DISSERTATION ON

"A COMPARATIVE STUDY TO ASSESS THE EFFECTIVENESS OF HONEY APPLICATION VERSUS CHLORHEXIDINE MOUTH WASH IN REDUCING ORAL MUCOSITIS AMONG CHILDREN OF 5 – 10 YEARS ADMITTED IN HEMATOLOGY WARD, INSTITUTE OF CHILD HEALTH & HOSPITAL FOR CHILDREN, CHENNAI."

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CERTIFICATE

This is to certify that this dissertation titled "A comparative study to assess the effectiveness of honey application versus chlorhexidine mouth wash in reducing oral mucositis among children of 5 – 10 years admitted in Hematology ward, Institute of Child Health & Hospital for children, Chennai" is a bonafide work done by Mrs. Sunila guna sundari.S, II year Msc (Nursing) student ,College of nursing ,Madras medical college ,chennai - 600003 submitted to The Tamilnadu Dr.M.G.R Medical university, Chennai . In partial fulfillment of the requirements for the award of degree of master of science in nursing ,Branch II, Child health nursing, under our guidance and supervision during the academic period from 2015 -2016

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Let us be grateful to people who make us happy; they are charming gardeners who make our souls blossom - Marcel Proust

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ABSTRACT

TITLE: A comparative study to assess the effectiveness of honey

application versus chlorhexidine mouth wash in reducing oral mucositis

among children 5-10 years admitted in Hematology ward, Institute

of child health & hospital for children, Chennai.

Oral mucositis is a common and significant

problem of cancer chemotherapy, especially patients who receives high-dose

therapy. Most of the cancer treatment gives rise to the complication which leads to

the reduction of the efficiency of therapy by reducing the dose, increasing the

health care cost, duration of hospital stay and affects the quality of life of patients.

Need for the study: Oral mucositis is a common and significant problem of

cancer chemotherapy, which affects the quality of life of patients. The

antibacterial property of honey and antimicrobial activity of chlorhexidine

mouthwash enables the examiner to conduct the study.

Objectives:

To assess the grade of the oral mucositis among children receiving chemotherapy.

To evaluate effectiveness of honey application on oral mucositis among

experimental group.

To evaluate effectiveness of chlorhexidine on oral mucositis among control group.

To compare the effectiveness of honey application and chlorhexidine on oral

mucositis.

To associate the effectiveness of honey application and chlorhexidine on oral

mucositis with selected demographic variables.

Key words: Chemotherapy, Oral mucositis, Honey, Chlorhexidine.

Methodology:

Research approach : Quantitative approach.

Research design : Quasi Experimental design.

Sampling technique: Convenient sampling.

Study population : Cancer children with oral mucositis of 5 -10 years of age.

Tool : WHO Oral mucositis assessment scale.

Data collection procedure:

A comparative study was carried out to find the effectiveness of honey application versus chlorhexidine mouth wash in treatment of oral mucositis of 5-10 years cancer children with oral mucositis .60 samples were selected from the hematology ward.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. Intervention was given 3 times a day for 5 days. Oral mucositis was assessed before and after the intervention using WHO oral mucositis assessment scale.

Data analysis: Data were analysed by using Descriptive statistics (mean, median ,standard deviation, frequency, percentage) and Inferential statistics(Student unpaired 't' test ,student paired 't' test ,Chi square ,).

.**Result:** 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.

Conclusion : The findings showed that the calculated paired 't' value of t = 7.663 was found to statistically significant at p<0.001 level. This clearly shows that both honey application and chlorhexidine are effective in reducing oral mucositis , comparatively honey application was more effective in treatment of oral mucositis among cancer children receiving chemotherapy .the antimicrobial property of honey helps in reducing the severity of oral mucositis.this study can be conducted for a large population .

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LIST OF ABBREVIATIONS

ABBREVIATIONS

EXPANSIONS

WHO World Health Organization

OM Oral mucositis

SEER Surveillance, Epidemiology, and End

Results

ICH Institute of child health

RCC Regional cancer center

FDA Food and Drug Administration

OAG Oral assessment guide

CHAPTER I

INTRODUCTION

"A child is a beam of sunlight from the Infinite and Eternal, with possibilities of virtue and vice, but as yet unstained."

— Lyman Abbott.

School age starts from 6years to 12 years. As children enter into school-age, their abilities and understanding of concepts and the world around them continue to grow. While children may progress at different rates. Avery important part of growing up is the ability to interact and socialize with others. During the schoolage years, parents will see a transition in their child as he or she moves from playing alone to having multiple friends and social groups. While friendships become more important, the child is still fond of his or her parents and likes being part of a family. While every child is unique and will develop different personalities. By age 5, most children are ready to start learning in a school setting. The first few years focus on learning the fundamentals. Children use more complex sentences as they grow. The nurse is responsible for assisting the parents in understanding the changes that occur in the appearance, skill, and behaviour of schoolers. In addition parents need guidance in health maintenance, health promotion, accident prevention and health supervision.

1.1 Background of the study:

Cancer:

WHO definition (2014): Cancer is the uncontrolled growth of cells, which can invade and spread to distant sites of the body.

National cancer institute (2015): Cancer is the name given to a collection of related diseases. In all types of cancer, some of the body's cells begin to divide without stopping and spread into surrounding tissues.

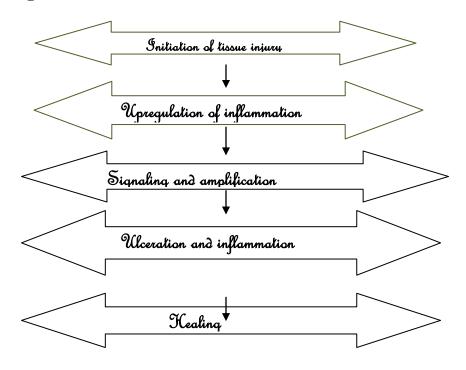
Oral mucositis:

Oral cancer foundation(2011):oral mucositis ,also called stomatitis,isacommon ,debilitating complication ofcancer chemotherapy and radiotherapy, occurring in about 40 % of patients.

Clinical features of oral mucositis:

- Red shiny ,oral swollen mouth and gums.
- Blood in the mouth
- Sores in the mouth or on the gums or tongue
- Soreness or pain in the mouth or throat
- Difficulty swallowing or talking
- Feeling of dryness, mild burning, or pain while eating.
- Soft whithish patch or pus in the mouth or on the tongue.
- Increased mucous or thicker saliva in the mouth.

Fig 1:Pathogenisis of oral mucositis:



1.2 Need for the study:

Each year the American Cancer Society estimates the numbers of new cancer cases and deaths that will occur in the United States in the current year and compiles the most recent data on cancer incidence, mortality, and survival. Incidence data were collected by the **National Cancer Institute** (Surveillance, Epidemiology, and End Results [SEER] Program), the Centers for Disease Control and Prevention (National Program of Cancer Registries), and the North American Association of Central Cancer Registries. Mortality data were collected by the National Center for Health Statistics. A total of 1,658,370 new cancer cases and 589,430 cancer deaths are projected to occur in the United States in 2015. During the most recent 5 years for which there are data (2007-2011), delay-adjusted cancer incidence rates (13 oldest SEER registries) declined by 1.8% per year in men and were stable in women, while cancer death rates nationwide decreased by 1.8% per year in men and by 1.4% per year in women. The overall cancer death rate decreased from 215.1 (per 100,000 population) in 1991 to 168.7 in 2011, a total relative decline of 22%. However, the magnitude of the decline varied by state, and was generally lowest in the South (15%) and highest in the Northeast (20%). For example, there were declines of 25% to 30% in Maryland, New Jersey, Massachusetts, New York, and Delaware, which collectively averted 29,000 cancer deaths in 2011 as a result of this progress. Further gains can be accelerated by applying existing cancer control knowledge across all segments of the population. C.

In India: 1.6 to 4.8% 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.

In Chennai: A total of 1,334 childhood cancers registered in population based cancer registry, Chennai, India, during 1990–2001 and categorized by International Classification of Childhood Cancer norms formed the study material. Cases included for survival analysis were 1,274 (95.5%). Absolute survival was calculated by actuarial method. The age-standardized rates for all childhood cancers together were 127 per million boys and 88 per million girls. A decreasing trend in incidence rates with increasing 5-year age groups was observed in both sexes.

Table 1 Census of Hematology ward, ICH, Chennai for the past 5 years

YEAR	ADMISSION	DISCHARGE	MUCOSITIS	DEATH
2015 (Jan-	2237	2798	2232	58
Aug)	2207	2,76		
2014	2978	3122	3189	67
2013	2447	2549	2122	54
2012	1550	1629	1222	45
2011	1955	2083	1845	58
2010	2212	2277	1978	57

When the Investigator was posted in hematology ward during the clinical ,had a chance to come across children with oral mucositis who undergo chemotherapy. The children were not able to eat, they also had severe pain, So the investigator decided to provide a intervention which is cost effective easily available and of high antimicrobial reaction. The investigator decided to assess the effectiveness of honey and chlorhexidine mouth wash.

Honey is a supersaturated sugar solution, created by bees, and used by human beings as a sweetener. However, honey is more than just a supersaturated sugar solution; It also contains acids, minerals, vitamins, and amino acids in varying quantities.

Indeed, medicinal importance of honey has been documented in the world's oldest medical literatures, and since the ancient times, it has been known to possess antimicrobial property as well as wound-healing activity. The healing property of honey is due to the fact that it offers antibacterial activity, maintains a moist wound condition, and its high viscosity helps to provide a protective barrier to prevent infection. Its immune modulatory property is relevant to wound repair too. The antimicrobial activity in most honeys is due to the enzymatic production of hydrogen peroxide.

Honey is not only used as nutrition but also used in wound healing and as an alternative treatment for clinical conditions ranging from gastrointestinal tract (GIT) problems to ophthalmic conditions. We did the literature search and found interesting facts about the nutritional and medicinal value of honey. No wonder, it is a good source of nutrition, the results of the studies prove that it also helps in wound healing. On burns, it has an initial soothing and later rapid healing effects. It has been used as wound barrier against tumour implantation in laparoscopic oncological surgery. No infection has been reported from the application of honey to open wounds. It has a potential therapeutic role in the treatment of gingivitis and periodontal disease. Based on these facts, the use of honey in the surgical wards is highly recommended and patients about to undergo surgery should ask their surgeons if they could apply honey to their wounds post operation.

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

With reference to the above cited literature the researcher was interested in comparing the effects of the antimicrobial agents ,so the investigator selected honey and chlorhexidine mouth wash which is easily available and also at low cost with good medicinal properties.

1.3 Statement of the problem:

"A comparative study to assess the effectiveness of honey application versus chlorhexidine mouth wash in reducing oral mucositis among cancer children of 5-10 years admitted in Hematology ward, Institute of Child Health & Hospital for Children, Chennai."

1.4 Objectives:

- 1. To assess the grade of the oral mucositis among children receiving chemotherapy.
- 2. To evaluate effectiveness of honey application on oral mucositis among experimental group.
- 3. To evaluate effectiveness of chlorhexidine on oral mucositis among control group.
- 4. To compare the effectiveness of honey application and chlorhexidine on oral mucositis.
- 5. To associate the effectiveness of honey application and chlorhexidine on oral mucositis with selected demographic variables.

1.5 Operational definitions:

1. Effectiveness

It refers to the capability of producing a desired result.

2. Honey

It refers to the a sweet sticky yellowish –brown fluid made by bees and other insects from nectar collected from flowers.

3. Chlorhexidine

It refers to a synthetic compound used as a mild antiseptic.

4.Oral mucositis

It is an inflammation and ulceration of the oral mucosa which occur for cancer children.

5.Children

Subjects who are under the age group of 5 to 10 years and of both sexes.

6. Cancer

Cancer is a general term used to refer to a condition where the body's cells begin to grow and reproduce in an uncontrollable way. These cells can then invade and destroy healthy tissue, including organs

1.6 Assumption:

Antibacterial property in honey and antiseptic property of chlorhexidine may help in healing of oral mucositis.

1.7 Hypothesis:

- ➤ H1 There will be a difference between the pre test and post test value of oral mucositis among cancer children.
- ➤ H2 There will be a association between healing of mucositis and selected demographic variables.

1.8 Delimitation:

- > The data collection is done for four weeks.
- > Study finding cannot be generalized and limited to ICH. Chennai.

CHAPTER II

REVIEW OF LITERATURE

- 2.1 Review of literature.
- 2.2 Conceptual framework.
- 2.1 The review of literature is divided under the following headings:
- 2.1.1 Research studies related to oral mucositis.
- 2.2.2 Research studies related to effectiveness of honey application.
- 2.3 .3Research studies related to effectiveness of chlorhexidine mouthwash

2.1.1 Research studies related to oral mucositis.

Karthikeya Patil et al., (2015) A Pilot study was conducted in Jss dental college Mysore To evaluate the efficacy and safety of curcumin mouthwash in the management of Oral Mucositis in cancer patients undergoing radio-chemotherapy. The research group consisted of 20 cancer clients undergoing radio-chemotherapy at the Regional Oncology Centre, who were evaluated for signs and symptoms of oral mucositis and then randomly divided into two groups. Standard preventive oral care i.e. chlorhexidine mouthwash 0.2% was given to one group while the other group was provided with was given to one group while the other group was provided with freshly prepared curcumin mouthwash; each to be used thrice daily. Oral mucositis was assessed at days 0, 10 and 20. The World Health Organization (WHO) scale, the Oral Mucositis Assessment Scale (OMAS), and a Numerical Rating Scale (NRS; patient reporting scale of 0-10) were used. Adverse events

were tracked. Statistically significant difference was found in the NRS (p=0.000), Erythema (p=0.050), ulceration (p=0.000) and WHO scores (p=0.003) between the two groups. Curcumin was found to be better than chlorhexidine mouth wash in terms of rapid wound healing and better patient compliance in management of radio-chemotherapy induced oral mucositis. No oral or systemic complications were reported.

Sonis et al(2014). This 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.

Deborah B. Janet. S (2013) The purpose of this project was to evaluate research in basic oral care interventions to update evidence-based practice guidelines for preventing and treating oral mucositis (OM) in cancer patients

undergoing radio- or chemotherapy. A systematic review of available literature was conducted by the Basic Oral Care Section of the Mucositis Study Group. Seven interventions - oral care protocols, dental care, normal saline, sodium bicarbonate, mixed medication mouthwash, chlorhexidine, and calcium. The evidence for basic oral care interventions supports the use of oral care protocols in patient populations receiving radiation and/or chemotherapy and does not support chlorhexidine for prevention of mucositis in head and neck cancer patients receiving radiotherapy. Additional well-designed research is needed for other interventions to improve the amount and quality of evidence guiding future clinical care.

Rodrigiez et al., (2012) A Medline search for double blind randomized controlled clinical trials between 1985 and 2010 was carried out. The keywords were oral mucositis, radiotherapy, chemotherapy, and head and neck. The different therapeutic approaches found for cancer treatment-induced oral mucositis included: intensive oral hygiene care; use of topical antiseptics and antimicrobial agents; use of anti-inflammatory agents; cytokines and growth factors; locally applied non-pharmacological methods; antioxidants; immune modulators; and homoeopathic agents. To date, no intervention has been able to prevent and treat oral mucositis on its own. It is necessary to combine interventions that act on the different phases of mucositis. It is still unclear which strategies reduce oral mucositis, as there is not enough evidence that describes a treatment with a proven efficiency and is superior to the other treatments for this condition.

June et al.,(2011) To present a clinical update of evidence that applies to the development of a nursing plan of care for the prevention and treatment of oral mucositis related to cytotoxic therapy. Although high-level research evidence regarding mucositis remains limited, more is known now than at the time of the original article 4 years ago. Use of multiple types of evidence in developing a

structured plan of care facilitates improved patient outcomes and the advancement of the current body of knowledge toward the shared health care professional goal of improved patient outcomes. Nurses play a key role in the identification and use of evidence to guide the care of patients at risk for cytotoxic therapy-related oral mucositis.

Rebeccagreen et al., (2010) The purpose of this qualitative study was to explore the eating experiences of children and adolescents receiving chemotherapy when they had problems with nausea and mucositis. Eight children and adolescents and their caregivers were interviewed to describe how and what the children and adolescents ate when they were nauseated and/or had a sore mouth. Findings reveal that these children and adolescents all experienced nausea and frequently preferred not to eat during these periods. Eating problems related to mucositis also limited oral intake in this sample. These children and adolescents and their caregivers tried a variety of foods and strategies to maintain intake, including those recommended by health care providers. Prevention and management of nausea remains a challenge for children and adolescents receiving chemotherapy. Health care providers need to offer detailed eating suggestions throughout therapy so that these patients can maintain adequate nutrition and weight for optimal treatment tolerance as well as normal growth and development. Continued research is needed to test the effectiveness of interventions focused on maintaining oral intake during cancer treatment.

Stephen T.sonis et al.,(2009) The history of mucositis is as old as radiation- and chemotherapy. Despite being regularly reported and documented as one of the worst side effects of cancer therapy, relatively little was appreciated about the complexities of mucositis' pathogenesis until relatively recently. More frustrating for patients and clinicians, no effective treatment existed. Fortunately, the situation is changing; ongoing research is leading to a comprehensive understanding of the

biology of mucositis, which has resulted in the development of novel interventions. While the FDA's approval of palifermin in 2004 was limited to only a small percentage of the at-risk population, the fact that the first registered anti-OM agent derived its efficacy from its pleotropic activities was conceptually demonstrative of the therapeutic potential of drugs that selectively interfere with mucositis' pathogenesis. A number of eclectic molecules, all designed to interfere with pathways that lead to injury are in pre-clinical and clinical development.

Palazzi M, Tomatis S,etal., (2008) A study was conducted in Italy between the period of 2004 to 2006. In this study they have selected 149 patients with head and neck cancer undergoing radiation therapy with or without chemotherapy. 32% of patients were treated with conventional fractionation radiation therapy with or with out radiotherapy. Patients were monitored on weekly basis. 28 % of the patients have developed grade 3 and 4 oral mucositis.

2.1.2 Research studies related to effectiveness of honey application:

Dr. Ashutosh Mukerji et al (2015) The research design used in this study was Randomized Control Trial with single blinding method in radiotherapy unit of Regional Cancer Centre (RCC), JIPMER. The study population included total of 28 patients Participants in experimental group were given 15 ml natural honey for applying on oral mucosa and in control group 15ml plain water were given. Assessment of oral mucosa was done after every 5 doses of radiation therapy using RTOG scale and severity of oral mucositis was assessed. There was a statistically significant difference in degree of oral mucositis between the experimental and control group in week 4, 5 and 6.(p<0.01). During the whole course of study, 9(64.28%) participants in control group developed grade III oral mucositis. The study concluded that natural honey was effective for

oral mucositis among patients receiving external beam radiation therapy for head and neck cancers.

