1-2 years duration of illness, children had two cycles of chemotherapy and occurrence of mucositis only once and treated. Whereas in group II, Chi square test reveals that, there was a significant association between the level of oral mucositis and the duration of illness ( $\chi^2= 10.23$ ) ( $P=0.05$ ), Number of cycles for chemotherapy children ( $\chi^2= 11.67$ ) ( $P=0.01$ ), Occurrence of mucositis ( $\chi^2= 11.18$ ) ( $P=0.02$ ) at 0.05 level (i-e) 1-2 years duration of illness and had Two cycles of chemotherapy with occurrence of mucositis only once and treated.

This study was supported by **Ebtissam, Z.MurshidTahani, A.AzizalrahmanAziza, J.AIJohar., (2017)** The purpose of this study was to

determine the incidence and severity of oral mucositis in Saudi children newly diagnosed with Acute lymphoblastic leukemia (ALL) following chemotherapy, and to evaluate the significance of independent risk factors (age, gender, parents' educational level, family income, oral hygiene practices, dietary habits and different chemotherapy regimens) on the development of oral mucositis. Sixty Saudi children newly diagnosed with ALL of both genders, aged (6–14 years) were examined and their parents were interviewed and asked to fill a questionnaire before and within the third week of receiving chemotherapy. The World oral mucositis Health Organization's (WHO) oral toxicity scale was used to record oral mucositis. The prevalence of oral mucositis was 23.3% with a mean age of 8.36 (2.98). 92.9% High risk patients had oral mucositis and 7.1% with Low risk patients. The results showed a highly significant difference between oral hygiene practices before and within the third week of receiving chemotherapy in relation to oral mucositis. Also, there were strong associations between presence of oral mucositis, and frequency of oral hygiene practice in and dietary habits within the third week of receiving chemotherapy. There is a strong correlation between oral hygiene practices and the developmental severity of oral mucositis in ALL children before and during chemotherapy treatment. Oral mucositis severity associated with chemotherapy treatment has a significant effect on the dietary habits of ALL children and the use of different treatment regimens with ALL children is considered to be an important risk factor for the development of oral mucositis.

**Thus the hypotheses H4: There is a significant association between the level of oral mucositis among children undergoing chemotherapy in group I, group II and their selected socio demographic and clinical variables was accepted.**

*Summary,  
Conclusion,  
Implications &  
Recommendations*

## **CHAPTER-VI**

### **SUMMARY, CONCLUSION, IMPLICATIONS AND RECOMMENDATIONS**

This chapter presents the summary of the study and conclusion drawn, clarifies the limitation of the study, the implications and the recommendations, different areas like nursing practice, nursing education, nursing administration and nursing research deserve implication.

#### **6.1 Summary of the study**

The present study was done to evaluate the effectiveness of sodium bicarbonate mouth wash versus chlorhexidine mouth wash on oral mucositis among children undergoing chemotherapy at Government Rajaji hospital Madurai.”

#### **Objectives of the study were**

1. To assess the level of the oral mucositis among children undergoing chemotherapy at Government Rajaji hospital, Madurai.
2. To evaluate effectiveness of sodium bicarbonate mouth wash on oral mucositis among children undergoing chemotherapy in group I.
3. To evaluate effectiveness of chlorhexidine mouth wash on oral mucositis among children undergoing chemotherapy in group II
4. To compare the level of oral mucositis among children undergoing chemotherapy in group I and group II.
5. To associate the level of oral mucositis among children undergoing chemotherapy in group I and group II and their selected socio demographic and clinical variables.

**The following hypotheses were tested at 0.05 level of significance**

**H<sub>1</sub>:** There is a significant difference between the pre test and posttest level of oral mucositis among children undergoing chemotherapy in group I.

**H<sub>2</sub>:** There is a significant difference between the pre test and post test level of oral mucositis among children undergoing chemotherapy in group II.

**H<sub>3</sub>:** There is a significant difference between the post test level of oral mucositis among children undergoing chemotherapy in group I and group II.

**H<sub>4</sub>:** There is a significant association between the level of oral mucositis among children undergoing chemotherapy in group I, group II and their selected socio demographic variables.

**The Study assumptions were**

1. Cancer Children undergoing chemotherapy develops varying level of Oral mucositis
2. Ability to increase salivary pH and suppress the growth of acid uric micro-organisms property of sodium bicarbonate and antiseptic property of chlorhexidine helps in healing of oral mucositis.