AL dany A.atwa et al., (2014) A randomized controlled study was conducted to assess the effects of honey were compared to treatment with either 10% sucrose or 10% sorbitol that served as positive and negative controls, respectively. The pH of plaque was measured using a digital pH meter prior to baseline and at 2, 5, 10, 20, and 30 min after chewing honey or rinsing with control solutions and the numbers of *Streptococcus mutans*, *Lactobacilli*, and *Prophymonas gingivalis* in respective plaques were determined. The antibacterial activity of honey was tested against commonly used antibiotics using the disk diffusion method Honey can be used as an alternative to traditional remedies for the prevention of dental caries and gingivitis following orthodontic treatment.

International Journal of Science and Research (2014) An experimental pre-test, post-test experimental design were used. The 40 patients were selected by purposive sampling technique. The onset of mucositis and the severity of mucositis were graded during the course of the radiotherapy and 5th and 10th day after radiotherapy,. The mean score of 0.7, Std. Deviation .571 in reducing level of mucositis in Orasep group and mean score honey group of 0.55, Std. Deviation 0.510. Null hypothesis accepted therefore there is no significant difference on radiation induced mucositis in Orasep and honey groups after the 10th day intervention. No significant reduction in mucositis in honey-received patients compared with orasep applied patient succored. There were no differences between the groups. There all variables do not show significant association between a radiations induced mucositis and demographic variables. Conclusion: natural honey is an effective agent in managing radiation induced oral mucositis. Honey could be a simple, potent and inexpensive agent, which is easily available, and it can be a better therapeutic agent in managing radiation mucositis in developing countries like India for the management of this morbidity. Also in

orasep help to relief of pain and dry, scratchy mouth for the relief of pain associated with canker sores, irritation of the mouth and gum

Mohammed ali raeessi(2014) This was a double blinded randomised clinical trial of a total of 75 eligible adult participants which they randomly fell into three treatment groups. For all the participants a syrup-like solution was prepared. Each 600 grams of the product consisted of "20 eight-mg Betamethasone solution ampoules" in the Steroid (S) group, "300 grams of honey plus 20 grams of instant coffee" in the Honey plus Coffee (HC) group, and "300 grams of honey" for the Honey (H) group. The participants were told to sip 10 ml of the prescribed product, and then swallow it every three hours for one week. Severity of lesions was clinically evaluated before the treatment and also one week after the initiation of the intervention. This study showed that all three treatment regimens reduce the severity of lesions. The best reduction in severity was achieved in HC group. H group and S group took the second and third places. In other words, honey plus coffee regimen was the most effective modality for the treatment of oral mucositis. Oral mucositis can be successfully treated by a combination of honey and coffee as an alternative medicine in a short time. Further investigations are warranted in this field.

Mina mottallebnejad.s et al., (2014) In this randomized single blind (examiner blind) clinical trial 40 patients with head and neck cancer requiring radiation to the oropharyngeal mucosa were randomly assigned to two groups. Twenty patients assigned to the study group received honey, while both the study and control groups received standard head and neck radiation therapy based on a standard protocol. In the study group patients were instructed to take 20 ml of honey 15 minutes before radiation therapy, then again at intervals of 15 minutes and six hours after radiation. In the control group patients were instructed to rinse with 20 ml of saline before and after radiation. Patients were evaluated weekly for progression of mucositis using the Oral Mucositis Assessing Scale (OMAS). Data

were analyzed using the independent t-test, Mann-Whitney, and Friedman tests. A significant reduction in mucositis among honey-received patients compared with controls (p=0.000)occurred. Within the limits of this study the results showed the application of natural honey is effective in managing radiation induced mucositis. Natural honey is a product with rich nutritional qualities that could be a pleasant, simple, and economic modality for the management of radiation mucositis.

European journal of individual medicine (2013) To evaluate the effectiveness of honey in the management of oral mucositis in head and neck cancer patients undergoing radiotherapy. The review of the literature was based on a keyword strategy and pre-determined inclusion and exclusion criteria. The keywords "head and neck cancer", "radiotherapy", "oral mucositis", "controlled trial" and "honey" were used as search terms. In total, 5 studies met the criteria and were included in the systematic review. Three studies assessed the effectiveness of honey against other products including golden syrup, lignocaine and saline and two studies assessed the effectiveness of honey against standard treatment regimes. Four out of the five studies demonstrated significant reduction in the mucositis levels and one study reported that honey had no statistical association with less severe mucositis. Methodologically the quality of most studies was moderate due to the small sample size, which might impact upon the significance of the findings. Although honey appears to be a simple, affordable, available and cost-effective treatment for the management of radiation-induced oral mucositis, there is a need for further multi-centre randomized trials to validate these findings.

Iraj shedgi et al .,(2013) In this randomized clinical trial 48 patients with acute leukemia requiring chemotherapy were assigned to three equal groups. During induction or reinduction period of chemotherapy, first group received honey plus normal saline; the second one received just normal saline and third, (in control group) did not receive any prophylaxis. Patients were evaluated weekly for

progression of mucositis according to the WHO mucositis scale. Data were analyzed with the Pearson Chi-Square and Fisher Exact test, by fifteen edition of SPSS software. In group of 'honey plus normal saline' no patients developed mucositis, while in normal saline group 4 patients and in control group 12 patients developed mucositis. The rate of mucositis was significantly lower in both intervention groups compared to control (P < 0.001). This study demonstrates that using either honey or normal saline can reduce the rate and severity of chemotherapy induced mucositis.

Song, Jason J. et al, .(2012) Recently, 4 separate human controlled trials reported that honey appeared to protect from the effects of radiation-induced oral mucositis formation, a complication of radiation therapy that is responsible for pain and overall reduction in quality of life. In this systematic review and meta-analysis, the authors examined 3 of these controlled trials (n = 120) that met the inclusion and exclusion criteria to determine whether honey had protective effects against radiation-induced oral mucositis. The meta-analysis demonstrated an overall relative risk reduction of 80% in the honey treatment group compared with the control. Although favorable, the data must be approached with caution because of lack of description of the method of randomization and potential bias in all 3 of the individual studies included in the meta-analysis. The results are promising, and further studies are needed to strengthen the current evidence prior to a firm clinical recommendation being given.

A.Simon et al.,(2012) While the ancient Egyptians and Greeks used honey for wound care, and a broad spectrum of wounds are treated all over the world with natural unprocessed honeys from different sources, Medihoney has been one of the first medically certified honeys licensed as a medical product for professional wound care in Europe and Australia. Our experience with medical honey in wound care refers only to this product. In this review, we put our clinical experience into

a broader perspective to comment on the use of medical honey in wound care. More prospective randomized studies on a wider range of types of wounds are needed to confirm the safety and efficacy of medical honey in wound care. Nonetheless, the current evidence confirming the antibacterial properties and additional beneficial effects of medical honey on wound healing should encourage other wound care professionals to use CE-certified honey dressings with standardized antibacterial activity, such as Medihoney products, as an alternative treatment approach in wounds of different natures.

Jayachandran, N. Balaji.N(2011) This study was conducted in the Department of Oral Medicine and Radiology, Tamilnadu Government Dental College and Hospital, Chennai, from April to December 2010. The sample size comprised of 60 patients, of both genders, diagnosed with oral malignancy clinically and histopathologically and planned for radiotherapy. The patients were assigned into three groups by random sampling. Each group consisted of 20 patients. Group 1 patients were instructed for topical application of natural honey, groups 2 and 3 were instructed for topical application of 0.15% benzydamine hydrochloride and 0.9% normal saline respectively. The onset of mucositis and the severity of mucositis were graded during the course of the radiotherapy and two weeks after radiotherapy, with WHO mucositis grading in all the three groups and statistically analysed with SPSS version 11 software. A significant reduction in mucositis in honey-received patients compared with 0.15% benzydamine hydrochloride, 0.9% normal saline applied patients occurred. The differences between the groups were statistically significant (P < 0.001). Pure natural honey can be an effective agent in managing radiation induced oral mucositis.

B.Kanal et al,. (2010) A single-blinded, randomized, controlled clinical trial was carried out to compare the mucositis-limiting qualities of honey with lignocaine. A visual assessment scale permitted scoring of degrees of mucositis and statistical

evaluation of the results was performed using the χ^2 test. Only 1 of 20 patients in the honey group developed intolerable oral mucositis compared with the lignocaine group, indicating that honey is strongly protective (RR = 0.067) against the development of mucositis. The proportion of patients with intolerable oral mucositis was lower in the honey group and this was statistically significant (p = 0.000). Honey applied topically to the oral mucosa of patients undergoing radiation therapy appears to provide a distinct benefit by limiting the severity of mucositis. Honey is readily available, affordable and well accepted by patients making it useful for improving the quality of life in irradiated patients.

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

2.1.3 Research studies related to effectiveness of chlorhexidine mouthwash.

A.Hashemi MD et al.,(2015) The purpose of this review was to evaluate studies in basic oral care interventions to update evidence based practice guidelines for preventing oral mucositis (OM) in cancer patients undergoing chemotherapy. Pub Med database and Google Scholar were searched for all papers published between 2000 and December 2014 in English that were conducted using the search terms including "mocusitis, chemotherapy, mouth-rinses, oral care, oral care protocol, dental care, dental cleaning, oral decontamination, oral hygiene", and the combined

phrases in order to obtain all relevant studies. Among these, chlorhexidine, normal saline, sodium bicarbonate, iseganan, benzydamine, sucralfate and Granulocyte macrophage colony-stimulating factor have been used in the form of mouth-rinse for prevention of chemotherapy induced mucositis. However, none of these mouthrinses have been shown to be definitely effective in preventing chemotherapy induced oral mucositis.

Rômulo Augusto de Paiva Macedo et al(2015) A systematic search of articles published between January 2000 and January 2015 was carried out in Pubmed/Medline, Science Direct and lilacs databases. After systematic search, 6 articles have fulfilled all methodological inclusion criteria. Chlorhexidine is an important means of preventing and treating oral mucositis and studies refer that 0.12% chlorhexidine gluconate effectiveness is probably related to its bactericide action. Adequate oral hygiene is important to prevent mucositis and other therapeutic modalities have shown to be effective to treat and prevent oral mucositis. Chlorhexidine gluconate does not totally eliminate oral mucosa injuries, but is able to decrease their frequency and intensity without significant noxious effects. However, other drugs compared to chlorhexidine in this study may present better results.

Dr. Ali Raad Abdul Azeez et al.,(2014): to determine the effect of 0.2% chlorhexidine digluconate mouthwash and visible blue light on anaerobic periodontal pathogens namely Aggregatibacter actinomycetemcomitans and Porphyromonas gingivalis. Strains of Aggregatibacter actinomycetemcomitans and Porphyromonas gingivalis were isolated from pockets of systemically healthy patients aged between 35-55 years old with pocket depths of 5-6 mm, the bacteria cultured on blood Agar plates containing holes filled with 0.1 ml of 0.2% chlorhexidine, subjected to visible blue light emitted from commercially available light cure devise (LED curing light); that emits blue light (400-500nm) of 1000mw

energy at different rates of time exposures, then the inhibition zones of each plate was measured by special ruler after 48hours of anaerobic incubation. Results showed that there was an increase in inhibition zone around the chlorhexidine holes, measured by millimeters as we proceed from zero, 20, 40 and 60 seconds of blue light exposure. Conclusion there is a synergistic effect between visible blue light emitted from the light curing device and 0.2% chlorhexidine digluconate mouth wash against the anaerobic periodontal pathogens.

Basheer Mohamed Abdalrahman (2014): Different Chlorhexidine preparations and formulations are available in local markets. Some preparations contain Anti-discoloration systems, additional antimicrobials like Cetylpyridinium chloride, or alcohol. The aim of this study was to compare the antimicrobial efficacies of 3 different chlorhexidine preparations. A disk diffusion test was performed using pure cultures of the organisms Streptococcus mutans and Candida albicans, in addition to mixed cultures (facultative and strict anaerobes) prepared from 14 study participants' oral rinse samples. The means and standard deviations of the diameters of inhibition zones were calculated for the different culture types. it can be concluded that both pure and alcohol containing chlorhexidine preparations are more potent against C.albicans than alcohol-free chlorhexidine preparations.

Sayar ji et al.,(2013):The study compared the efficacy of a .1% curcumin extract mouthwash + .01% eugenol (Group A) to a more strongly concentrated .2% chlorhexidine gluconate mouthwash (Group B), in subjects with mild to moderate gingivitis. Both Group A and Group B consisted of 30 subjects who were advised to use 10 ml of mouthwash with equal dilution of water for 1 min twice a day 30 min after brushing. They were then tracked for plaque and gingival changes at day 0, day 14h and day 21. Both their direct experience (subjective) and objective criteria were assessed at days 14 and 21. In all three objective parameters tested, turmeric extract was at least as effective as chlorhexidine mouthwash at improving the patient's oral health. However, technically, the curcumin formulation beat

out the chemical mouthwash in all 3 measurements, and at only one-half the concentration.

Cheng K.K et al (2012): This study compared the efficacy of two protocols for oral care using either chlorhexidine or benzydamine as oral rinses to alleviate mucositis in children undergoing chemotherapy. Eligible participants were randomised to receive either protocol for 3 weeks in a two-period crossover design. The occurrence of ulcerative lesions and severity of mucositis were measured at baseline and twice weekly, using the modified Oral Assessment Guide (OAG). Data were continuously analysed by plotting them directly on predefined sequential charts. According to this sequential analysis, the study could be terminated at the 34th within subject comparison, with a statistically significant reduction in ulcerative lesions.

Qutob AF et al (2012): This systematic review investigated, critically appraised, and rated the evidence on agents used to prevent oral mucositis in children. A comprehensive search of the relevant literature was performed up to December 2011.. Seven articles on chlorhexidine mouthwash and three on laser therapy had conflicting evidence of its use. The preventative agents that were supported by one articles included: benzydamine mouthwash, or two iseganan mouthwash, granulocyte-macrophage colony-stimulating factor mouthwash, oral/enteral glutamine, oral propantheline and cryotherapy, oral cryotherapy, oral sucralfate suspension, prostaglandin E2tablets, and chewing gum. reduction in the rates of occurrence of oral mucositis when using agents of fair (B) to good (A) evidence ranged from 22% to 52%. In conclusion, this review suggests the use of oral care protocols to prevent oral mucositis in children because of their strength of evidence (fair to good). The authors suggest avoiding agents with fair to good evidence against their use (oral <u>sucralfate</u> suspension, <u>prostaglandin</u> <u>E2</u> tablets, and <u>GM-CSF</u> mouthwash). Agents with conflicting evidence (chlorhexidine mouthwash (used solely), laser

therapy, and glutamine) should also be avoided until further research confirms their efficacy.

Dodd M.J et al., (2012): Randomized, double-blind, placebo-controlled, clinical trial. settings: 23 outpatient clinics and office practices in California. sample: 222 patients who were starting a cycle of mucositis-inducing chemotherapy. Participants were followed over three chemotherapy cycles. All patients were provided the psma program. Random assignment to a mouthwash occurred prior to the development of oral mucositis. Researchers used the Oral Assessment Guide to assess the patients oral cavities monthly (with the patients cycles of chemotherapy) and when patients reported any oral changes between cycles. Type of mouthwash, incidence, days to onset, and severity of chemotherapy-induced oral mucositis. No significant differences existed between the two mouthwashes in regard to incidence, days to onset, and severity of mucositis. Because chlorhexidine (S20 per pint) was no more effective than water, a substantial cost savings can be realized by rinsing with water. Interestingly, the psma program appeared to reduce the incidence of mucositis from on a prior estimate of 44% to less than 26%.

R.L foote et al(2011): To determine whether a chlorhexidine mouthwash could alleviate radiation-induced oral mucositis. Patients scheduled to receive radiation therapy to include greater than one third of the oral cavity mucosa were selected for study. Following stratification, they were randomized in a double-blind manner to receive a chlorhexidine mouthwash or a placebo mouthwash. Both groups were then similarly evaluated for mucositis and mouthwash toxicity. Twenty-five patients were randomized to receive the chlorhexidine mouthwash, while 27 received the placebo mouthwash. Treatment arms were well balanced. There was a trend for more mucositis and there was substantially more toxicity (eg, mouthwash-induced discomfort, taste alteration, and teeth staining) on the

chlorhexidine arm. In contrast to the prestudy hypothesis that a chlorhexidine mouthwash might provide benefit for patients receiving radiation therapy to the oral mucosa, this study provides strong evidence suggesting that a chlorhexidine mouthwash is detrimental in this clinical situation.

J.Sorensen, T.Skovsgaard (2010): A study was conducted in Denmark ,206 (70 patients in chlorhexidine group, 64 patients in normal saline and 63 patients in cryotherapy) patients with colon or gastric cancer receiving the chemotherapy were divided into three groups 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 .each group has75 patients who were given with a questionairebased on common toxicity criteria. But only 206 patients were answered to the queationaire mucositis of grade 3 & 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.

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 eachday after intervention .It was found that honey with chlorhexidine mouth wash was effective than chorhexidine mouth wash.

2.2 Part II

Conceptual frame work:

Modified Weidenbach's helping art of clinical nursing theory for assessing the effectiveness of honey application versus chlorhexidine mouth wash in treatment of oral mucositis:

The Conceptual framework is derived from modified Weidenbach's helping art of clinical nursing theory.

Emesitine weidenbach formed this theory which was first published in 1964 and further modified and published in 1970. This theory is described of a desired situation and the ways to attain it. It consist of the three factors, central purpose, prescription, and realities. The nurse develops a prescription based on a central purpose and implements it according to the realities of the situation.

Central purpose is what the nurse wants to accomplish to attain the good quality of health. In this study, the central purpose is to assess the reduction in severity of oral mucositis using the intervention.

Prescription refers to the plan of care for the patient or nursing practice. In this study, honey application and chlorhexidine mouth wash is given to the cancer children with oral mucositis. 60 children were selected among them 30 were given honey application and 30 were given chlorhexidine mouth wash.

Realities refer to the physical, physiological, emotional and spiritual factors that come into play in a situation involving nursing actions. The five realities identified by Weidenbach's are agent, recipient, goal, means and framework.

The **agent** is the practicing nurse is characterized by the personal attributes, capacities, and commitment and here the investigator is considered as agent.

The **recipient**, the patient is characterized by personal attributes, and here the recipients are the cancer children with oral mucositis.

The **goal** is the desired outcome to achieve and here, it is reduction in severity of oral mucositis.

The mean comprise the activities and devices through which the practioner is enabled to attain the goal and here the mean was honey application and chlorhexidine mouth wash.

The **framework** consists of human, environment, professional and organizational facilities. In thus, cancer ward, Institute of child health &hospital for children.

According to Weidenbach, nursing practice consists of 3 steps

- 1. Identifying need for help
- 2. Ministering the needed help.
- 3. Validating that the need was met.

1.Identifying need for help.

The Investigator identifies the cancer children with oral mucositis and its severity .demographic variables were assessed using semi structured questionnaire and oral mucositis is assessed using standard WHO oral mucositis assessment scale .The samples were divided into experimental and control group.

2. Ministering the needed help.

The children in experimental group were given honey application and control group were given chlorhexidine mouth wash ,three times a day for 5 days.

3. Validating that the need was met.

The investigator does a post test assessment with the same scale on the sixth day of intervention.

Projected outcome: Honey application reduces the severity of oral mucositis more effectively than chlorhexidine mouth wash.

CENTRAL PURPOSE

ASSESS THE EFFECTIVENESS OF HONEY APPLICATION VERSUS CHLORHEXIDINE MOUTH WASH IN REDUCING ORAL MUCOSITIS

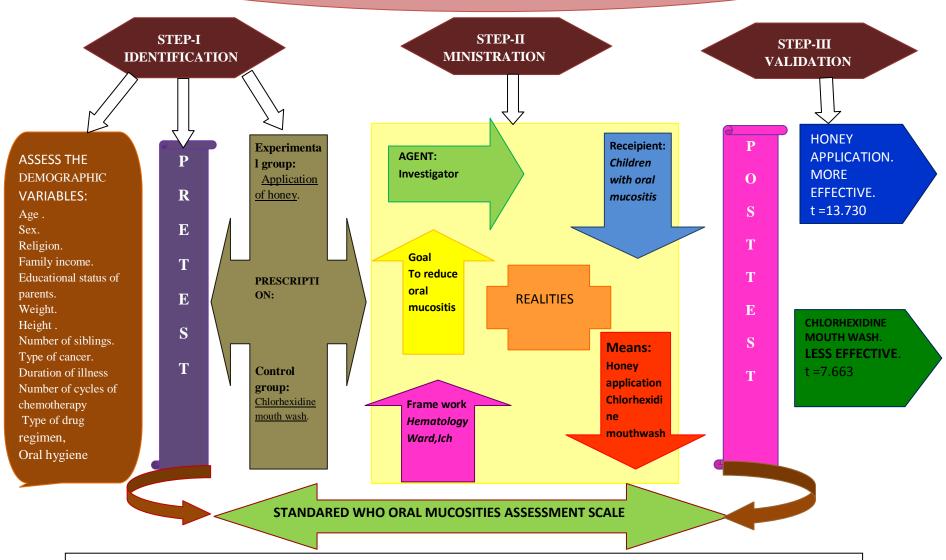


Fig. 2.2 Modified Weidenbach's helping art of clinical nursing theory

CHAPTER III

METHODOLOGY

This chapter deals with the brief description of the different steps the researcher did 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 selected was quantitative approach

3.2 Data collection period:

The study was conducted for a period of four weeks from 15.07.2015 to 17.08.2015.

3.3 Study setting:

The study was conducted in hematology ward at Institute of Child Health &Hospital for Children, Chennai. The bed strength of the hospital is 837. The bed occupancy rate of the ward is 125%. Average length of stay of a patient is 7 -9 days. Institute of Child Health &Hospital for children is the second biggest hospital in South East Asia providing excellent care to children. The institute is rendering meritorious care and has been contributing to various research in the field of Child health.

3.4 Study design:

A <u>detailed outline</u> of how an investigation will take place. A research design will typically include how <u>data</u> is to be collected, what <u>instruments</u> will be <u>employed</u>, how the instruments will be used and the intended <u>means</u> for analyzing data collected. The **research design** was **Quasi experimental design**.

Experimental	01	X1	02
group			
Control group	1	X2	2

01 -Pre test of experimental group

X1 – Honey application

02 - Post test of experimental group

1 - Pretest of control group

X2 – chlorhexidine mouth wash

2 – Post test of control group.

3.5 Study population:

The study population was, all children admitted in hematology ward within the age group from 5 to 10 years undergoing chemotherapy and had oral mucositis in Institute of Child Health and Hospital for Children, Chennai.

3.6 Sample size:

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The sample size was N = 60
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Experimental group n=30

Control group n= 30

3.7 Criteria for sample selection:

3.7.1 Inclusion criteria:

- Children who are willing to participate.
- Children who are conscious, oriented able to follow instructions.
- Cancer children of age group 5 -10 years both sexes.
- Children who are available at the period of study.
- Children with oral mucositis due to chemotherapy.
- Parents who can understand and speak English and / or Tamil.

3.7.2 Exclusion criteria:

- Diet restriction on honey.
- Children with bleeding gums.
- Severely ill children.
- Parents who are taking home remedies for oral mucositis.

3.8 Sampling technique:

The sampling technique used was **convenient sampling technique**. Every day 5 children with oral mucositis were taken for study after consulting with hematologist.

3.9 Research variables:

3.9.1 Dependant variable:

In this study the dependant variable is healing of oral mucositis of children undergoing chemotherapy.

3.9.2 Independent variable:

In this study the independent variable is honey application versus chlorhexidine mouth wash for five days.

3.10 Development and Description of the tool:

3.10.1 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, statistical 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.

3.10.2 Description of the tool:

➤ Section A – This section consists of demographic and baseline data of children like age, weight, height, educational status of the parents, diagnosis, number of chemotherapy cycles, duration of oral mucositis, oral hygiene followed.

> Section B- This section includes standard WHO grading system for oral mucositis.

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

SECTION B: TABLE 3.1 Standard WHO grading system for oral mucositis.

GRADE	ORAL MUCOSITIS	BEFORE	AFTER	
	WHO GRADING	INTERVENTION	INTERVE	NTION
			3 rd day	5 th day
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:

- 0 No oral mucositis.
- 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.

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

3.10.3 Intervention protocol:

	Experimental group	Control group
Place	Hematology ward	Hematology ward
Intervention tool	Honey application	Chlorhexidine mouth wash
Duration	Five days	Five days
Frequency	Three times a day After food	Three times a day After food
Time	8 a.m,12 n, 5 p.m	8 a.m,12 n, 5 p.m
Administered by	The Investigator	The Investigator

3.10.4 Content validity

Validity is an important characteristic of a scientific instrument .the term validity refers to the degree to which a test measures what it claims to measure .The validity was ascertained by the experts in the field of medicine and nursing. the suggestion of experts were incorporated in the study and the tool was finalized. The refined tool was used for data collection and content validity was obtained.

3.11 Ethical consideration:

Approval obtained from the Institutional Ethics Committee, Madras medical college, Chennai. 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. Thus the investigator followed the ethical guidelines , which were issued by research committee or by authority. Written permission was obtained from all parents.

3.12 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 &hospital for children, Chennai. The children who met the inclusion and exclusion criteria were selected for the study. Number of samples selected were 10 ,5 for honey application and 5 for chlorhexidine mouth wash. Informed written consent was obtained from the mothers of the sample baseline data were collected from the medical records and interview. each child's oral mucositis are assessed by using WHO grade for assessment of oral mucositis. After initial assessment, one child was treated with honey application and next child with chlorhexidine mouth wash alternatively. The intervention was given 3 times a day for 5 days and post assessment was done on 3rd and 5th day using WHO oral mucositis scale. Through pilot study the instrument was found reliable for proceding with the main study.

3.13 Reliability:

After Pilot study the reliability of the tool was assessed by using test retest method. Efficacy questionnaire reliability was assessed using test and retest method and its correlation coefficient value is r = 0.84. The correlation coefficient is very high and it is good tool for assessing the effectiveness of honey application versus chlorhexidine mouth wash on oral mucositis.

3.14 Data collection procedure:

The data collection was done for 4 weeks from 15.07.2015 to 17.08.2015.

A self introduction was given by the investigator. Children with oral mucositis who met the inclusion criteria were selected .demographic variables were assessed. After the explanation, consent was obtained from the mother. Samples selected were 60 in which 30 was taken for honey application and 30 was taken for chlorhexidine mouth wash. The steps of therapy were explained to the mother with its benefits before the assessment. The intervention were given alternatively to the children.

The steps were divided into three parts.

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

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

Part 3:

For experimental group:

Steps in honey application.

- 1. Explain the procedure to the mother.
- 2. Place the child in comfortable position.
- 3. Provide 3 ml of honey in a small disposable cup.
- 4. Apply the honey on the oral cavity with a sterile cotton swab.
- 5. Provide this treatment for 3 times a day for 5 days.
- 6. Assess the healing of oral mucositis on the 3rd and 5th day using standard WHO oral mucositis scale.

For control group:

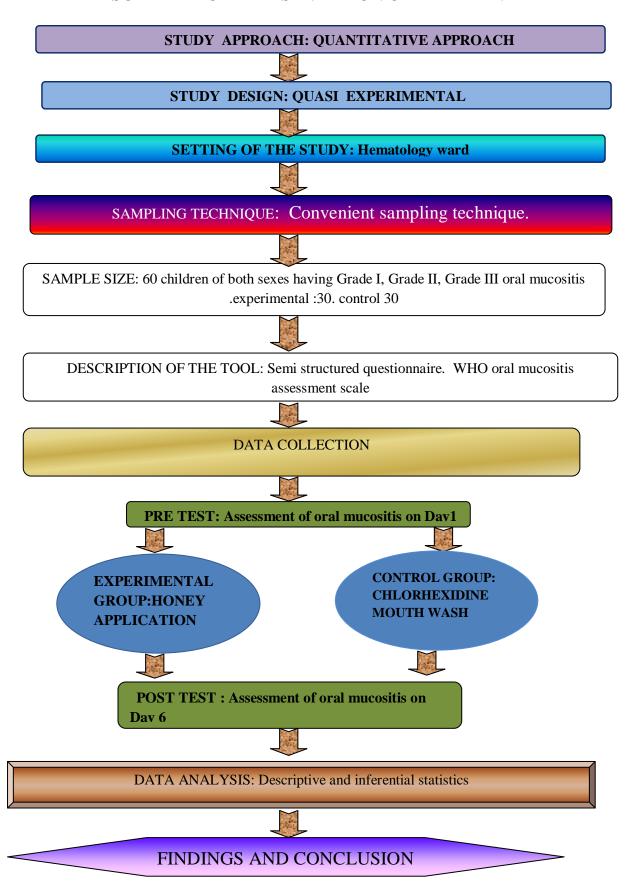
Steps in chlorhexidine mouth wash:

- 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 chlohexidine mouth wash to the child for rinsing the mouth for 30 seconds.
- 5. Then ask the child to spit it out.
- 6. Provide chlorhexidine three times a day for five days.
- 7. Assess the healing of oral mucositis on the 3rd and 5th day using standard WHO oral mucositis scale.

3.15 Data entry and analysis:

The data were analyzed using descriptive statistics and inferential statistics. Data was presented in frequency table to compare the pre test and post test assessment differences between experimental group(honey) and control group (chlorhexidine).statistical analysis of paired 'T' test was applied to test the mean value pre test and post test assessment of oral mucositis.

SCHEMATIC REPRESENTATION OF THE PLAN



CHAPTER – IV

DATA ANALYSIS AND INTERPRETATION

This chapter deals with the analysis and interpretation of data collected from 30 cancer children of 5 - 10 years, to assess the effectiveness of honey application versus chlorhexidine mouth wash in reducing oral mucositis among cancer children of 5 - 10 years. The data collected for the study was grouped and analyzed as per the objectives set for the study. The findings based on the descriptive and inferential statistical analysis are presented under the following sections.

ORGANIZATION OF DATA

The findings of the study were grouped and analyzed under the following sessions.

- **Section A:** Description of the demographic variables.
- **Section B:** Assessment of pretest and post test level of oral mucositis among cancer children receiving chemotherapy in experimental and control group.
- **Section C:** Effectiveness of honey application and chlorhexidine on oral mucositis among cancer children receiving chemotherapy.
- **Section D:** Association of post test level of oral mucositis among cancer children receiving chemotherapy with their selected demographic variables in the experimental and control group.

SECTION A: DESCRIPTION OF THE DEMOGRAPHIC VARIABLES.

Table 4.1: Distribution of demographic variables of cancer children receiving chemotherapy.

N = 60(30+30)

	Experime	ntal Group	Contro	l Group
Demographic Variables			Frequency	
A 641 1911	Frequency	percentage	•	Frequency
Age of the child	17	56.67	1.5	50.00
5 to 7 years	17	56.67	15	50.00
7 to 8 years	8 5	26.67	6	20.00
8 to 10 years	5	16.67	9	30.00
Sex of the child		56.67	10	62.22
Male child	12	56.67	19	63.33
Female child	13	43.33	11	36.67
Religion	1.5	70.00		
Hindu	15	50.00	21	70.00
Christian	8	26.67	7	23.33
Muslim	7	23.33	2	6.67
Others	0	0.00	0	0.00
Fathers educational status				
No-formal education	10	33.33	8	26.67
Primary school	11	36.67	12	40.00
Middle school	9	30.00	10	33.33
High school	0	0.00	0	0.00
Higher secondary school	0	0.00	0	0.00
Graduate	0	0.00	0	0.00
Mothers educational status				
No-formal education	16	53.33	11	36.67
Primary school	9	30.00	10	33.33
Middle school	5	16.67	9	30.00
High school	0	0.00	0	
Higher secondary school	0	0.00	0	0.00
Graduate	0	0.00	0	0.00
Father's occupation				
Unemployed	13	43.33	10	33.33
Unskilled worker	9	30.00	15	50.00
Skilled worker	8	26.67	5	16.67
Business	0	0.00	0	0.00
Profession	0	0.00	0	0.00
Family income				
1000 to 3000	8	26.67	4	13.33
3000 to 5000	16	53.33	21	70.00
5000 to 7000	6	20.00	5	16.67
7000 to 10000	0	0.00	0	0.00
Residential area				
Urban	7	23.33	9	30.00
Semi urban	9	30.00	9	30.00
Rural	14	46.67	12	40.00
Type of family				
Joint family	17	56.67	17	56.67

	Experime	ntal Group	Control Group	
Demographic Variables	Frequency	percentage	Frequency	Frequency
Nuclear family	13	43.33	13	43.33
Extended family	0	0.00	0	0.00
No. of siblings				
0	14	46.67	9	30.00
1	11	36.67	17	56.67
2	5	16.67	4	13.33
More than 2	0	0.00	0	0.00
Height of the child in cms				
95 - 105 cms	17	56.67	12	40.00
105 - 125 cms	12	40.00	12	40.00
125 - 145 cms	1	3.33	6	20.00
Weight of the child in kgs				
05 - 10 kgs	14	46.67	15	50.00
10 -20 kgs	15	50.00	11	36.67
20 -30 kgs	1	3.33	4	13.33
Type of cancer				
ALL/CLL	10	33.33	20	66.67
AML/CML	6	20.00	5	16.67
NHL/HL	14	46.67	5	16.67
Other type of cancer	0	0.00	0	0.00
Duration of illness				
Below 6 months	0	0.00	5	16.67
1 to 2 years	22	73.33	16	53.33
2 to 3 years	8	26.67	9	30.00
More than 2 years	0	0.00	0	0.00
Type of chemotherapy				
Single drug regimen	0	0.00	2	6.67
Two drug regimen	15	50.00	16	53.33
More than two drug regimen	15	50.00	12	40.00
Number of cycles of chemotherapy				
1st cycle	0	0.00	1	3.33
2nd cycle	6	20.00	9	30.00
3rd cycle	24	80.00	19	63.33
More than 3 cycle	0	0.00	1	3.33
Occurrence of oral mucositis				
Freshly occurred	4	13.33	1	3.33
Occurred once and treated	9	30.00	10	33.33
Occurred twice and treated	17	56.67	19	63.33
Occurred but not treated	0	0.00	0	0.00
Oral hygiene followed by the child				
Brushes once daily	28	93.33	28	93.33
Brushes twice daily	2	6.67	0	0.00
Brushes with mouth wash	0	0.00	2	6.67

The table 1 shows that,

Age:In the experimental group, 17(56.67%) were in the age group of 5 to 7 years, 8(26.6%) were in the age group of 7 to 8 years,5(16.67%) were in the age group of 8 to 10 years. In control group 15(50%) were of 5 -7 years,6(20%) were of 7 to 8 years,9(30%) in the age group of 8 to 10 years.

Sex: In experimental group about 17 (56.67%) were male children,13(43.3%) and 13(43.33%) were female children. In control group 19(63.33%) were male and 11(36.6%) were female.

Religion : In the experimental group,15(50.0%) were hindus ,8(26.67%) were Christian,7 (23.33%) were muslim and there were none in other religion. In control group 21(70%) were hindus ,7(23.33%) were Christians,2(6.67%) were muslims and there were none in other religion. Had primary school education

Fathers educational status: In experimental group ,10 (33.33%) had no formal education,11(36.67%) Had primary school education,9 (30.00%) had middle school education, None were in higher secondary and were graduates. In control group, 8(26.67%) had no formal education,12(40%) Had primary school education,10(33.33%) had middle school education, None were in higher secondary and were graduates.

Mothers educational status: In experimental group ,16(53.33%) had no formal education, 9 (30.%) had primary school education, 5(16.67%) had middle school education, None were in higher secondary and were graduates. In control group, 11(36.67%) had no formal education,10(33.33%) Had primary school education,9 (30.%) had middle school education, None were in higher secondary and were graduates.

Father's occupation: In Experimental group,13 (43.33%) were unemployed,9(30%) were unskilled worker,8(26.67%) were skilled worker. no father were in business and profession. In control group, 10 (33.33%) were

unemployed, 15(50%) were unskilled worker, 5 (16.67%)were skilled worker. no father were in business and profession.

16(53.33%) had 3000 -5000,6 (20%) had 5000- 7000,none were under 7000 - 10000. In control group 4(13.33%) had the income of Rs. 1000 -3000,21(70%) had 3000 -5000,5 (16.67%) had 5000- 7000,none were under 7000 -10000.

Residential area: in experimental group, 7 (23.33%) belongs to urban,9(30%)belongs to semiurban,14 (46.67%) were in rural area.

Type of family: In experimental group,17(56.67%) belongs to joint family,13 (43.33%) belongs to nuclear family, no one belongs to extended family. In control group,17 (56.67%) %) belongs to joint family,13 (43.33%) belongs to nuclear family, no one belongs to extended family.

Number of siblings: In experimental group,14 (46.67%)had no siblings,11 (36.67%) had 1 sibling,5 (16.67%) had 2 siblings, none of had more than 2 siblings. In control group,

9 (30%)had no siblings,17 (56.67%) had 1 sibling,4 (13.33%) had 2 siblings, none of had more than 2 siblings.