The study was conducted in Pediatric hematology oncology ward, institute of child health & research center at Government Rajaji Hospital, Madurai. The conceptual framework adopted was Modified J.W. Kenny's open system model. True-experimental pre test post test design was used. 60 children was selected by probability simple random) sampling. After testing the validity and reliability of tool a pilot study was conducted on 10 non-study subjects. The main study was started from 4.06.18 to 13.07.18. Sodium bicarbonate mouth wash for group I and chlorhexidine mouth wash for group II was given for 5 days. WHO oral mucositis grading scale was used in this study to assess the level of oral mucositis among Children

undergoing chemotherapy, before and after Sodium bicarbonate mouth wash in group I and chlorhexidine mouth wash in group II. Based on the objective and hypotheses the data were analysed by using descriptive and inferential statistics.

The data collection tools consisted of two parts.

### **Section I**

1. **Socio demographic variables** - age, gender, religion, place of residence, educational status of the parents, occupation status of the parents, monthly income. weight, height, number of siblings.
2. **Clinical variables** – type of cancer, duration of illness, type of chemotherapy, number of chemotherapy cycles, occurrence of oral mucositis and oral hygiene.

### **Section II.**

#### WHO oral mucositis grading Scale

<b>Grade</b>	<b>Description</b>
0 (none)	None
I (mild)	Oral soreness, erythema
II (moderate)	Oral erythema, ulcers, solid diet
III (severe)	Oral ulcers, liquid diet only
IV(life-threatening)	Oral alimentation impossible

Content validity of tool was obtained from five of experts in the field of medicine and child Health nursing.

## 6.2 Major findings of the study were

- It is interesting to note that while considering the age in group I, majority of the subjects 14 (46.67%) belongs to the age group between 5 - 7 years. In group II, 13 (43.33%) belongs to the age group between 5 -7 years.
- According to the gender in Group I, majority 17 (56.67%) were male child. In group II, 15(50.00%) were male and female child.
- While stating the religion in group I, majority 25 (83.33%) were Hindu. In group II, 29 (90.67%) were Hindu.
- As far as place of residential area in group I, majority 17 (56.67%) hailed from semi urban area. In group II, 16 (53.33%) hailed from semi urban area `
- With respect of type of family in group I, majority of the subjects 24 (80.00%) belongs to nuclear family. In group II, 24 (80.00%) % belongs to nuclear family.
- While comparing the family income in group I, majority 16 (53.33%) were earned between Rs.3000 -5000. In group II, 20 (80%) were earned between Rs.3001 -5000
- When discussing mother's educational status in group I, majority 9 (30%) studied up to primary school and middle school. In group II, 12 (40.00. %) studied up to middle school.
- When discussing father's educational status in group I, majority 8 (26.67%) studied up to primary school and middle school. In group II, 11 (36.67%) studied up to primary school.
- While stating father's occupation in group I, majority 20 (66.67%) were coolie. In group II, 22 (73.33%) were coolie.

- While stating mother's occupation in group I, majority 20 (66.66%) were house wife. In group II, 21 (70.00%) were house wife.
- Considering the number of siblings in group I, majority 23 (76.67%) had 1 sibling. In group II, 20 (66.67%) had 1 sibling.
- In the aspect of height of the child in group I, majority 11 (36.67%) were had between 95 -105 cms, 11 (36.67%) were had between 106 -125 cms. In group II, 14 (46.67%) were had between 106 -125 cms.
- In the aspect of weight of the child in group I, majority 16 (53.33%) were had 10 -20 kgs. In group II, 17 (56.67%) were had 10 -20 kgs.
- In the aspect of Height in group I, majority 11 (36.67%) were between 95 -105 cms, 11 (36.67%) were between 106 -125 cms. In group II, 14 (46.6%) were between 106 -125 cms.
- In the aspect of weight in group I, majority 16 (53.33%) were 10 -20 kgs, 12 (40%) were 21 -30 kgs. In group II, 17 (56.67%) were 10 -20 kgs, 10 (33.33%) were 21 -30 kgs .
- While mentioning the type of cancer in group I children, majority 27 (90.00%) were had ALL/CLL. In group II, 29 (96.67%) were had ALL/CLL.
- While depicting the duration of illness in group I, majority 18 (60.00%) had 1 to 2 years. In group II, 21 (70.00%) had 1 to 2 years.
- While denoting the type of chemotherapy in group I, majority 29 (96.67%) had more than two drug regimen. In group II, 29 (96.67%) had more than two drug regimen.
- Regarding Number of cycles for chemotherapy in group I, majority 15 (50%) were in 2nd cycle. In group II, 15 (50%) were in 2nd cycle.

- While stating the occurrence of oral mucositis in group I, majority 18 (60.00%) were occurred once and treated. In group II, 15 (50%) were occurred once and treated.
- On the basis of oral hygiene in group I, majority 28 (93.33%) were doing brushes once a day. In group II, 27 (90%) were doing brushes once a day.
- In Group I, the pre test level of oral mucositis, majority 12 (40.00%) had severe level of oral mucositis, 10 (33.33%) had moderate level of oral mucositis, remaining 8 (26.67%) had mild level of oral mucositis and none of them had no or life-threatening oral mucositis. Whereas in the Group II, majority 11(36.67%) had moderate level of oral mucositis, 10 (33.33%) had severe level of oral mucositis, remaining 9 (30.00%) had mild level of oral mucositis and none of them had no or life-threatening level of oral mucositis.
- Considering the pretest and posttest level of oral mucositis in group I, in pre test majority 12 (40.00%) had severe level of oral mucositis, 10 (33.33%) had moderate level of oral mucositis, remaining 8 (26.67%) had mild level of oral mucositis and none of them had no or life-threatening oral mucositis. Whereas in the post test majority 20 (66.67%) had no oral mucositis, remaining 10 (33.33%) had mild level of oral mucositis and none of them had moderate or severe or life-threatening level of oral mucositis. Generalized McNemar's test was done to find out difference between pre test and post test level of oral mucositis in group I. The  $\chi^2= 27.22$  was greater than table value, which was significant at 0.001 level.
- Considering the pretest and posttest level of oral mucositis in group II, in the pre test, majority 11(36.67%) had moderate level of oral mucositis, 10 (33.33%) had severe level of oral mucositis, remaining 9 (30.00%) had mild

level of oral mucositis and none of them had no or life-threatening oral mucositis. Whereas in the post test 16 (53.33%) had mild level of oral mucositis, 8 (26.67%) had no oral mucositis, 6 (20.00%) had moderate level of oral mucositis and none of them had severe or life-threatening level of oral mucositis. Generalized McNemar's test was done to find out difference between pre test and post test level of oral mucositis. The  $\chi^2 = 19.09$  was greater than table value, which was significant at 0.001 level.

- Pre test and post test level of oral mucositis mean score shows in Considering Group I, the pre test mean score was 2.13 (53.3%) with standard deviation 0.81 whereas in post test the mean score was 0.33 (8.3%) with standard deviation 0.47 and the mean difference 1.8 and the calculated Z value 4.89 at 0.001 level. When comparing in group II, the pre test mean score was 2.03 (50.8%) with standard deviation 0.80 whereas in post test the mean score was 0.93 (23.3%) with standard deviation 0.69 and the mean difference 1.1 and the calculated Z value 3.33 at 0.001 level. Considering percentage of mean reduction score, Group I were had 45% (Z= 4.89 II) whereas in group II, 27.5 (Z= 3.33). The calculated Z value shows difference between group I and group
- There is a significant association between the post test level of oral mucositis and socio demographic variables among children, in group I such as the age of the children ( $\chi^2=6.71$ ) ( $P=0.03$ ), Residential area ( $\chi^2=6.05$ ) ( $P=0.05$ ) at 0.05 level (i-e) 5 to 7 years of children and rural children. Whereas, in group II such as the level of oral mucositis and the age of the children ( $\chi^2=10.52$ ), ( $P=0.05$ ), Residential area ( $\chi^2=9.03$ ) ( $P=0.05$ ) at 0.05 level (i-e) 5 to 7 years of children and children from rural area.

- There is a significant association between the post test level of oral mucositis and clinical variables among children, in group I such as the duration of illness ( $\chi^2=6.92$ ) ( $P=0.03$ ), Number of cycles for chemotherapy children ( $\chi^2=6.04$ ) ( $P=0.04$ ), Occurrence of mucositis ( $\chi^2=9.25$ ) ( $P=0.01$ ) at 0.05 level (i-e) 1-2 years duration of illness, children had two cycles of chemotherapy and occurrence of mucositis only once and treated. Whereas in group II, such as the duration of illness ( $\chi^2= 10.23$ ) ( $P=0.05$ ), Number of cycles for chemotherapy children ( $\chi^2= 11.67$ ) ( $P=0.01$ ), Occurrence of mucositis ( $\chi^2= 11.18$ ) ( $P=0.02$ ) at 0.05 level (i-e) 1-2 years duration of illness and had Two cycles of chemotherapy with occurrence of mucositis only once and treated.

### **6.3 Conclusion**

Oral mucositis is an inevitable side effect of chemotherapy among cancer children. Nursing intervention for oral mucositis is practiced in pediatric ward such as Listerine, povidoneiodine, salt (sodium chloride), Benzylamine, sodium bicarbonate, chlorhexidine mouth washes. Among these oral care Sodium bicarbonate mouth wash is effectively reduced oral mucositis than chlorhexidine mouth wash and also reduce the pain and burning sensation, increase the appetite and comfort among children undergoing chemotherapy.