Height of the child in(cms): In experimental group,17 (56.67%) were of 95 -105 cms,12 (40%) were of 105 -125 cms,1 (3.33%) was of 125 -145 cms. In control group,12 (40%) were of 95 -105 cms,12 (40%) were of 105 -125 cms,4 (13.33%) was of 125 -145 cms.

Weight of the child in (kgs): In experimental group, 14 (46.67%) were of 5 -10 kgs, 15 (50%) were 10 -20 kgs ,1 (3.33)was of 20 -30 kgs. In control group,15 (50%) were 5 -10 kgs,11 (36.67%) were 10 -20 kgs ,4 (13.33%) were 20 -30 kgs.

Type of cancer: In experimental group,10(33.33%) were ALL/CLL,6 (20%)were AML/CML ,14(46.67%) were NHL/HL. In control group,20(66.67%) were ALL/CLL,5 (16.67%)were AML/CML,5(16.67%) were NHL/HL.

Duration of illness: In experimental group,0(0%) belongs to below 6 months,22(73.33%) were of 1 to 2 years duration,8(26.67%) were of 2 to 3 years duration. None were of more than 2 years duration. In control

group,5(16.67%)were of below 6 months duration,16(53.33%)were of 1 to 2 years duration,9(30%)were of 2 to 3 years duration. none were of more than 2 years duration.

Type of chemotherapy: In experimental group,0(0%) were of single drug regimen,15 (50%) were of two drug regimen,15 (50%) were of more than two drug regimen. In control group,2 (6.67%) were of single drug regimen,16(53.33%) were of two drug regimen,12(40%) were of more than two drug regimen.

Number of cycles of chemotherapy: In experimental group, none were of 1^{st} cycle,6 (20%) were of 2^{nd} cycle,24(80%) were of 3^{rd} cycle. no one were of more than 3 cycle.

In control group,1(3.33%) were of 1^{st} cycle,9(30%) were of 2^{nd} cycle,19(63.33%) were of 3^{rd} cycle,1(3.33%) were of more than 3 cycle.

Occurrence of oral mucositis: In experimental group,4 (13.33%) were of freshly occurred mucositis,9(30%) were of once occurred and treated,17(56.67%) were of twice occurred and treated, none of them were of occurred but not treated. In control group,1 (3.33%) were of freshly occurred,10 (33.33%) were of once occurred and treated,19(63.33%) were of twice occurred and treated, none of them were of occurred but not treated.

Oral hygiene followed by the child: In experimental group,28(93.33%) belongs to brushes once daily,2 (6.67%) belongs to brushes twice daily, none of them were doing mouth wash with brushing. In control group,28(93.33%) belongs to brushes once daily, none of them brushes twice daily,2(6.67%) brushes once and uses mouthwash.

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SECTION B: ASSESSMENT OF PRETEST AND POST TEST LEVEL OF ORAL MUCOSITIS AMONG CANCER CHILDREN RECEIVING CHEMOTHERAPY IN EXPERIMENTAL AND CONTROL GROUP.

Table 4. 2: Frequency and percentage distribution of pretest and post test level of oral mucositis among cancer children receiving chemotherapy in experimental group.

n = 30

Oral Mucositis	None (0)		Mild (1)		Mode (3)	erate	Sever (4)	•	Life threat (5)	ening
	No.	%	No.	%	No.	%	No.	%	No.	%
Pretest	0	0	6	20.0	14	46.67	10	33.33	0	0
Pos t Test	18	60.0	12	40.0	0	0	0	0	0	0

The table 2 shows that in the pretest, majority 14(46.67%) had moderate level of oral mucosiis, 10(33.33%) had severe and 6(20%) had mild level of oral mucositis. Whereas in the post test after the honey application, majority 18(60%) had no oral mucositis and 12(40%) mild level of oral mucositis among cancer children receiving chemotherapy

Table 4.3: Frequency and percentage distribution of pretest and post test level of oral mucositis among cancer children receiving chemotherapy in control group.

n = 30

Oral Mucositis	None (0)		Mild (1)		Mode (3)	erate	Seven (4)	r	Life threat (5)	ening
	No.	%	No.	%	No.	%	No.	%	No.	%
Pretest	0	0	9	30.0	14	46.67	7	23.33	0	0
Pos t Test	7	23.33	23	76.67	0	0	0	0	0	0

The table 3 shows that in the pretest, majority 14(46.67%) had moderately level of oral mucosiis, 9(30%) had mild and 7(23.33%) had severe level of oral mucositis. Whereas in the post test after the chlorhexidine mouth wash, majority 23(76.67%) had mild level of oral mucositis and 7(23.33%) no oral mucositis among cancer children receiving chemotherapy in control group.

Table 4.4: Frequency and percentage distribution of pretest and post test level of oral mucositis among cancer children receiving chemotherapy in control group.

n = 30

Oral Mucositis	None (0)	,	Mild (1)		Mode (3)	erate	Sever (4)	r	Life threat (5)	ening
	No.	%	No.	%	No.	%	No.	%	No.	%
Pretest	0	0	9	30.0	14	46.67	7	23.33	0	0
Pos t Test	7	23.33	23	76.67	0	0	0	0	0	0

The table 3 shows that in the pretest, majority 14(46.67%) had moderately level of oral mucositis, 9(30%) had mild and 7(23.33%) had severe level of oral mucositis. Whereas in the post test after the chlorhexidine mouth wash, majority 23(76.67%) had mild level of oral mucositis and 7(23.33%) no oral mucositis among cancer children receiving chemotherapy in control group.

SECTION C: EFFECTIVENESS OF HONEY APPLICATION AND CHLORHEXIDINE ON ORAL MUCOSITIS AMONG CANCER CHILDREN RECEIVING CHEMOTHERAPY.

Table 4.5: Comparison of pretest and post test oral mucositis score among cancer children receiving chemotherapy in the experimental group

$$n = 30$$

Oral Mucositis	Mean	S.D	Paired 't' Value
Pretest	2.13	0.73	t = 13.730
Post Test	0.40	0.49	p = 0.000, S

^{***}p<0.001, S – Significant

The table 4 shows that in the pretest, the mean score of oral mucositis was 2.13 ± 0.73 whereas in the post test the mean score of oral mucositis was 0.40 ± 0.49 . The calculated paired 't' value of t=13.730 was found to statistically significant at p<0.001 level. This clearly shows that after honey application among cancer children receiving chemotherapy there was significant decrease in the level of oral mucositis in the post test level among cancer children in the experimental group.

Table 4.6: Comparison of pretest and post test oral mucositis score among cancer children receiving chemotherapy in the control group

n = 30

Oral Mucositis	Mean	S.D	Paired 't' Value
Pretest	1.93	0.73	t = 7.663
Post Test	0.76	0.43	p = 0.000, S

***p<0.001, S – Significant

The table 5 shows that in the pretest, the mean score of oral mucositis was 1.93 ± 0.73 whereas in the post test the mean score of oral mucositis was 0.76 ± 0.43 . The calculated paired 't' value of t=7.663 was found to statistically significant at p<0.001 level. This clearly shows that after chlorhexidine mouth wash among cancer children receiving chemotherapy there was significant decrease in the level of oral mucositis in the post test level among cancer children in the control group.

Table 4.7: Comparison of post test oral mucositis score among cancer children receiving chemotherapy between the experimental and control group n=30

Oral Mucositis	Mean	S.D	Unpaired 't'
			Value
Experimental Group	0.40	0.49	t = 3.051 $p = 0.003, S**$
Control Group	0.76	0.43	P 0.000, 2

**p<0.01, S – Significant

The table 6 shows that in the experimental group, the post test mean score of oral mucositis was 0.40 ± 0.49 whereas in the control group, the post test the mean score of oral mucositis was 0.76 ± 0.43 . The calculated unpaired 't' value of t=3.051 was found to statistically significant at p<0.01 level. This shows that there was significant difference between the level of oral mucositis among children in the experimental group and control group. This clearly indicates that honey application was found to be effective than chlorhexidine mouth wash in reducing the level of oral mucositis among cancer children receiving chemotherapy.

SECTION D: ASSOCIATION OF POST TEST LEVEL OF ORAL MUCOSITIS AMONG CANCER CHILDREN RECEIVING CHEMOTHERAPY WITH THEIR SELECTED DEMOGRAPHIC VARIABLES IN THE EXPERIMENTAL AND CONTROL GROUP.

Table 4.8: Association of post test level of oral mucositis among cancer children receiving chemotherapy with their selected demographic variables in the experimental group.

n = 30

	None		Mild			
Demographic Variables	(0)		(1)		Chi-Square Value	
	No.	%	No.	%		
Age of the child					$\chi^2 = 0.490$	
5 to 7 years	11	36.7	6	20.0	d.f=2	
7 to 8 years	4	13.3	4	13.3	p = 0.783	
8 to 10 years	3	10.0	2	6.7	N.S	
Sex of the child					$\chi^2 = 0.023$	
Male child	10	33.3	7	23.3	d.f=1	
F 1 171	8	26.7	5	16.7	p = 0.880	
Female child					N.S	
Religion	11	267	4	12.2	$\chi^2 = 2.822$	
Hindu	11	36.7	4	13.3	$-\int_{d.f=2}^{\chi-2.622}$	
Christian	3	10.0	5	16.7	p = 0.244	
Muslim	4	13.3	3	10.0	N.S	
Others	-	-	-	-	14.5	
Fathers educational status						
Non-formal education	8	26.7	6	20	2	
Primary school	10	33.3	5	16.7	$\chi^2 = 1.825$	
Middle school	0	0	1	3.3	d.f=2	
High school	-	-	-	-	p = 0.401	
Higher secondary school	-	-	-	-	N.S	
Graduate						
Mothers educational status						
Non-formal education	9	30.0	7	23.3		
Primary school	6	20.0	3	10.0	$\chi^2 = 0.260$	
Middle school	3	10.0	2	6.7	d.f=2	
High school	-	-	-	-	p = 0.878	
Higher secondary school	-	-	-	-	N.S	
Graduate	-	-	-	-		
Father's occupation						
Unemployed	8	26.7	5	16.7	$\chi^2 = 2.886$	
Unskilled worker	7	23.3	2	6.7	d.f=2	
Skilled worker	3	10.0	5	16.7	p = 0.236	
Business	-	-	-	-	N.S	
Profession	-	-	-	-		
Family income					2	
1000 to 3000	5	16.7	3	10.0	$\chi^2 = 0.313$	
3000 to 5000	10	33.3	6	20.0	d.f=2	
5000 to 7000	3	10.0	3	10.0	p = 0.855	
7000 to 10000	-	-	-	-	N.S	
Residential area					$\chi^2 = 0.238$	
Urban	4	13.3	3	10.0	d.f=2	
Semi urban	6	20.0	3	10.0	p = 0.888	
Rural	8	26.7	6	20.0	N.S	
Type of family	T T				$\chi^2 = 1.833$	
Joint family	12	40.0	5	16.7	d.f=1	
Nuclear family	6	20.0	7	23.3	p = 0.176	
Extended family	-	-	-	-	N.S	
No. of siblings		<u> </u>			$\chi^2 = 3.290$	
0	6	20.0	8	26.7	$\chi = 3.290$ d.f=2	
V						
1	8	26.7	3	10.0	p = 0.193	

Demographic Variables	None (0)		Mild (1)		Chi-Square Value
	More than 2	-	-	-	-
Height of the child in cms					$\chi^2 = 1.324$
95 - 105 cms	8	26.7	2	6.7	d.f=2
105 - 125 cms	3	10.0	8	26.7	p = 0.516
125 - 145 cms	7	23.3	2	6.7	N.S
Weight of the child in kgs					$\chi^2 = 7.761$
05 - 10 kgs	8	26.7	2	6.7	d.f=2
11 - 20 kgs	3	10.0	8	26.7	p = 0.021
21 - 30 kgs	7	23.3	2	6.7	S*
Type of cancer					2 2 202
ALL/CLL	7	23.3	3	10.0	$\chi^2 = 2.302$
AML/CML	2	6.7	4	13.3	d.f=2
NHL/HL	9	30.0	5	16.7	p = 0.316 N.S
Other type of cancer	-	-	-	-	N.S
Duration of illness					2 0 155
Below 6 months	-	-	-	-	$\chi^2 = 0.455$
1 to 2 years	14	46.7	8	26.7	d.f=1
2 to 3 years	4	13.3	4	13.3	p = 0.500
More than 2 years	-	-	-	-	N.S
Type of chemotherapy					$\chi^2 = 0.556$
Single drug regimen	-	-	-	-	d.f=1
Two drug regimen	10	33.3	5	16.7	p = 0.456
More than two drug regimen	8	26.7	7	23.3	N.S
Number of cycles of chemotherapy					$\chi^2=0.313$
1st cycle	-	-	-	-	
2nd cycle	3	10.0	3	10.0	
3rd cycle	15	50.0	9	30.0	p = 0.576 N.S
More than 3 cycle	-	-	-	-	C11
Occurrence of oral mucositis					$\chi^{2}=0.459$ d.f=2 p = 0.795 N.S
Freshly occurred	3	10.0	1	3.3	
Occurred once and treated	5	16.7	4	13.3	
Occurred twice and treated	10	33.3	7	23.3	
Occurred but not treated	-	-	-	-	- 112
Oral hygiene followed by the child					$\chi^2 = 0.089$ d.f=1
Brushes once daily	17	56.7	11	36.7	
Brushes twice daily	1	3.3	1	3.3	p = 0.765
Brushes with mouth wash	-	-	-	-	N.S

*p<0.05, S – Significant, N.S – Not Significant

The table 7 shows that the demographic variable weight of the child had shown statistically significant association with post test level of oral mucositis among cancer children at p<0.05 level and the other demographic variables had not shown statistically significant association with post test level of oral mucositis among cancer children in the experimental group.

Table 4.9: Association of post test level of oral mucositis among cancer children receiving chemotherapy with their selected demographic variables in the control group.

n = 30

Demographic Variables	None (0)		Mild (1)		Chi Carrana Valera
	No.	%	No.	%	Chi-Square Value
Age of the child					$\chi^2 = 0.435$
5 to 7 years	3	10.0	12	40.0	d.f=2
7 to 8 years	2	6.7	4	13.3	p = 0.805
8 to 10 years	2	6.7	7	23.3	N.S
Sex of the child					$\chi^2=0.151$
Male child	4	13.3	15	50.0	d.f=1
Table Silie					p = 0.698
Female child	3	10.0	8	26.7	N.S
Religion					2
Hindu	6	20.0	15	50.0	$\chi^2 = 1.251$
Christian	1	3.3	6	20.0	d.f=2
Muslim	0	0	2	6.7	p = 0.535
Others	_	_	-	_	N.S
Fathers educational status					
No-formal education	4	13.3	4	13.3	\dashv
Primary school	2	6.7	10	33.3	$\chi^2 = 4.472$
Middle school	1	3.3	9	30.0	d.f=2
High school	-	-	-	-	p = 0.107
Higher secondary school		-	 -	-	N.S
Graduate Secondary school					
	-	-	-	-	
Mothers educational status				20.0	
Non-formal education	2	6.7	9	30.0	2 0 410
Primary school	3	10.0	7	23.3	$\begin{array}{c} \chi^2 = 0.418 \\ \text{d.f} = 2 \\ \text{p} = 0.811 \\ \text{N.S} \end{array}$
Middle school	2	6.7	7	23.3	
High school	-	-	-	-	
Higher secondary school	-	-	-	-	N.5
Graduate	-	-	-	-	
Father's occupation					
Unemployed	3	10.0	7	23.3	$\chi^2 = 0.373$
Unskilled worker	3	10.0	12	40.0	d.f=2
Skilled worker	1	3.3	4	13.3	p = 0.830 N.S
Business	-	-	-	-	
Profession	-	-	-	-	
Family income					2
1000 to 3000	1	3.3	3	10.0	$\chi^2 = 0.040$
3000 to 5000	5	16.7	15	50.0	d.f=2
5000 to 7000	1	3.3	4	13.3	p = 0.980
7000 to 10000	-	-	<u> </u>	-	N.S
Residential area				1	$\chi^2 = 5.000$
Urban	0	0	9	30.0	d.f=2
Semi urban	4	13.3	5	16.7	p = 0.082
Rural	3	10.0	9	30.0	N.S
Type of family		- 5.0		2 3.0	$\chi^2 = 0.709$
Joint family	3	10.0	14	46.7	d.f=1
Nuclear family	4	13.3	9	30.0	p = 0.400
Extended family		-	-	-	N.S
No. of siblings				- 	1
0	3	10.0	6	20.0	$\chi^2 = 3.365$ d.f=2
1	2	6.7	15	50.0	
					p = 0.186
2	2	6.7	2	6.7	N.S
More than 2	-	-	-	-	

Demographic Variables	None (0)		Mild (1)		Chi-Square Value
	No.	%	No.	%	- Square value
Height of the child in cms					$\chi^2 = 1.118$
95 - 105 cms	2	6.7	10	33.3	d.f=2
105 - 125 cms	4	13.3	8	26.7	p = 0.572
125 - 145 cms	1	3.3	5	16.7	N.S
Weight of the child in kgs					$\chi^2 = 0.2653$
10 - 20 kgs	4	13.3	11	36.7	d.f=2
20 - 30 kgs	2	6.7	9	30.0	p = 0.877
30 - 40 kgs	1	3.3	3	10.0	N.S
Type of cancer					_
ALL/CLL	5	16.7	15	50.0	$\chi^2 = 0.093$
AML/CML	1	3.3	4	13.3	d.f=2
NHL/HL	1	3.3	4	13.3	p = 0.954
Other type of cancer	-	-	-	-	N.S
Duration of illness					
Below 6 months	1	3.3	4	13.3	$\begin{array}{c} \chi^2 = 3.323 \\ \text{d.f=2} \\ \text{p} = 0.190 \end{array}$
1 to 2 years	2	6.7	14	46.7	
2 to 3 years	4	13.3	5	16.7	
More than 2 years	-	-	-	-	N.S
Type of chemotherapy					χ ² =1.467
Single drug regimen	0	0	2	6.7	d.f=2 p = 0.030 S*
Two drug regimen	5	16.7	11	36.7	
More than two drug regimen	2	6.7	10	33.3	
Number of cycles of chemotherapy	$\chi^2 = 3.455$				
1st cycle	0	0	1	3.3	$\begin{array}{c} \chi = 5.455 \\ \text{d.f} = 2 \\ \text{p} = 0.327 \\ \text{N.S} \end{array}$
2nd cycle	4	13.3	5	16.7	
3rd cycle	3	10.0	16	53.3	
More than 3 cycle	0	0	1	3.3	
Occurrence of oral mucositis					$\chi^{2}=0.608$ d.f=2 p = 0.738
Freshly occurred	0	0	1	3.3	
Occurred once and treated	3	10.0	7	23.3	
Occurred twice and treated	4	13.3	15	50.0	N.S
Occurred but not treated	-	-	-	-	
Oral hygiene followed by the child	$\chi^2 = 0.652$				
Brushes once daily	7	23.3	21	70.0	d.f=1 p = 0.419 N.S
Brushes twice daily	-	-	-	-	
Brushes with mouth wash	0	0	2	6.7	

^{*}p<0.05, N.S – Not Significant ,S –Significant.