### **6.4 Implications of the study**

The investigator had drawn several implications from this study for various areas such as nursing practice, nursing education, nursing administration and nursing research.

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

1. This helps to reduce the anxiety of the children and parents related to oral mucositis and also reduce the risk to discontinue the chemotherapy treatment.
2. Nurses play a vital role in helping children undergoing chemotherapy to adjust to changes in oral cavity and to reduce the level of depression by inculcating the concept of practicing Sodium bicarbonate mouth wash.
3. Nurses can intervene to alter the physical discomfort like oral mucositis among children undergoing chemotherapy by the way of giving frequent oral care with Sodium bicarbonate mouth wash.
4. Practicing Nurses need to identify those children undergoing chemotherapy who are at greater risk to develop oral mucositis and required to reinforcement by giving oral mouth wash with Sodium bicarbonate.

#### **6.4.2 Implications for nursing education**

1. Student nurses must motivate to prepare and use WHO oral mucositis assessment scale on assessing oral mucositis among children undergoing chemotherapy.
2. Student nurses should incorporate the importance of nursing interventions like oral care in their individuals and health talk in pediatric ward postings.

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

1. Nurse researcher should channelize to perform scientific work and take part in assessment, application and evaluation of oral care for children with oral mucositis.
2. This may increase the awareness among nurses, and also highlight the role, the nurses can play in decreasing the Oral mucositis in children receiving chemotherapy.

3. This study calls for further studies on physical comfort of the children on Oral mucositis.

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

1. Continuing nursing education and in-service education can be planned by nurse administrators also aid in formulating policies and protocols to Practicing oral care with Sodium bicarbonate mouth wash among children with oral mucositis.
2. Appropriate and feasible organizational intervention like health education, domiciliary care services and health promotion activities will plan for oral care with Sodium bicarbonate mouth wash by nursing administrators.
3. The nurse administrator should organize activities to explain and train the nurses about their role in decreasing the severity of Oral mucositis and its complications among children undergoing chemotherapy.

#### **6.5 Recommendations**

1. A study can be done to find out the prevalence of chemotherapy induced oral mucositis among children undergoing chemotherapy.
2. A similar study can be replicated with larger sample for generalization.
3. A similar study can be conducted in various settings like Medical oncology and radiology ward among general population.

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# *Appendices*

# APPENDIX – I

## ETHICAL COMMITTEE APPROVAL LETTER



**MADURAI MEDICAL COLLEGE**  
**MADURAI, TAMILNADU, INDIA -625 020**  
(Affiliated to The Tamilnadu Dr.MGR Medical University,  
Chennai, Tamil Nadu)



Prof Dr V Nagaraajan MD MNAMS  
DM (Neuro) DSc.(Neurosciences )  
DSc ( Hons)  
Professor Emeritus in Neurosciences,  
Tamil Nadu Govt Dr MGR Medical  
University  
Chairman, IEC

Dr.M.Shanthi, MD.,  
Member Secretary,  
Professor of Pharmacology,  
Madurai Medical College, Madurai.

### Members

1. Dr.V.Dhanalakshmi, MD,  
Professor of Microbiology &  
Vice Principal,  
Madurai Medical College

2. Dr.Sheela Mallika rani, M.D.,  
Anaesthesia , Medical  
Superintendent Govt. Rajaji  
Hospital, Madurai

3.Dr.V.T.Premkumar,MD(General  
Medicine) Professor & HOD of  
Medicine, Madurai Medical & Govt.  
Rajaji Hospital, College, Madurai.

4.Dr.S.R.Dhamotharan, MS.,  
Professor & H.O.D i/c, Surgery,  
Madurai Medical College & Govt.  
Rajaji Hospital, Madurai.

5.Dr.G.Meenakumari, MD.,  
Professor of Pathology, Madurai  
Medical College, Madurai

6.Mrs.Mercy Immaculate Rubalatha,  
M.A., B.Ed., Social worker, Gandhi  
Nagar, Madurai

7.Thiru.Pala.Ramasamy, B.A.,B.L.,  
Advocate, Palam Station Road,  
Sellur.

8.Thiru.P.K.M.Chelliah, B.A.,  
Businessman,21, Jawahar Street,  
Gandhi Nagar, Madurai.

### ETHICS COMMITTEE CERTIFICATE

Name of the Candidate : P.Chitra  
Course : M.Sc., in Child Health Nursing  
Period of Study : 2016-2018  
College : MADURAI MEDICAL COLLEGE  
Research Topic :  
A study to evaluate the  
effectiveness of sodium bicarbonate mouth wash versus  
chlorhexidine mouth wash on oral mucositis among  
children undergoing chemotherapy at GRH Madurai  
Ethical Committee as on : 13.04.18

The Ethics Committee, Madurai Medical College has decided to inform  
that your Research proposal is accepted.