The table 8 shows that the demographic variable type of chemotherapy had shown statistically significant association with post test level of oral mucositis among cancer children at p<0.05 level and the other demographic variables had not shown statistically significant association with post test level of oral mucositis among cancer children in the control group.

CHAPTER V

SUMMARY OF THE RESULT

5.1 SUMMARY

Research design adopted was quasi experimental design. the study was conducted in the Institute of Child Health and Hospital for Children, Chennai. The sampling technique used was convenient sampling technique. Sixty samples were selected among which 30 were taken for honey application and 30 samples for chlorhexidine mouth wash.

Validity and reliability of the tool was tested through pilot study. Questionnaire was prepared to obtain the baseline data.pre and post assessment of oral mucositis was done using WHO oral mucositis assessment scale. Intervention like honey application and chlorhexidine mouth wash were given 3 times a day. The healing of mucositis was assessed on 3rd and 5th day of the intervention.

5.2.1 Findings of the study:

Findings of socio demographic data:

The study shows that in the experimental group, majority 17(56.67%) were in the age group of 5 to 7 years, 17(56.67%) were male, 15(50%) were Hindus, 11(36.67%) of fathers were educated up to primary school, 16(53.33%) of mothers had no formal education, 13(43.33%) of fathers were unemployed, 16(53.33%) had a family income of Rs.3000 to 5000, 14(46.67%) were from rural area, 17(56.67%) belonged to joint family, 14(46.67%) had no siblings. 17(56.67%) were in the height range of 95 - 105 cms, 15(50%) were weighed 10 - 20 kgs, 14(46.67%) had NHL/HL type of cancer, 22(73.33%) were suffering from cancer for 1 to 2 years, 15(50%) had two drug regimen and more than two drug regimen

respectively, 24(80%) had 3rd cycle of chemotherapy, 17(56.67%) had the occurrence of oral mucositis twice and treated and 28(93.33%) brushed once daily.

Whereas in the control group, majority 15(50%) were in the age group of 5 to 7 years, 19(63.33%) were male, 21(70%) were Hindus, 12(40%) of fathers were educated up to primary school, 11(36.67%) of mothers had no formal education, 15(50%) of fathers were unskilled workers, 21(70%) had a family income of Rs.3000 to 5000, 12(40%) were from rural area, 17(56.67%) belonged to joint family, 17(56.67%) had one sibling, 12(40) were in the height range of 95 – 105 cms and 105 125 cms respectively, 15(50%) were weighed 10 – 20 kgs, 20(66.67%) had ALL/CLL type of cancer, 16(53.33%) were suffering from cancer for 1 to 2 years, 16(53.33%) had two drug regimen, 19(63.33%) had 3rd cycle of chemotherapy, 19(63.33%) had the occurrence of oral mucositis twice and treated and 28(93.33%) brushed once daily.

5.2.2 Findings on level of pre test level of oral mucositis.

In the pretest, majority 14(46.67%) had moderate level of oral mucosiis, 10(33.33%) had severe and 6(20%) had mild level of oral mucositis in the experimental group. the pretest, majority 14(46.67%) had moderately level of oral mucosiis, 9(30%) had mild and 7(23.33%) had severe level of oral mucositis in the control group.

5.2.3Findings on level of post test level of oral mucositis:

In experimental group the post test level of oral mucositis after the honey application, majority 18(60%) had no oral mucositis and 12(40%) mild level of oral mucositis among cancer children receiving chemotherapy. The post test after the chlorhexidine mouth wash, majority 23(76.67%) had mild level of oral

mucositis and 7(23.33%) no oral mucositis among cancer children receiving chemotherapy in control group.

5.2.4 Findings on pretest and post test level of oral mucositis:

The pretest, majority 14(46.67%) had moderately level of oral mucosiis, 9(30%) had mild and 7(23.33%) had severe level of oral mucositis. Whereas in the post test after the chlorhexidine mouth wash, majority 23(76.67%) had mild level of oral mucositis and 7(23.33%) no oral mucositis among cancer children receiving chemotherapy in control group.

5.2.5 Findings on association between pretest and posttest level of oral mucositis with demographic variables:

The demographic variable weight of the child had shown statistically significant association with post test level of oral mucositis among cancer children at p<0.05 level and the other demographic variables had not shown statistically significant association with post test level of oral mucositis among cancer children in the experimental group. the demographic variable type of chemotherapy had shown statistically significant association with post test level of oral mucositis among cancer children at p<0.05 level and the other demographic variables had shown statistically significant association with post test level of oral mucositis among cancer children in the control group.

CHAPTER VI

DISCUSSION

The discussion brings the right report to closure. Discussion section make sense of research study. This is the most important section of any research report.

The focus of the study was to compare the effectiveness of honey application versus chlorhexidine mouth wash in treatment of oral mucositis among children with chemotherapy .A standard semi structured questionnaire and WHO oral mucositis assessment scale was used to assess the effectiveness of honey application versus chlorhexidine mouth wash on oral mucositis among children with chemotherapy. The sample size taken was 60 children with oral mucositis.

The study was conducted in institute of child health and hospital for children, Chennai. Cancer children with chemotherapy induced oral mucositis were assessed and divided into two groups. One group received honey application and the other group received chlorhexidine mouth wash. The mucosal ulceration were assessed using WHO oral mucositis assessment scale on 3rd and 5th day of treatment.

This research study had been discussed based on the objectives and the following supported studies:

The study shows that in the experimental group, majority 17(56.67%) were in the age group of 5 to 7 years, 17(56.67%) were male, 15(50%) were Hindus, 11(36.67%) of fathers were educated upto primary school, 16(53.33%) of mothers had no formal education, 13(43.33%) of fathers were unemployed, 16(53.33%) had a family income of Rs.3000 to 5000, 14(46.67%) were from rural area,

17(56.67%) belonged to joint family, 14(46.67%) had no siblings. 17(56.67%) were in the height range of 95 - 105 cms, 15(50%) were weighed 10 - 20 kgs, 14(46.67%) had NHL/HL type of cancer, 22(73.33%) were suffering from cancer for 1 to 2 years, 15(50%) had two drug regimen and more than two drug regimen respectively, 24(80%) had 3^{rd} cycle of chemotherapy, 17(56.67%) had the occurrence of oral mucositis twice and treated and 28(93.33%) brushed once daily.

Whereas in the control group, majority 15(50%) were in the age group of 5 to 7 years, 19(63.33%) were male, 21(70%) were Hindus, 12(40%) of fathers were educated upto primary school, 11(36.67%) of mothers had no formal education, 15(50%) of fathers were unskilled workers, 21(70%) had a family income of Rs.3000 to 5000, 12(40%) were from rural area, 17(56.67%) belonged to joint family, 17(56.67%) had one sibling, 12(40) were in the height range of 95 – 105 cms and 105—125 cms respectively, 15(50%) were weighed 10 – 20 kgs, 20(66.67%) had ALL/CLL type of cancer, 16(53.33%) were suffering from cancer for 1 to 2 years, 16(53.33%) had two drug regimen, 19(63.33%) had 3rd cycle of chemotherapy, 19(63.33%) had the occurrence of oral mucositis twice and treated and 28(93.33%) brushed once daily.

Objective 1:

To assess the grade of the oral mucositis among children receiving chemotherapy:

The present study shows that among 60 samples in the pretest, majority 14(46.67%) had moderately level of oral mucositis, 10(33.33%) had severe and 6(20%) had mild level of oral mucositis. Whereas in the post test after the honey application, majority 18(60%) had no oral mucositis and 12(40%) mild level of oral mucositis among cancer children receiving chemotherapy.

The study was supported by **Sonis**, **et al** (**2013**), in which it was implicated that there is 90% incidence of mucositis in children under 10 years of age treated with standard chemotherapy.

This study was supported by **Peterson douglas** (2010),Oral mucositis is a common toxicity of high-dose chemotherapy and upper mantle head and neck radiation. Published evidence from the past 14 months provides insight into the multiple possible mechanisms. In addition, the data highlight the clinical importance that this lesion exerts relative to infection risk, quality of life, and cost of care. Oral mucositis has emerged as a dose-limiting toxicity in selected cancer therapy models. Thus, it has direct impact on duration of disease remission, cure rates, and long-term survival.

Hypothesis H1; There will be a statistically significant difference between the pretest and post test value of oral mucositis among cancer children.

The pretest mean score of oral mucositis was 0.73 and the paired 't' =7.663, whereas the post test mean score of oral mucositis was 0.43 and the paired 't' =3.051, hence the hypothesis H1 is statistically proven.

Objective 2:

To evaluate the effectiveness of honey application on oral mucositis among experimental group.

There was quick recovery of oral mucositis following honey application as it is evident by this findings the pretest, majority 14(46.67%) had moderately level of oral mucositis, 10(33.33%) had severe and 6(20%) had mild level of oral mucositis. Whereas in the post test after the honey application, majority 18(60%) had no oral mucositis and 12(40%) mild level of oral mucositis among cancer children receiving chemotherapy.

This study was supported by Khanal,B. et al., (2010)the literature indicates that honey appears to promote wound healing, so the authors investigated whether its anti-inflammatory properties might limit the severity of radiation-induced oral mucositis. A single-blinded, randomized, controlled clinical trial was carried out to compare the mucositis-limiting qualities of honey with lignocaine. A visual assessment scale permitted scoring of degrees of mucositis and statistical evaluation of the results was performed using the χ^2 test. Only 1 of 20 patients in the honey group developed intolerable oral mucositis compared with the lignocaine group, indicating that honey is strongly protective (RR = 0.067) against the development of mucositis. The proportion of patients with intolerable oral mucositis was lower in the honey group and this was statistically significant (p = 0.000). Honey applied topically to the oral mucosa of patients.

This study was supported by **Song et al.**, (2012) 4 separate human controlled trials reported that honey appeared to protect from the effects of radiation-induced oral mucositis formation, a complication of radiation therapy that is responsible for pain and overall reduction in quality of life. In this systematic review and meta-analysis, the authors examined 3 of these controlled trials (n = 120) that met the inclusion and exclusion criteria to determine whether honey had protective effects against radiation-induced oral mucositis. The meta-analysis demonstrated an overall relative risk reduction of 80% in the honey treatment group compared with the control. Although favorable, the data must be approached with caution because of lack of description of the method of randomization and potential bias in all 3 of the individual studies included in the meta-analysis. The results are promising, and further studies are needed to strengthen the current evidence prior to a firm clinical recommendation being given.

Objective 3:

To evaluate the effectiveness of chlorhexidine on oral mucositis among control group

There was gradual recovery of oral mucositis after the use of chlorhexidine mouth wash as it is evident by the study result that the pretest, majority 14(46.67%) had moderately level of oral mucositis, 9(30%) had mild and 7(23.33%) had severe level of oral mucositis. Whereas in the post test after the chlorhexidine mouth wash, majority 23(76.67%) had mild level of oral mucositis and 7(23.33%) no oral mucositis among cancer children receiving chemotherapy in control group.

This study was supported by **Potting C.M et al.**.(2010) Daily chlorhexidine mouthwash is often recommended for preventing chemotherapy-induced oral mucositis. Povidone-iodine, NaCl 0.9%, water salt soda solution and chamomile mouthwash are also recommended. However, the effectiveness of these mouthwashes is unclear. Therefore, we performed a systematic review to assess the effectiveness of mouthwashes in preventing and ameliorating chemotherapy-induced oral mucositis. Based on study quality, three out of five randomized controlled trials were included in a meta-analysis. The results failed to detect any beneficial effects of chlorhexidine as compared with sterile water, or NaCl 0.9%. 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 a povidone-iodine mouthwash as compared with sterile water in a single randomized controlled trial. These results do not support the use of chlorhexidine mouthwash to prevent oral mucositis.)

This study was supported by Rodrigeruz .A et al (2012) Head and neck cancer represents one of the main oncological problems. Its treatment, radiotherapy and chemotherapy leads to mucositis, and other side effects. The authors reviewed high-quality evidence published over the last 25 years on the treatment of cancer treatment-induced oral mucositis. A Medline search for double blind randomized controlled clinical trials between 1985 and 2010 was carried out. The keywords were oral mucositis, radiotherapy, chemotherapy, and head and neck. The different therapeutic approaches found for cancer treatment-induced oral mucositis included: intensive oral hygiene care; use of topical antiseptics and antimicrobial agents; use of anti-inflammatory agents; cytokines and growth factors; locally applied non-pharmacological methods; antioxidants; immune modulators; and homoeopathic agents. To date, no intervention has been able to prevent and treat oral mucositis on its own. It is necessary to combine interventions that act on the different phases of mucositis. It is still unclear which strategies reduce oral mucositis, as there is not enough evidence that describes a treatment with a proven efficiency and is superior to the other treatments for this condition.

Objective 4:

To compare the effectiveness of honey application and chlorhexidine on oral mucositis.

There was more effective recovery of oral mucositis following honey application than chlorhexidine mouth wash in reduction of oral mucositis as it is evident by this study result that the pretest, the mean score of oral mucositis was 2.13 ± 0.73 whereas in the post test the mean score of oral mucositis was 0.40 ± 0.49 . The calculated paired 't' value of t=13.730 was found to statistically significant at p<0.001 level. This clearly shows that after honey application among cancer children receiving chemotherapy there was significant decrease in the level

of oral mucositis in the post test level among cancer children in the experimental group.

This study was supported by **Worthington et al(2012)**, in which he compared the efficacy of honey application versus chlorhexidine mouth wash on oral mucositis. Significant finding of this study was that application of honey was found more effective than chlorhexidine mouth wash in reduction of oral mucositis and it was statistically significant (p = 0.002).

Similar study was done by **Melaine Charalombous et al (2013)** In total, 5 studies met the criteria and were included in the systematic review. Three studies assessed the effectiveness of honey against other products including golden syrup, lignocaine and saline and two studies assessed the effectiveness of honey against standard treatment regimes. Four out of the five studies demonstrated significant reduction in the mucositis levels and one study reported that honey had no statistical association with less severe mucositis. Methodologically the quality of most studies was moderate due to the small sample size, which might impact upon the significance of the findings. Although honey appears to be a simple, affordable, available and cost-effective treatment for the management of radiation-induced oral mucositis, there is a need for further multi-centre randomized trials to validate these findings.

Objective 5

To associate the effectiveness of honey application and chlorhexidine on oral mucositis with selected demographic variables.

In the present study the weight of the child was statistically significant in the experimental group (p=<0.05) and the type of chemotherapy was statistically significant in the control group.

International Journal of Science and Research (2014) An experimental pre-test, post-test experimental design were used. The 40 patients were selected by purposive sampling technique. The onset of mucositis and the severity of mucositis were graded during the course of the radiotherapy and 5th and 10th day after radiotherapy,. The mean score of 0.7, Std. Deviation .571 in reducing level of mucositis in Orasep group and mean score honey group of 0.55, Std. Deviation 0.510. Null hypothesis accepted therefore there is no significant difference on radiation induced mucositis in Orasep and honey groups after the 10th day intervention. No significant reduction in mucositis in honey-received patients compared with orasep applied patient succored. There were no differences between the groups. There all variables do not show significant association between a radiations induced mucositis and demographic variables. Conclusion: natural honey is an effective agent in managing radiation induced oral mucositis. Honey could be a simple, potent and inexpensive agent, which is easily available, and it can be a better therapeutic agent in managing radiation mucositis in developing countries like India for the management of this morbidity. Also in orasep help to relief of pain and dry, scratchy mouth for the relief of pain associated with canker sores, irritation of the mouth and gum

Hypothesis 2: There will be an association between healing of oral mucositis and selected demographic variables.

The demographic variable type of chemotherapy shows the Chisquare value of $x^2=1.467$ and p=0.030 which is less than p<0.05, Hence the hypothesis H2 was statistically proven.

CHAPTER VII

CONCLUSION AND RECOMMENDATION

The study was conducted to compare the effectiveness of honey application with chlorhexidine mouth wash in treatment of oral mucositis caused due to chemotherapy among cancer children. relevant literature ,journal were reviewed to enrich the knowledge on the selected study and it facilitates in selection of appropriate conceptual frame work, developing a model and research plan.

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6.1 NURSING IMPLICATION:

The findings of the study have depicted that honey application is more effective than chlorhexidine mouth wash in reducing the severity of oral mucositis in children receiving chemotherapy. honey is a simple, easily available, cost effective method for oral mucositis which in turn improves the dietary intake of the child.

Nursing practice:

This study has important implication in nursing care of cancer children with oral mucositis. Honey application is a cost effective method to bring down the severity of oral mucositis.

- This helps to reduce the anxiety of the child and parents related to oral mucositis.
- This also helps to improve the dietary intake of the child.
- This also reduce the risk to discontinue the chemotherapy treatment.

Nursing education:

Nursing students and beginners should develop knowledge and skill in the management of oral mucositis in cancer children and should gain more knowledge about the benefits of honey application in oral mucositis.

Nursing administration:

- Developing policies and protocols jointly fosters and stress collaboration and it discuss on the expectations of staff working in the pediatric care unit.
- Provision for the successive implementation of honey application.
- Develop a separate written protocol on honey application and chlorhexidine mouth wash.
- Conduct in service education to the staff nurses on these therapies.

Nursing research:

The main goal of nursing research is to provide better care to the patients. The present study implies base to conduct the qualitative and quantitative studies on the effectiveness of honey application in treatment of the oral mucositis. Nurses should be provided opportunity to conduct small research projects on this topic. Emphasis should be given to the utilization of research findings. Utilization of the research findings helps in evidence based practice.

6.2 Limitations

Interventions were administered only to inpatients.

Study is limited only to 60 patients.

6.3 Recommendations for further study:

- o Honey application can be compared with candid gel.
- The study can be conducted in a larger population.
- A new protocol can be prepared regarding the honey application.
- In service education can be conducted regarding benefits of honey
- o application for treatment related to oral mucositis to the health care
- o professionals.
- Parents can be educated on the importance of honey application on oral
- o mucositis.

6.4 Conclusion:

Oral mucositis is an inevitable side effect of chemotherapy among cancer children. Many interventions are available to treat oral mucositis. In this study, honey application and chlorhexidine mouth wash were given to alternative samples. This study implies that both honey application and chlorhexidine mouth wash were beneficial in reducing oral mucositis. Comparatively honey application is more effective than chlorhexidine mouth wash there by it reduces the stress and pain among the children undergoing chemotherapy.