  
Member Secretary Chairman

Prof Dr V Nagaraajan  
M.D., MNAMS, D.M., Dsc.(Neuro), Dsc (Hon)  
CHAIRMAN  
IEC - Madurai Medical College  
Madurai

  
Dean / Convenor  
DEAN  
Madurai Medical College  
Madurai-20



## APPENDIX – II

### CONTENT VALIDITY CERTIFICATE

This is to certify that the content and tool

Section – A: **Socio demographic data**

Section – B: **WHO oral mucositis assessment scale.**

Prepared for data collection by Mrs.P.Chitra , II Year M.Sc (N) student , College of Nursing , Madurai Medical College, Madurai-20, who has undertaken the study field on thesis entitled on “**A study to evaluate the effectiveness of sodium bicarbonate mouth wash versus chlorhexidine mouth wash on oral mucositis among children undergoing chemotherapy at GRH Madurai**” has been validated by me

SIGNATURE OF THE EXPERT

NAME: **S.SHANMUGASUNDARAM**

DESIGNATION:

ADDRESS:

DATE:

  
24.5.18  
Professor of Paediatrics  
Institute of Child Health &  
Research Centre.  
Govt. Rajaji Hospiatl, Madurai-20

This is to certify that the content and tool

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Section – B: **WHO oral mucositis assessment scale.**

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SIGNATURE OF THE EXPERT

NAME: **Dr. S. BALASANKAR MD DCH.,**

DESIGNATION:

ADDRESS:

DATE:

DIRECTOR I/C  
INSTITUTE OF CHILD HEALTH &  
RESEARCH CENTRE  
GOVT. RAJAJI HOSPITAL  
MADURAI-625020.

This is to certify that the content and tool

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SIGNATURE OF THE EXPERT

NAME:

DESIGNATION:

ADDRESS:

DATE:

R. Jothi Lakshmi

R. JOTHI LAKSHMI

Professor

Sacred Heart Nursing College  
Madurai - 20.

R. JOTHI LAKSHMI, M.Sc.(N)Ph.D  
Associate Professor  
Sacred Heart Nursing College  
MADURAI - 20

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SIGNATURE OF THE EXPERT : *N. Jessie*  
NAME: *DR. N. JESSIE, MSc. Ph.D. [N].,*  
DESIGNATION: *Professor cum Head of*  
ADDRESS: *the Department Child*  
*Health Nursing.*  
DATE: *C S I Jeyaraj Annapackiam*  
*CoN,*  
*Madurai.*

This is to certify that the content and tool

Section – A: **Socio demographic data**

Section – B: **WHO oral mucositis assessment scale.**

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SIGNATURE OF THE EXPERT

NAME: *Dr. A. HELEN NI PERDITA .*

DESIGNATION: *Principal*

ADDRESS: *Madurai Apollo Con .*

DATE: *Eliyarpathy village .*

*Madurai - 22*

PRINCIPAL  
MADURAI APOLLO COLLEGE OF NURSING  
ELIYARPATHI VILLAGE  
MADURAI SOUTH TAMIL NADU - MADURAI-22

This is to certify that the content and tool

Section – A: **Socio demographic data**

Section – B: **WHO oral mucositis assessment scale.**

Prepared for data collection by Mrs.P.Chitra , II Year M.Sc (N) student , College of Nursing , Madurai Medical College, Madurai-20, who has undertaken the study field on thesis entitled on **“A study to evaluate the effectiveness of sodium bicarbonate mouth wash versus chlorhexidine mouth wash on oral mucositis among children undergoing chemotherapy at GRH Madurai ”** has been validated by me

Name: P. ATHIGNANAKUMARAN

Designation: Asst Head master

Institution: SETUPATI - HIGHER SECONDARY SCHOOL

SETUPATI HIGHER SECONDARY SCHOOL  
MADURAI-625 001

P. ATHIGNANAKUMARAN

Signature

## **APPENDIX – III**

### **INFORMED CONSENT FORM**

Name:

Date:

Here I am acknowledge that information regarding the project study topic was explain to me and the positive reason was pointed out. I am voluntarily willing to participate with my child in the study. At any time I am free to exclude from the study and promised that my all personal information should be kept in confidential.

Signature of the participants

## ஆராய்ச்சி ஒப்புதல் கடிதம்

பெயர் :

தேதி:

இந்த ஆராய்ச்சியின் விவரங்களும் அதன் நோக்கங்களும் எனக்கு தெளிவாக விளக்கப்பட்டது. எனக்கு விளக்கப்பட்ட விவரங்களை நான் புரிந்து கொண்டு நான் எனது சம்மதத்தை தெரிவிக்கிறேன். இந்த ஆராய்ச்சியில் பிறரின் நிபந்தனையின்றி என் சொந்த விருப்பத்தின் பேரில் தான் பங்கு பெறுகிறேன். மற்றும் நான் இந்த ஆராய்ச்சியில் இருந்து எந்நேரமும் பின் வாங்கலாம் என்பதையும் அதனால் எந்த பாதிப்பும் ஏற்படாது என்பதையும் புரிந்து கொண்டேன். நான் இந்த ஆராய்ச்சியின் விவரங்களை கொண்டு தகவல் தாளை பெற்று கொண்டேன். நான் என்னுடைய சுய நினைவுடன் மற்றும் முழு சுதந்திரத்துடன் இந்த ஆராய்ச்சியில் என்னையும் என் குழந்தையையும் இணைத்துக்கொள்ள சம்மதிக்கிறேன்.

கையொப்பம்

## APPENDIX – IV

### Letter Seeking Permission to Conducting the Study

From

P. Chitra  
II Year M.Sc(N)  
College of Nursing,  
Madurai Medical College,  
Madurai-20

To

The Director i/c  
Institute of Child Health and Research Centre  
Government Rajaji Hospital  
Madurai

Through the proper channel,

Respected sir

Sub: College of Nursing, Madurai Medical College, Madurai II Year  
M.Sc(N) Child Health Nursing - permission for conducting pilot study & main  
study from 21<sup>st</sup> May onwards in pediatric ward ,GRH, Madurai - Request regarding

As per Indian nursing council and The Tamil Nadu Dr.M.G.R Medical  
university curriculum requirement of M.Sc Nursing candidates are required to conduct  
a dissertation study for the partial fulfillment of the course in their respective  
department.

I wish to conduct study on **“A study to evaluate the effectiveness of sodium  
bicarbonate mouthwash versus chlorhexidine mouthwash on reducing oral  
mucositis among children undergoing chemotherapy at GRH Madurai.”** I assure  
you that I will not interfere with routine activities of the department

Hence, I kindly request you to consider my requisition and permit me to conduct  
the study in this setting.

Thanking you,

Place: Madurai

Date: 18-05-18

Yours Obediently

P. Chitra  
(P.Chitra)

N. D. Raju  
Study may conduct  
S.P.  
18/5/18  
FORWARDED  
DIRECTOR I/C  
INSTITUTE OF CHILD HEALTH  
RESEARCH CENTRE  
GOVT. RAJAJI HOSPITAL  
MADURAI-625020.

**APPENDIX – V**  
**QUESTIONNAIRE INSTRUMENT**

Interview /observational semi structured schedule

Sample No:

Date:

Time:

**SECTION – A**

Demographic data of the child

1. Age of the child

a. 5 to 7 years

b. 8 to 9 years

c. 10 to 12 years

2. Sex of the child

a. Male child

b. Female child

3. Religion

a. Hindu

b. Christian

c. Muslim

d. Others

4. Residential Area

a. Rural

b. Urban

c. Semi urban

5. Type of family

a. nuclear family

b. joint family

c. extended family.

6. Family Income

- a. 1000 to 3000
- b. 3001 to 5000
- c. 5001 to 7000
- d. 7001 to 10000

7. Mothers educational – status

- a. No – formal education
- b. Primary school
- c. Middle school
- d. High school
- e. Higher secondary school
- f. Graduate

8. Fathers Educational – status

- a. No – formal education
- b. Primary school
- c. Middle school
- d. High school
- e. Higher secondary school
- f. Graduate

9. Father's Occupation

- a. Unemployed
- b. coolie
- c. self-employee
- d. Business
- e. profession

10. Mother's occupation

- a. House wife
- b. coolie
- c. self-employee
- d. Business

e. profession

11. No of siblings

a. 0

b. 1

c. 2

d. more than 2

12. Height of the child in Cms.

a. 95 – 105 cms

b. 106 -125 cms

c. 126 – 150 cms

13. Weight of the child in kilograms

a. 10 – 20 kgs

b. 21 – 30 kgs

c. 31 – 40 kgs.

### **Clinical variables**

1. Type of cancer

a. ALL/CLL

b . AML /CML

c. NHL/ HL

d. Other type of cancer

2. Duration of illness

a. Below 6 months.

b. 1 to 2 years

c. 2 to 3 years

d. more than 3 years.

3. Type of chemotherapy

a. Single drug regimen

b. Two drug regimen

c. More than two drug regimen.

4. Number of cycles for chemotherapy

a. 1st Cycle

b. 2nd Cycle

c. 3rd Cycle

d. more than 3 cycle.

5. Occurrence of Oral mucositis

a. Newly occurred

b. occurred once and treated.

c. occurred twice and treated.

d. occurred but not treated.