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INSTITUTIONAL ETHICS COMMITTEE MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No.ECR/270/Inst./TN/2013 Telephone No. 044 25305301 Fax: 044 25363970

CERTIFICATE OF APPROVAL

To MRS.SUNILA GUNA SUNDARI.S M.Sc., (Nursing) College of Nursing Madras Medical College, Chennai – 600 003.

Dear MRS.SUNILA GUNA SUNDARI.S,

The Institutional Ethics Committee has considered your request and approved your study titled a Comparative Study to assess the effectiveness of Honey Application versus chlorhexidine mouth wash in reducing oral mucositis among cancer Children of 5 to 10 years admitted in Cancer Ward, institute of Child Health & Hospital for Children, Egmore. No.07102014.

The following members of Ethics Committee were present in the meeting held on 21.10.2014 conducted at Madras Medical College, Chennai-3.

Dr.C.Rajendran, M.D.,
 Dr.R.Vimala, M.D., Dean, MMC, Ch-3
 Prof.B.Kalaiselvi, M.D., Vice-Principal, MMC, Ch-3
 Member Secretary

Prof.B.Kalaiselvi, M.D., Vice-Principal, MMC, Ch-3
 Prof.R.Nandhini, M.D., Inst. of Pharmacology, MMC
 Prof.K.Ramadevi, Director i/c, Inst. of Biochemistry, MMC
 Prof.Saraswathy, M.D., Director, Pathology, MMC, Ch-3
 Prof.S.G.Sivachidambaram, M.D., Director i/c,
 Member
 Member
 Member

Prof.S.G.Sivachidambaram, M.D., Director i/c,
 Inst.of Internal Medicine, MMC

8. Dr.Balakrishnan, M.S., Director, Inst.of Surgery, MMC : Member 9. Thiru S.Rameshkumar, Administrative Officer : Lay Person 10.Thiru S.Govindasamy, B.A., B.L., : Lawyer

11. Tmt. Arnold Saulina, M.A., MSW., : Social Scientist

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Seditetary, Ethics Committee
MEMBER SECRETA
INSTITUTIONAL ETHICS COM
MADRAS MEDICAL COLLE

CHENNAI-600 003

CERTIFICATE FOR CONTENT VALIDITY

This is to certify that a tool prepared by Ms.Sunila Guna Sundari. S, studying M.Sc Nursing, II Year, College of Nursing, Madras Medical College, undertaking a Research study on "A COMPARATIVE STUDY TO ASSESS THE EFFECTIVENESS OF HONEY APPLICATION VERSUS CHLORHEXIDINE MOUTH WASH IN REDUCING ORAL MUCOSITIS AMONG CANCER CHILDREN OF 5 TO 10 YEARS ADMITTED IN CANCER WARD, INSTITUTE OF CHILD HEALTH & HOSPITAL FOR CHILDREN, EGMORE" has been validated by me and is found to be valid up to date and she can proceed with this tool to conduct the main study.

SIGNATURE WITH SEAL HOSpital
Rajivgandhi Gort, Gan, Hospital
Rajivgandhi Gort, Gan, Hospital
Rajivgandhi No. 42044

Name

Dr. A. KARTHIKEYAN, MD., DM., (HAEM-

Designation:

Assistant Professor
Department of Haematology
ajlygandhi Gova, Gen. Hospital

Date

16/7/66 Chennai-800 003

Place

: EGHORE, CHENNALOS

CERTIFICATE FOR CONTENT VALIDITY

This is to certify that a tool prepared by Ms.Sunila Guna Sundari. S, studying M.Sc Nursing, II Year, College of Nursing, Madras Medical College, undertaking a Research study on "A COMPARATIVE STUDY TO ASSESS THE EFFECTIVENESS OF HONEY APPLICATION VERSUS CHLORHEXIDINE MOUTH WASH IN REDUCING ORAL MUCOSITIS AMONG CANCER CHILDREN OF 5 TO 10 YEARS ADMITTED IN CANCER WARD, INSTITUTE OF CHILD HEALTH & HOSPITAL FOR CHILDREN, EGMORE" has been validated by me and is found to be valid up to date and she can proceed with this tool to conduct the main study

Name

MRS. MAHIBA JANICE. J

Designation: LECTURER

Date

15.07.15

Place

CHENNAL -69.



From

Mrs. SUNILA GUNA SUNDARI. S,

M.Sc (Nursing) II Year, College of Nursing, Madras Medical College, Chennai – 3.

To

The Director,

Institute of Child Health and Hospital for Children, Egmore,

Chennai - 8.

Through Proper Channel,

Respected Sir,

Sub: Requesting Permission to conduct a Research study - regarding

I, Mrs.Sunila Guna Sundari. S, studying M.Sc Nursing II Year, College of Nursing, Madras Medical College, request you to kindly grant me permission to conduct nursing research study on the topic "A COMPARATIVE STUDY TO ASSESS THE EFFECTIVENESS OF HONEY APPLICATION VERSUS CHLORHEXIDINE MOUTH WASH IN REDUCING ORAL MUCOSITIS AMONG CANCER CHILDREN OF 5 TO 10 YEARS ADMITTED IN CANCER WARD, INSTITUTE OF CHILD HEALTH & HOSPITAL FOR CHILDREN, EGMORE". As partial fulfillment of dissertation study for the degree of Master of Science in Nursing.

I assure you that it will not interfere with the routine activities of the study setting as well as keep confidentiality and anonymity of each children.

Thanking you,

Place: CHENNAI.03

Yours obediently

Time: 01.07.2015 at

S. Sunto Gano Sunday

10 Am

(SUNILA GUNA SUNDARI.S)

Inverded.

enrector and superintenden.
(astitute of Child Health and
Hospital for Childern

Remore Chennai - 600 000

QUESTIONNAIRE INSTRUMENT

Interview /observational semistructured schedule

Sample No:	
Date :	
Time :	
SECTION – A	
Demographic data of the child	
1.Age of the child a. 5 to 7 years	
b. 7 to 8 years	
c. 8 to 10 years	
o. 6 to 16 years	
2.Sex of the child	
a. Male child	
b.Female child	
3.Religion	
a. Hindu	
b. Christian	
c. Muslim	
d. Others	
4. Mothers educational – status	
a. No – formal education	
b. Primary school	
c. Middle school	
d. High school	
e. Higher secondary school	
f.Graduate	

5.Fathers Educational – status	
a. No – formal education	
b. Primary school	
c. Middle school	
d. High school	
e.Higher secondary school	
f.Graduate	
6.Mother's occupation	
a. House wife	
b. Unskilled Worker	
c. Skilled Worker	
d.Buissness	
e.profession	
7.Father's Occupation	
a. Unemployed	
b. Unskilled Worker	
c. Skilled Worker	
d.Buissness	
e.profession	
8.Family Income	
a.1000 to 3000	
b. 3000 to 5000	
c.5000 to 7000	
d.7000 to 10000	
9.Residential Area	
a.Urban	
b.Sub urban	
c. Rural	

10. Type of family	
a. joint family	
b. nuclear family	
c.extended family.	
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. 105 -125 cms	
c. 125 – 145 cms	
13. Weight of the child in kilograms	
a. $10 - 20 \text{ kgs}$	
b. $20 - 30 \text{ kgs}$	
c.30 - 40 kgs.	
14.Type of cancer	
a.ALL/CLL	
b AML /CML	
c.NHL/HL	
d.Other type of cancer	
15.Duration of illness	
a.Below 6 months.	
b.1 to 2v years	
c.2 to 3 years	
d. more than 2 years.	

16.Type of chemotherapy	
a. Single drug regimen	
b. Two drug regimen	
c. More than two drug regimen.	
17. Number of cycles for chemotherapy?	
a. 1 st Cycle	
b. 2 nd Cycle	
c.3 rd Cycle	
d.more than 3 cycle.	
18.Occurence of Oral mucositis	
a. freshly occurred	
b.occured once and treated.	
c.occured twice and treated.	
d.occured but not treated.	
19 Oral hygiene followed by the child	
a. Brushes once daily.	
b Brushes twice daily.	
c. Brushes with mouth wash.	

சுய விவரப்படிவம்

1 .வயது	
அ.5 முதல் 7 வயது ஆ.7 முதல் 8வயது இ.8 முதல் 10 வயது	
2.பாலினம் அ.ஆண் ஆ.பெண்	
3.மதம் அ.இந்து ஆ.கிறிஸ்தவர் இ.இஸ்லாமியர் ஈ.மற்றவை	
4.தாயின் கல்வி நிலை அ.ஆரம்ப பள்ளி ஆ.நடுநிலை பள்ளி இ.உயர் நிலை பள்ளி ஈ.பட்டதாரி	
5.தந்தையின் கல்வி நிலை அ.ஆரம்ப கலவி ஆ.நடுநிலை பள்ளி இ.உயர் நிலை பள்ளி ஈ.பட்டதாரி	
6.தாயின் தொழில் அ.குடும்ப தலைவி ஆ.கூலி வேலை இ.சுயதொழில் ஈ.தொழில் சார்ந்த வேலை	
7.தந்தையின் தொழில் அ.வேலை இல்லை ஆ.சுயதொழில் இ.கூலி வேலை ஈ.தொழில் சார்ந்த வேலை	

8.குடும்ப வருமானம் அ.1000 முதல் 3000 ஆ.3000 முதல் 5000 இ.5000 முதல் 7000 ஈ.7000 முதல் 10,000	
9. இருப்பிடம் அ. நகரம் ஆ.டவுன் இ. கிராமம்	
10.குடும்ப வகை அ.கூட்டு குடும்பம் ஆ.தனி குடும்பம் இ.நீட்டிக்கப்பட்ட குடும்பம்	
11.உடன் பிறந்தோர் அ.0 ஆ.1 இ2 ஈ.2ற்கு மேல்.	
12.குந்தையின் உயரம் சென்டிமீட்டர் அ.95 -105 செ.மீ ஆ.105 -125 செ.மீ இ.125 -145 செ. மீ	
13.குழந்தையின் எடை கிலோகிராமில் அ.10 - 20 கி ஆ.20 -30 கி இ.30 -40 கி	
15.புற்று நோயின் வகை அ. அலிலு/கிலிலு ஆ. அமலு/கிமுல் இ.நஹெஸ்லு/ஹெச்லு ஈ மற்ற வகை புற்றுநோய்	
16.நோயின் கால அளவு அ.6 மாதத்திற்கு குறைவு ஆ.1 -2 ஆண்டு இ.2 -3 ஆண்டு ஈ 2 வருடத்திற்கு அதிகமாக	

17. மருந்து கொண்டு நோய் தீா்க்கும் முறையின் வகை அ.ஒரு வகை மருந்து ஆ.இருவகை மருந்து இ.இரண்டிற்கு மேற்பட்ட மருந்து	
18.மருந்து கொண்டு நோய் தீா்க்கும் முறையின் சுழற்சி அ.முதல் சுழற்சி ஆ.இரண்டாம் சுழற்சி இ.மூன்றாம் சுழற்சி ஈ.மூன்றிற்கு மேற்பட்ட சுழற்சி	
19.வாய்புண் ஏற்ப்பட்ட முறை அ.முதல் முறை வந்துள்ளது ஆ.இருமுறைவந்துசிகிச்சை அளிக்கப்பட்டுள்ளது இ.இருமுறை வந்து சிகிச்சை அளிக்கப்பட்டுள்ளது ஈ.வந்து சிகிச்சை அளிக்கப்படவில்லை.	
20.குழந்தை மேற்கொள்ளும் வாய் சுகாதாரம் அ.ஒரு முறை பல் துலக்குதல் ஆ.இருமுறை பல் துலக்குதல் இ.பல்துலக்குவதுடன் வாய் கொப்பளித்தல்	

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

Grade	Description
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

INFORMATION TO PARTICIPANTS

Title of the study : "A COMPARATIVE STUDY TO ASSESS THE EFFECTIVENESS OF HONEY APPLICATION VERSUS CHLORHEXIDINE MOUTH WASH IN TREATMENT OF ORAL MUCOSITIS AMONG CANCER CHILDREN OF -5 – 10 YEARS ADMITTED IN CANCER WARD, INSTITUTE OF CHILD HEALTH & HOSPITAL FOR CHILDREN, EGMORE."

Investigator: SUNILA GUNA SUNDARI.S

M.Sc (N) 1st year College of Nursing

M.M.C

Name of Participant:

What is the purpose of this study?

This study is conducted in Institutes of child and hospital for children, Chennai -08. Your child is invited to take part in this study. The information in this document is meant to help you decide your child whether or not to take part. Please feel free to ask if you have any queries or concerns.

What is the purpose of the study:

This research is conducted to evaluate the effectiveness of honey application versus chlorhexidine mouth wash in treatment of oral mucositis among cancer children of -5-10 years admitted in cancer ward, institute of child health & hospital for children, egmore." we have obtained the permission from ethical committee.

The study design

All children in this study will be divided into 2 groups. Your child will be assigned to either of the groups. One will receive honey application and the other group will receive chlorhexidine mouth wash.

Study Procedures

- Study will be conducted after approval of ethics committee
- Permission will be obtained from director ,ICH for the study.

- Explanation of the study, purpose, procedure to parents of children with cancer at cancer ward.
- Obtaining informed consent from willing parents.
- Enrolment of children who satisfy inclusion criteria.
- Assigning children to experimental and control group by lot method.
- Experimental group will receive honey application 3 times a day
- Control group will receive chlorhexidine mouth wash 3 times a day.
- The oral mucosa will be assessed for mucositis with WHO oral mucositis scale before and after the intervention.

Possible benefits to your child

Children will be free from oral mucositis with either honey application or chlorhexidine mouth wash.

Possible benefits to other people

The result of the research may provide benefits to cancer children and also empathetic care to them by the investigator.

Confidentiality of the information obtained from you

You have the right to confidentiality regarding the privacy of your child medical information (personal details, results of physical examinations, investigations, and your medical history). By signing this document, you child will be allowing the research team investigators, other study personnel, sponsors, institutional Ethics Committee and any person or agency required by law like the Drug Controller General of India to view your child data, if required.

The information from this study, if published in scientific journals or presented at scientific meeting s, will not reveal your child identity.

How will your decision to not participate in the study affect you?

Your decision not to participate in this research study will not affect your child medical care or your relationship with the investigator or the institution. Your child will be taken care of and your child will not lose any benefits to which your child are entitled.

Can you decide to stop participating in the study once you start?

The participation in this research is purely voluntary and you have the right to withdraw your child this study at any time during the course of the study without giving any reason. However, it is advisable that you talk to the research team prior to stopping the treatment/discontinuing of procedures etc.

The results of this study will be informed to you at the end of the study.

Signature of Investigator
Guardian

Date

Date

TITLE OF THE STUDY:

are publicly presented.

"A COMPARATIVE STUDY TO ASSESS THE EFFECTIVENESS OF HONEY APPLICATION VERSUS CHLORHEXIDINE MOUTH WASH IN TREATMENT OF ORAL MUCOSITIS AMONG CANCER CHILDREN OF -5 – 10 YEARS ADMITTED IN CANCER WARD, INSTITUTE OF CHILD HEALTH & HOSPITAL FOR CHILDREN, EGMORE."

NAME OF THE INVESTIGATOR: S.SUNILA GUNA SUNDARI

AG DA NA	me of the Participant: GE/SEX: ATE: AME OF THE INSTITUTION; INSTITUTE OF CHILD HEALTH & OSPITAL FOR CHILDREN,EGMORE."
I	have read the information in this form (or it has
am	en read to me. I was free to ask any questions and they have been answered. I over 18 years of age and, exercising my free power of choice, hereby give my asent to be included as a participant in this study.
1.	I have read and understood this consent form and the information provided to
me	
2.	I have had the consent document explained to me.
3.	I have been explained about the nature of the study
4.	I have been explained about my rights and responsibilities by the investigator
5.	I am aware of the fact that I can opt out of the study at any time without
hav	ving to give any reason and this will not affect my child future treatment in this
hos	spital.
6.	I hereby give permission to the investigators to release the information
obt	ained from my child as result of participation in this study to the sponsors.
Re	gulatory authorities. Govt. agencies and IEC.I understand that they are publicly
pre	sented.
7.	I have understand that my child identity will be kept confidential if my data

8. I have had my questions answered to my satisfaction.
9. I have decided for my child to by in the research study.
I am aware that if I have any question during this study. I should contact the
investigator. By signing this consent form I attest that the information given in this
document has been clearly explained to me and understood by me, I will be given
a copy of this consent document.
1. Name and signature / thumb impression of the Parent / Guardian (or legal representative if participant incompetent)
NameDate
 Name and Signature of impartial witness (required for illiterate Parent / Guardian

Address and contact number of the impartial witness. Name and Signature of the investigator or his representative obtaining consent.

Signature _____Date____

ஆராய்ச்சி ஒப்புதல் கடிதம்

ஆராய்ச்சி தலைப்பு : ஆராய்ச்சி தலைப்பு புற்றுநோய் உள்ள 5 முதல் 10 வயதுள்ள குழந்தைகளுகளின் வாய்புண்ணை குணப்படுத்துவதில் தேன் தடவுதல் மற்றும் க்லோர்ஹெக்ஸ்டின் வாய்கொப்பளிக்கும் திரவத்தினை உபய்யோகிப்பதன் தன்மையினை பற்றிய ஆய்வு.

ஆய்வாளர் பெயர் : சுனிலா குண சுந்தரி.சௌ

பங்கேற்பாளர் பெயர் : தேதி : வயது/பால் :

- ஆய்வாளர் மேற்கொள்ளும் ஆராய்ச்சியில் எனது குழந்தை பங்கேற்க யாருடைய கட்டாயமுமின்றி முழுமனதுடனும் சுயநினைவுடனும் சம்மதிக்கிறேன்.
- ஆய்வாளர் மேற்கொள்ளபோகும் பரிசோதனைகளை மிக தெளிவாக விளக்கிக்கூறினார்.
- எனக்கு விருப்பமில்லாத பட்சத்தில் ஆராய்ச்சியிலிருந்து எந்நேரமும் எனது குழந்தை விலகலாம் என்பதையும் ஆய்வாளர் மூலம் அறிந்து கொண்டேன்.
- இந்த ஆராய்ச்சி ஒப்புதல் கடிதத்தில் உள்ள விவரங்களை நன்கு புரிந்துகொண்டேன். எனது உரிமைகள் மற்றும் கடமைகள் ஆராய்ச்சியாளர் மூலம்விளக்கபட்டது.
- நான் ஆராய்ச்சியாளருடன் ஒத்துழைக்க சம்மதிக்கிறேன். எனது குழந்தைக்கு ஏதேனும் உடல்நலகுறைவு ஏற்பட்டால் ஆராய்ச்சியாளரிடம் தெரிவிப்பேன்.
- எனது குழந்தை வேறு எந்த ஆராய்ச்சியிலும் தற்சமயம் இடம்பெறவில்லை என்பதை தெரிவித்துகொள்கிறேன்.
- இந்த ஆராய்ச்சியின் தகவல்களை வெளியிட சம்மதிக்கிறேன். அப்படி வெளியிடும்போது எனது குழந்தையின் அடையாளம் வெளிவராது என்பதை அறிவேன்.
- எனக்கு இந்த ஒப்புதல் கடிதத்தின் நகல் கொடுக்கபட்டது.

ஆய்வாளர் கையொப்பம்

பங்கேற்கும் குழந்தையின் பெற்றோர் கையொப்பம் தேதி:

தேதி

CERTIFICATE OF ENGLISH EDITING

This is to certify that the dissertation work

topic "A comparative study to assess the effectiveness of honey versus

chlorhexidine mouth wash in treatment of oral mucositis among cancer

children of 5 - 10 years admitted in cancer ward Institute of child Health and

Hospital for Children, Chennai." done by Mrs.S.Sunila Guna Sundari, MSc

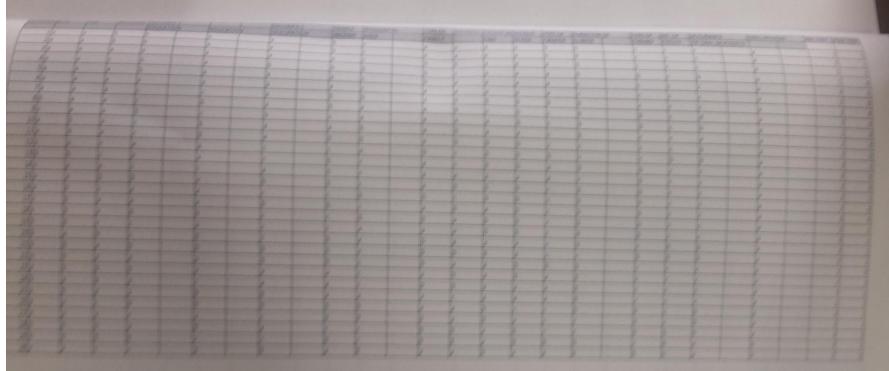
(N) second year student of College Of Nursing, Madras Medical College,

Chennai -03 is edited for English language appropriateness.

A. ARULRAG MATURES, M.Phil.,

Govt. High School, Munjurpet - 632 011. Vellore Dist.,

Date :



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CONTROL GROUP DEMOGRAPHICAL VARIABLE

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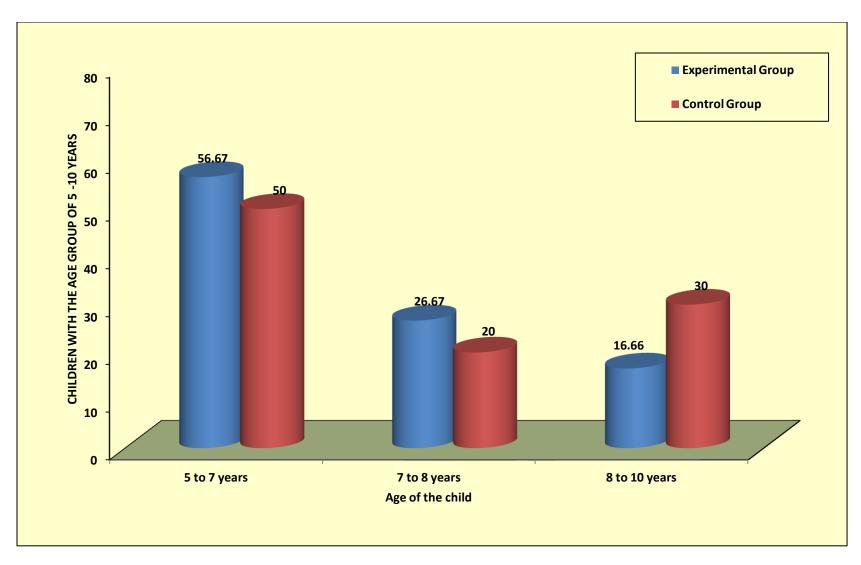


Fig 4.1: Agewise distribution of the child (100%)

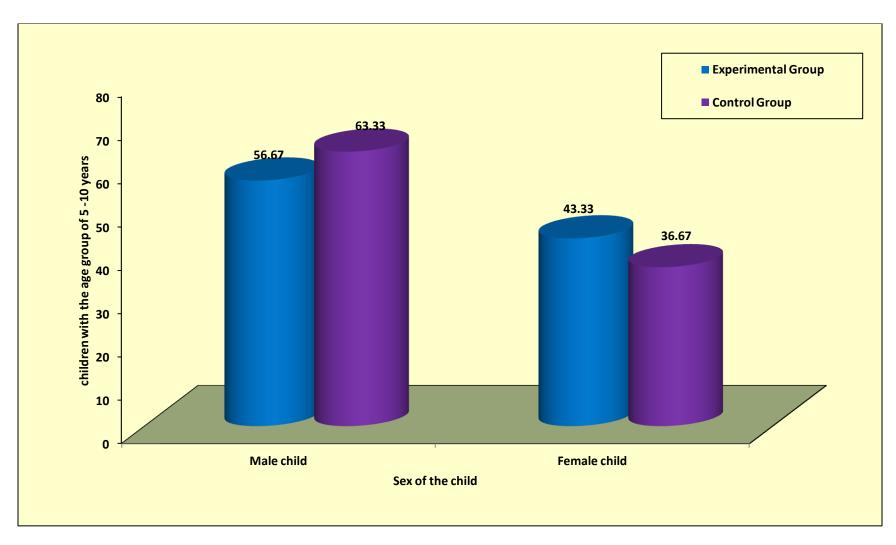


Fig 4.2 Sexwise distribution of the child

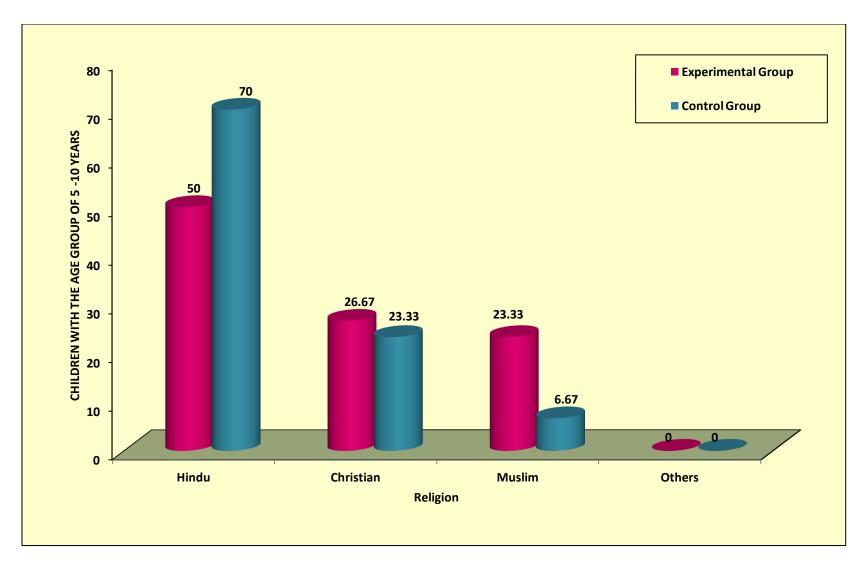


Fig 4.3: Religionwise distribution of the child (100%

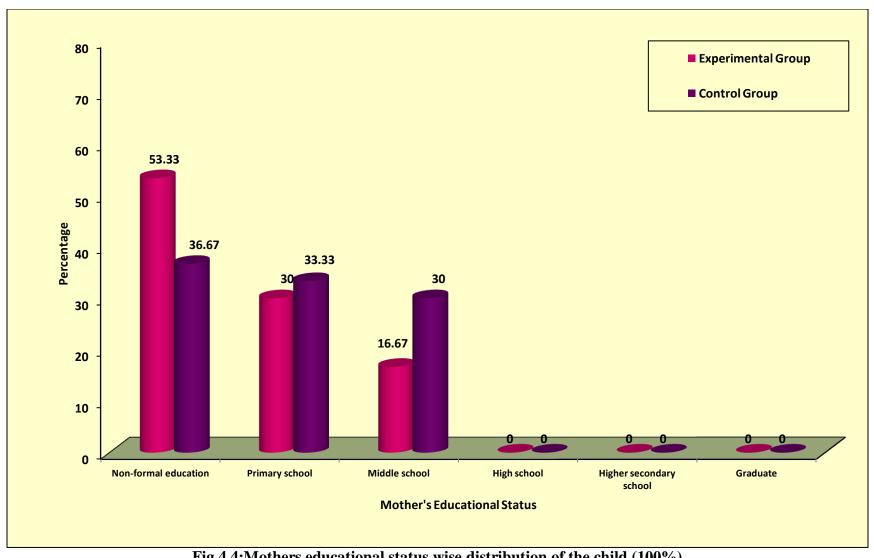


Fig 4.4:Mothers educational status wise distribution of the child (100%)

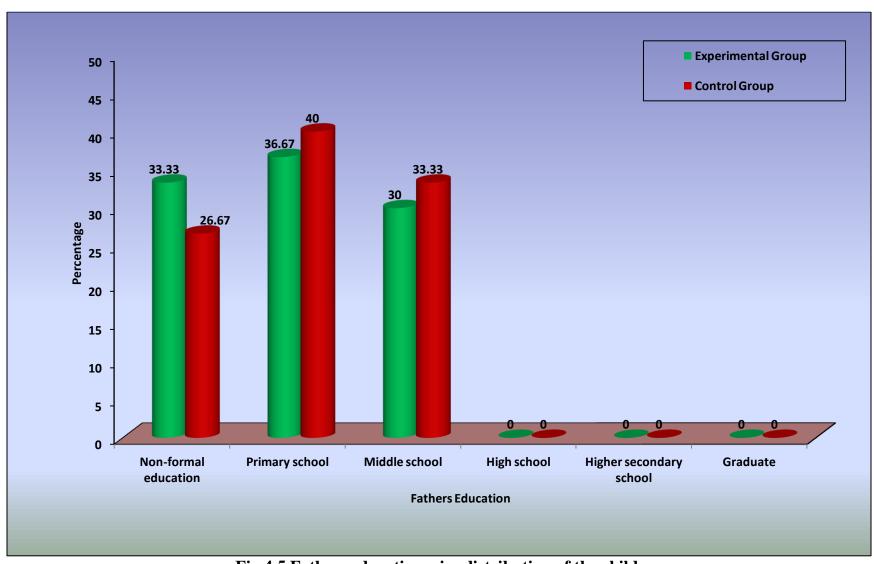


Fig 4.5 Fathers education wise distribution of the child

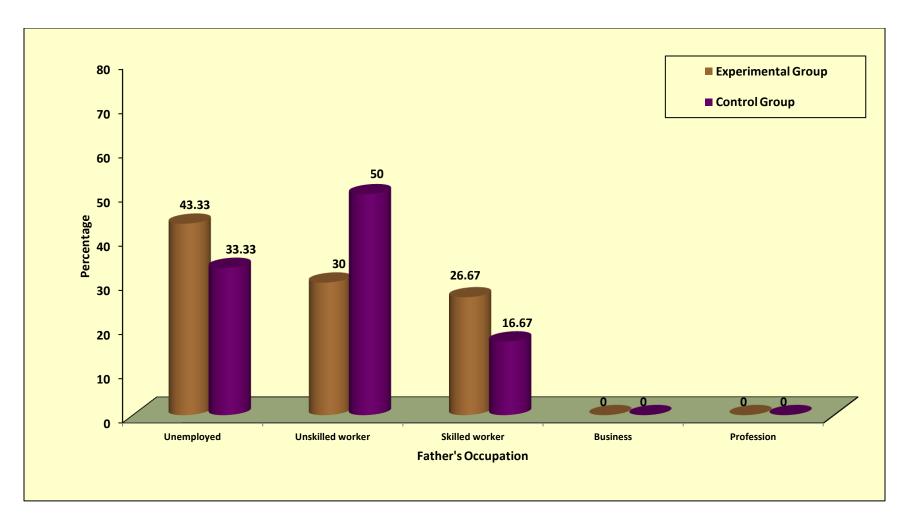


Fig 4.6 Father's occupation wise distribution of the child (100%)

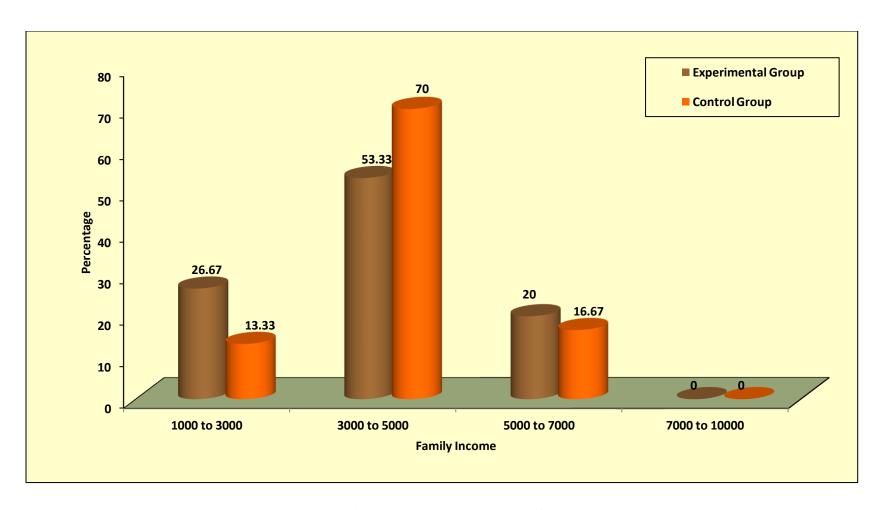


Fig 4.7 Family income wise distribution of the child (100%)

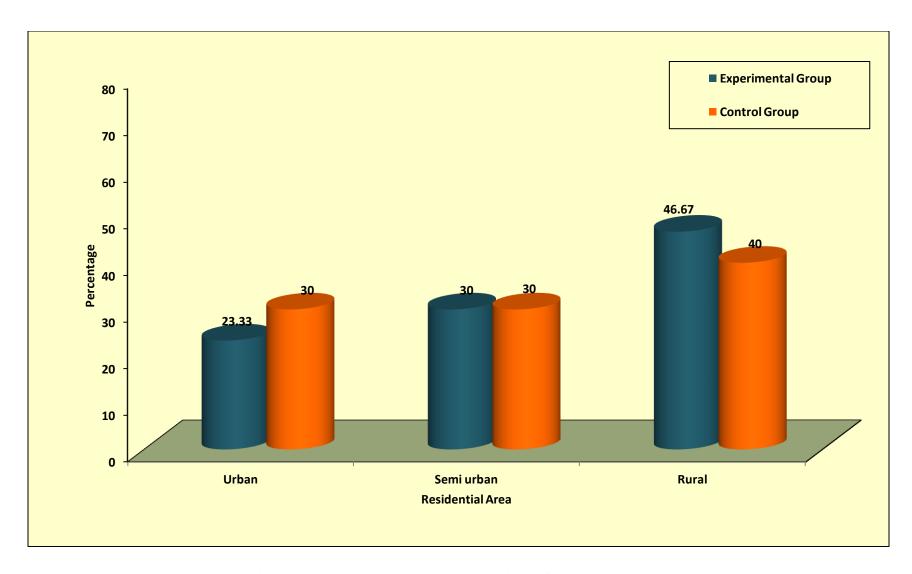


Fig 4.8 Residential area wise distribution of the child (100%)

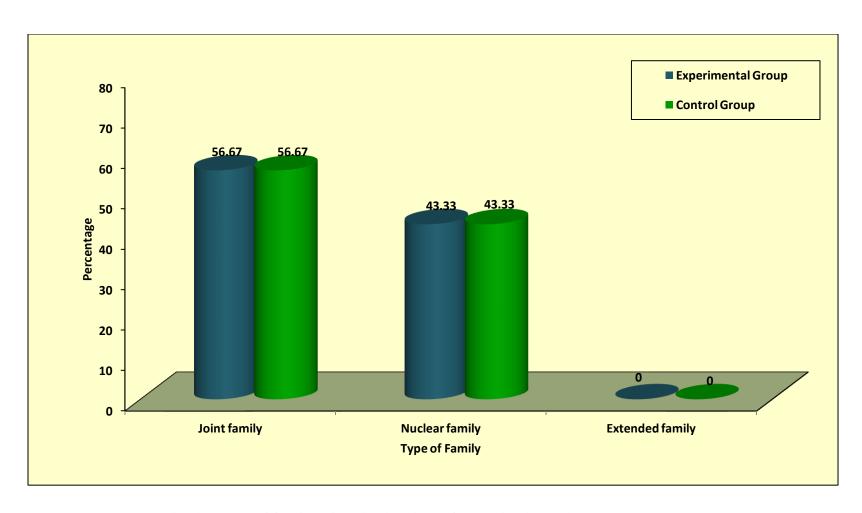


Fig 4.9 Type of family wise distribution of the child (100%)

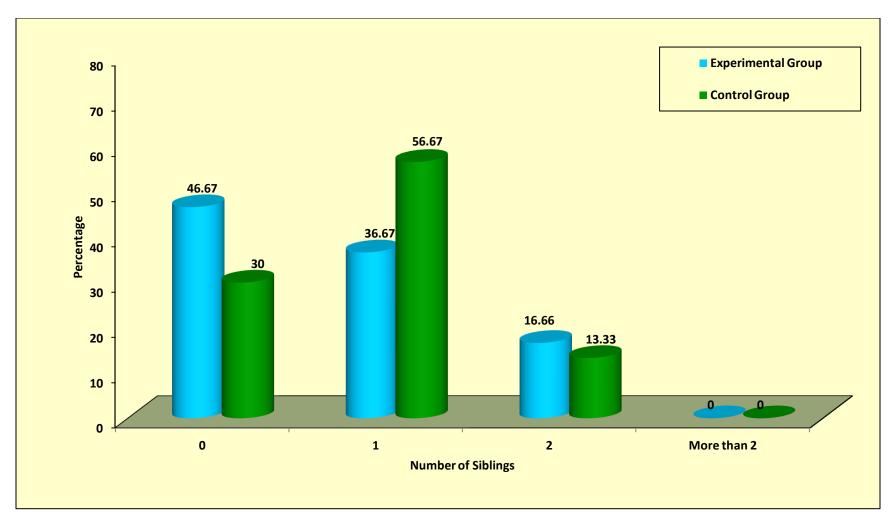


Fig 4.10 Number of siblings wise distribution of the child (100%)