6. Oral hygiene followed by the child

a. Brushes once daily.

b. Brushes twice daily.

c. Brushes with mouth wash.

**APPENDIX – VI**  
**RESEARCH TOOL – ENGLISH**

**WHO ASSESSMENT SCALE**

The World Health Organization has developed a grading system for mucositis based on clinical appearance and functional status. The WHO scale is dependent on both objective and subjective variables, and measures anatomical, symptomatic and functional components of oral mucositis.

**WHO Oral Mucositis Grading Scale**

<b>Grade</b>	<b>Description</b>
0 (none)	None
I (mild)	Oral soreness, erythema
II (moderate)	Oral erythema, ulcers, solid diet tolerated
III (severe)	Oral ulcers, liquid diet only
IV (life-threatening)	Oral alimentation impossible

**APPENDIX – VII**  
**SOCIO DEMOGRAPHIC DATA – TAMIL**

**சுய விவரப்படிவம்**

1. வயது 
  - a. 5 முதல் 7 வயது
  - b. 7 முதல் 9 வயது
  - c. 9 முதல் 12 வயது
2. பாலினம் 
  - a. ஆண்
  - b. பெண்
3. மதம் 
  - a. இந்து
  - b. கிறிஸ்தவர்
  - c. முஸ்லீம்
  - d. மற்றவை
4. இருப்பிடம் 
  - a. கிராமம்
  - b. நகரம்
  - c. துணை நகரம்
5. குடும்பவகை 
  - a. தனிக்குடும்பம்
  - b. கூட்டுக்குடும்பம்
  - c. விரிவாக்கப்பட்டகுடும்பம்
6. குடும்பவருமானம் 
  - a. 1000 - முதல் 3000
  - b. 3000 - முதல் 5000
  - c. 5000 - முதல் 7000
  - d. 7000 - முதல் 10,000

7. தாயின் கல்விநிலை

- a. மரபுசாராக்கல்வி
- b. ஆரம்பக்கல்வி
- c. நடுநிலைக்கல்வி
- d. உயர்நிலைப்பள்ளி
- e. மேல்நிலைக்கல்வி
- f. பட்டதாரி

8. தந்தையின் கல்விநிலை

- a. மரபுசாராக்கல்வி
- b. ஆரம்பக்கல்வி
- c. நடுநிலைக்கல்வி
- d. உயர்நிலைக்கல்வி
- e. மேல்நிலைக்கல்வி
- f. பட்டதாரி

9. தந்தையின் தொழில்

- a. வேலை இல்லை
- b. கூலிவேலை
- c. சுயதொழில்
- d. வியாபாரம்
- e. தொழில் சார்ந்தவேலை

10. தாயின் தொழில்

- a. குடும்பதலைவி
- b. கூலிவேலை
- c. சுயதொழில்
- d. வியாபாரம்
- e. தொழில் சார்ந்தவேலை

11. உடன் பிறந்தோர்

- a. 0
- b. 1
- c. 2
- d. 2 ற்குமேல்

12. குழந்தையின் உயரம் செண்டிமீட்டர்
- a. 95 -105 செ.மீ
  - b. 106 - 125 செ.மீ
  - c. 126 -150 செ.மீ
13. குழந்தையின் எடைகிலோகிராமில்
- a. 10 -20கி
  - b. 21 -30கி
  - c. 31 -40கி
14. புற்றுநோயின் வகை
- a. அலிலு / கிலிலு
  - b. அமலு / கிமுல்
  - c. நஹெஸ்லு / ஹெச்லு
  - d. மற்றவகைபுற்றுநோய்
15. நோயின் கால அளவு
- a. 6மாதத்திற்குகுறைவு
  - b. 1-2 ஆண்டு
  - c. 2-3 ஆண்டு
  - d. 3 வருடத்திற்கு அதிகமாக
16. மருந்து கொண்டு நோய் தீர்க்கும் முறையின் வகை
- a. ஒருவகைமருந்து
  - b. இரு வகைமருந்து
  - c. இரண்டிற்குமேற்பட்டமருந்து
17. மருந்துகொண்டுநோய் தீர்க்கும் முறையின் சுழற்சி
- a. முதல் சுழற்சி
  - b. இரண்டாம் சுழற்சி
  - c. மூன்றாம் சுழற்சி
  - d. மூன்றிற்றுமேற்பட்டசுழற்சி

18. வாய்புண் ஏற்பட்டமுறை

- a. முதல் முறை வந்துள்ளது
- b. இருமுறை வந்து சிகிச்சை அளிக்கப்பட்டுள்ளது.
- c. இருமுறை வந்து சிகிச்சை அளிக்கப்படவில்லை.
- d. வந்து சிகிச்சை அளிக்கப்படவில்லை

19. குழந்தைமேற்கொள்ளும் வாய் சுகாதாரம்

- a. ஒருமுறைபல் துலக்குதல்
- b. இருமுறைபல் துலக்குதல்
- c. பல் துலக்குவதுடன் வாய் கொப்பளித்தல்

## APPENDIX – VIII

### ENGLISH EDITING CERTIFICATE

#### TO WHOM SO EVER IT MAY CONCERN

This is to certify that the dissertation “**A study to evaluate the effectiveness of sodium bicarbonate mouth wash versus chlorhexidine mouth wash on oral mucositis among children undergoing chemotherapy at GRH Madurai.**” done by Mrs.Chitra.P, M.Sc Nursing II year student, College of Nursing, Madurai Medical College, Madurai – 20 has been edited for English language appropriateness.

Name: P.ATHIGNANAKUMARAN

Designation: Asst Head master

Institution: SETUPATI. HIGHER SECONDARY SCHOOL

SETUPATI HIGHER SECONDARY SCHOOL  
MADURAI-625 001

P.ATHIGNANAKUMARAN

Signature

## APPENDIX – IX

### TAMIL EDITING CERTIFICATE

#### TO WHOM SO EVER IT MAY CONCERN

This is to certify that the dissertation “A study to evaluate the effectiveness of sodium bicarbonate mouth wash versus chlorhexidine mouth wash on oral mucositis among children undergoing chemotherapy at GRH Madurai ” done by Mrs. Chitra.P, M.Sc Nursing II year student, College of Nursing, Madurai Medical College, Madurai – 20 has been edited for Tamil language appropriateness.

Name: சி. சித்ராபதி

Designation: M-A M.Ed.

Institution. சி. சித்ராபதி

Signature

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## **APPENDIX – X**

### **INTERVENTION**

#### **PROCEDURE FOR SODIUM BICARBONATE MOUTH WASH**

##### **DEFINITION**

In this study, it refers to oral care given to Group I who is receiving chemotherapy with 10 ml of Sodium bicarbonate solution for three times a day for 5 days and it is prepared with 250 ml of water and 1.3 grams of Sodium bicarbonate powder

##### **PURPOSES**

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

##### **EQUIPMENTS NEEDED**

Sodium bicarbonate in a bowl

Tea spoon to measure the sodium bicarbonate

Measuring glass to measure the boiled cooled water

Tumbler to take the prepared solution

Towel to wipe the mouth

##### **PROCEDURE TIPS**

Provide 10 ml of mouth wash in mouth

Hold it for 1 minute and spit out

Do not swallow the mouth wash

Rinse every 4 to 6 hours if indicated

### **PLAN OF ACTION**

<b>ACTION</b>	<b>RATIONALE</b>
Explain the procedure to the client	It helps to get cooperation from the client
Perform hand hygiene	Hand hygiene deter the spread of micro organisms
Fill 250 ml of boiled cooled water in a measuring Cup	For mixing the salt
Measure one teaspoon of sodium bicarbonate(1.3gm) in a measuring spoon	For preparing the Solution
Put the measured sodium bicarbonate into the cup of water and stir it in the water until the sodium bicarbonate dissolves.	Stirring helps to dissolve the salt completely
Take 10 ml of mouthwash from the measuring cup into the Tumbler and instruct the client to gargle the prepared solution for one minute and spit out.	Rising the solution promotes the healing process

## **PROCEDURE FOR CHLORHEXIDINE MOUTH WASH**

### **DEFINITION**

In this study Chlorhexidine mouth wash refers to oral care given to group II who is receiving chemotherapy with 10 ml of chlorhexidine and it is readily available solution.

### **PURPOSES**

- It has both bacteriostatic( inhibits the growth) and bacteriocidal( kills bacteria) action
- To prevent infection
- It reduce bleeding , inflammation and plaque
- It promotes wound healing
- To keep food debris out of healing wounds

### **EQUIPMENTS NEEDED**

- Chlorhexidine mouth wash
- Measuring glass to measure the Chlorhexidine solution.
- Tumbler to take the solution
- Towel to wipe

### **PROCEDURE TIPS**

- Rinse the mouth wash for 1 minute and spit out
- Do not swallow the mouth wash
- Rinse every 4 to 6 hours if indicated

## PLAN OF ACTION

<b>ACTION</b>	<b>RATIONALE</b>
Explain the procedure to the client	It helps to get cooperation from the client
Perform hand hygiene	Hand hygiene deter the spread of micro organisms
Take 10 ml of mouthwash from the measuring glass into the Tumbler and instruct the children to rinse the solution for one minute and spit out.	Rinsing the solution promotes the healing Process

**APPENDIX – XI**  
**PHOTOGRAPHS**