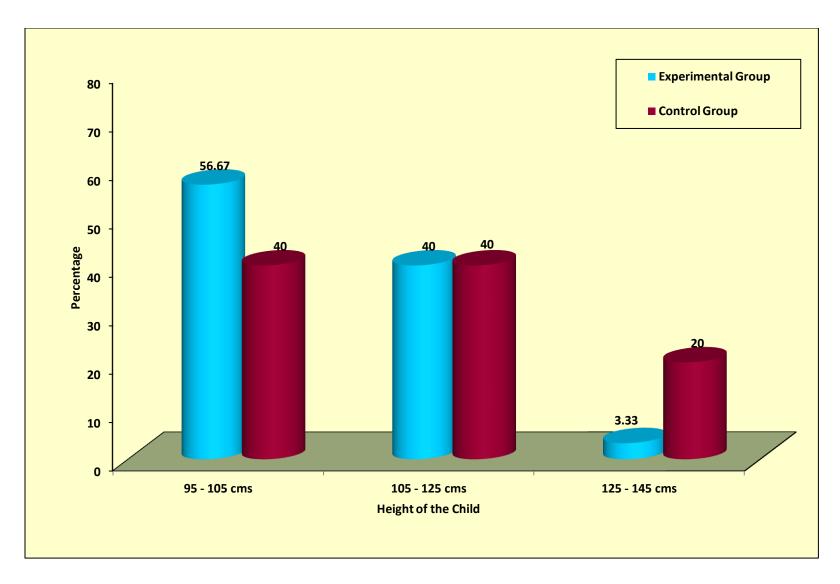


Fig 4.11 Height wise distribution of the child in cms (100%)

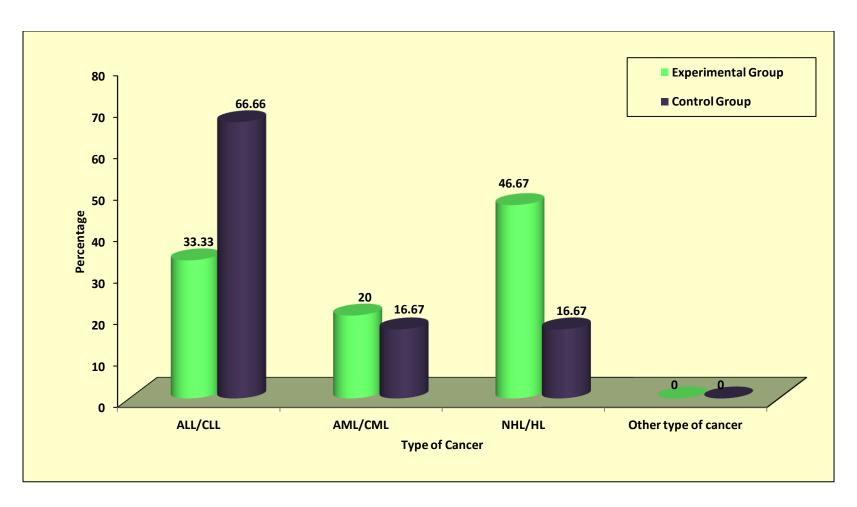


Fig4.12 Type of cancer wise $\,$ distribution of the child (100%)

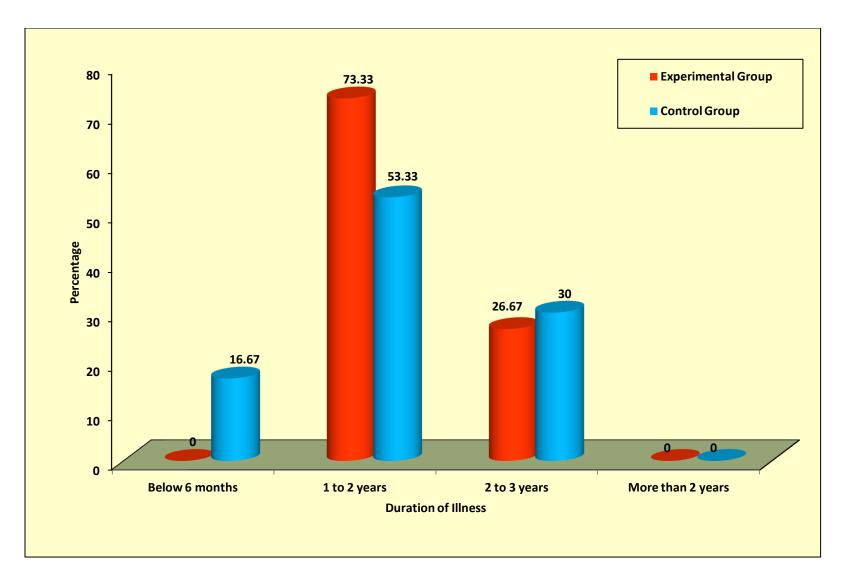


Fig 4.13 Duration of illness wise distribution of the child (100%)

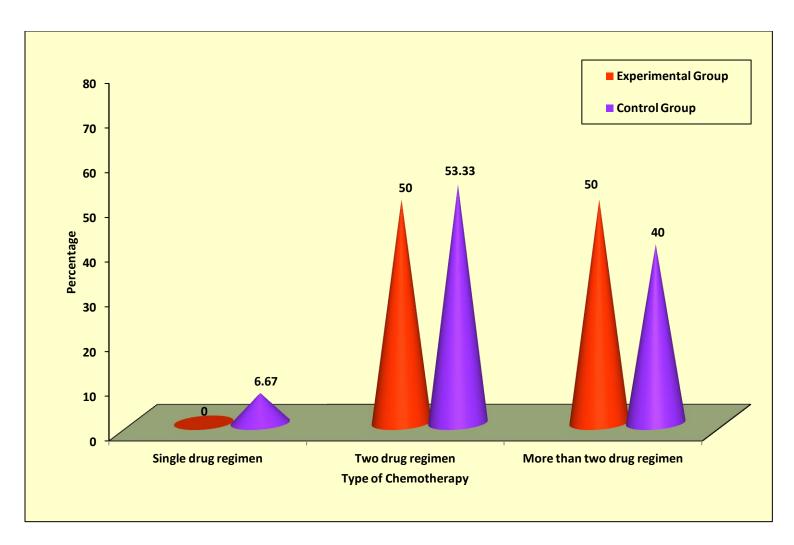


Fig 4.14 Type of chemotherapy wise distribution of the child

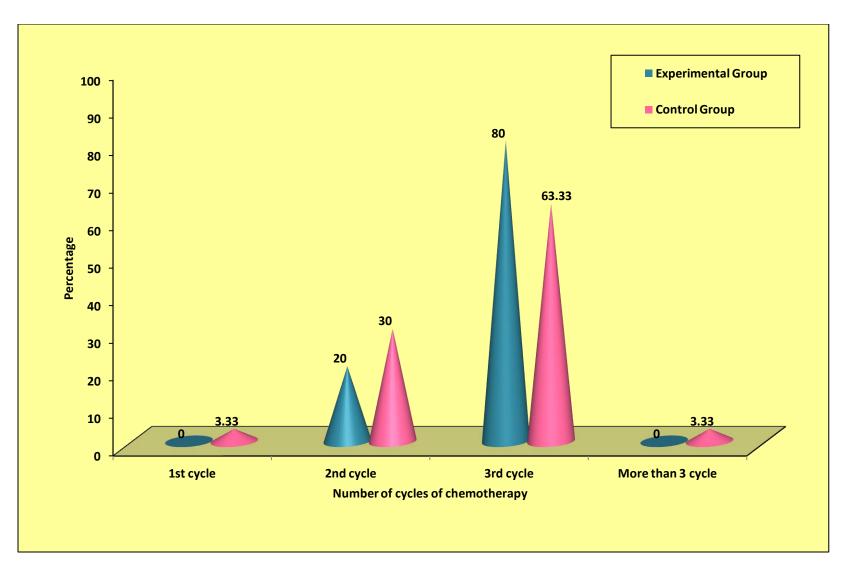


Fig 4.15 Number of cycles of chemotherapy wise distribution of the child(100%)

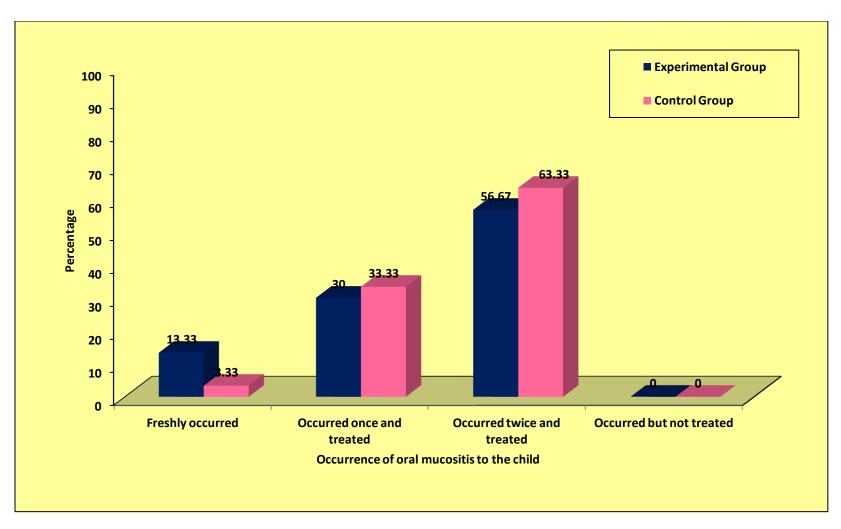


Fig 4.16 Occurrence of oral mucositis wise distribution to the child (100%)

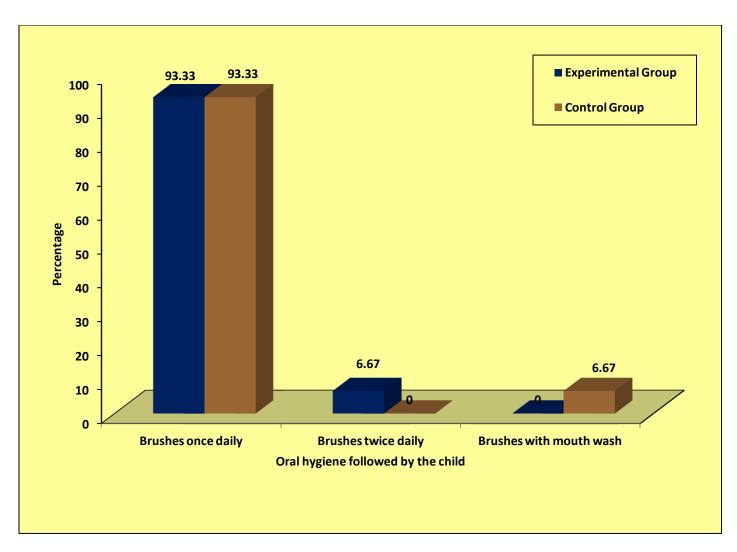


Fig 4.17 Oral hygiene wise distribution followed by the child(100%)

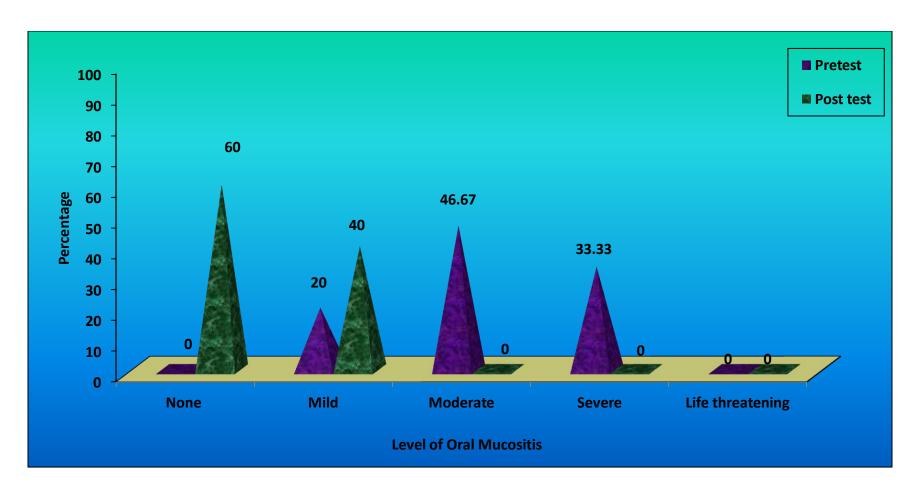


Fig 4.18 Distribution of pretest and post test level of oral mucositis among cancer children receiving chemotherapy in control group.

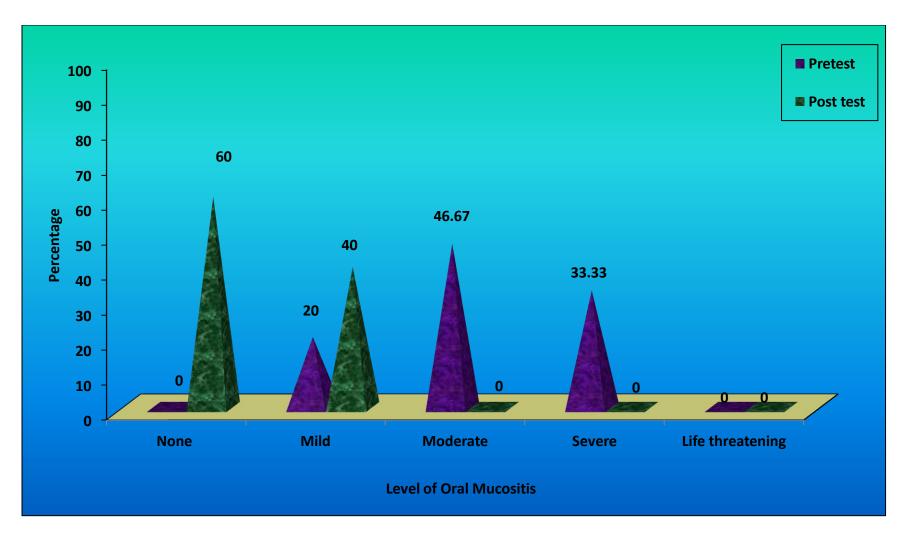


Fig 4.19 Percentage distribution of pretest and post test level of oral mucositis among cancer children receiving chemotherapy in the experimental g

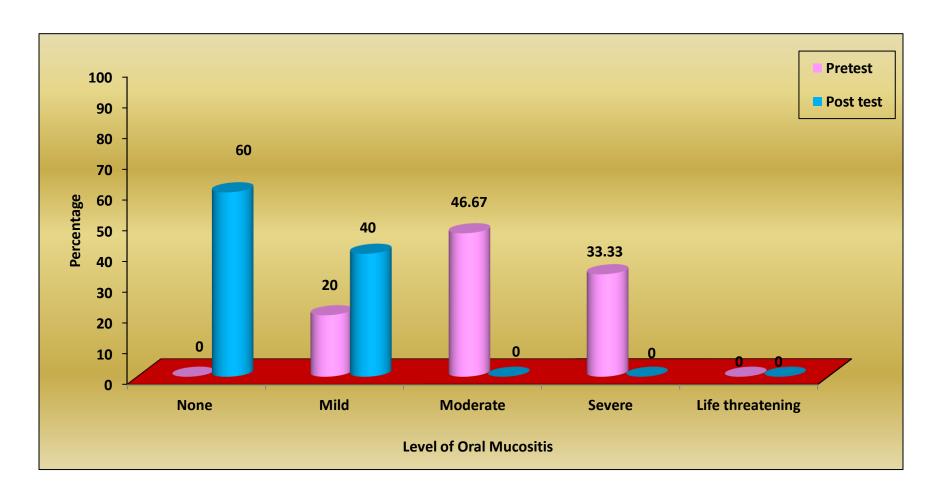


Fig 4.20 Percentage distribution of pretest and post test level of oral mucositis among cancer children receiving chemotherapy in the control group

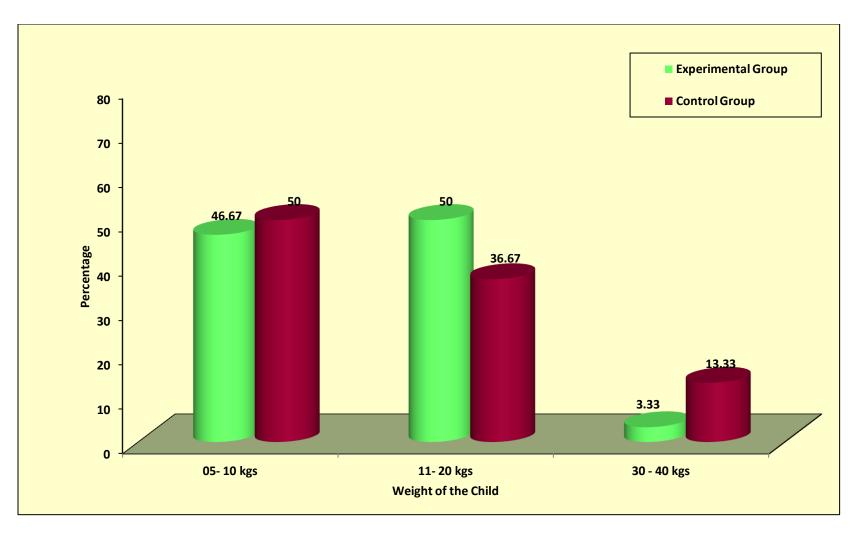


Fig 4.21 Percentage distribution of weight of the child in kgs(100%)

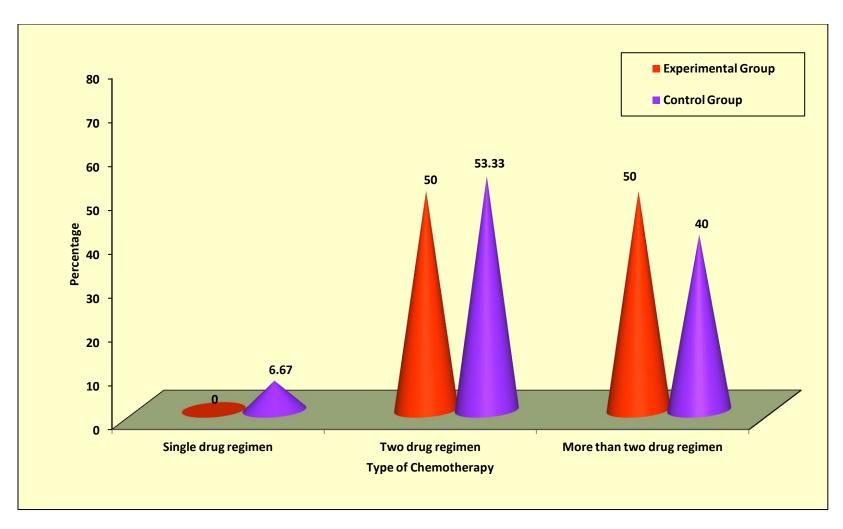


Fig4. 22 Percentage distribution of type of chemotherapy of the child