DISSERTATION ON

"A STUDY TO ASSESS THE EFFECTIVENESS OF APITHERAPY IN REDUCING ORAL MUCOSITIS AMONG HEAD AND NECK CANCER PATIENTS UNDERGOING RADIATION THERAPY AT RAJIV GANDHI GOVERNMENT GENERAL HOSPITAL, CHENNAI."

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A study to assess the effectiveness of apitherapy in reducing oral mucositis among head and neck cancer patients undergoing radiation therapy at Rajiv Gandhi Government General Hospital, Chennai.

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CERTIFICATE

This is to certify that this dissertation titled **"a study to assess the effectiveness of apitherapy in reducing oral mucositis among head and neck cancer patients undergoing radiation therapy at Rajiv Gandhi Government General Hospital, Chennai."** is a bonafide work done by **Mrs.Sonia.M, II year M.Sc Nursing student**, College of Nursing, Madras Medical College, Chennai submitted to **The TamilNadu Dr. M.G.R. Medical University, Chennai** in a partial fulfillment of the university rules and regulations towards the award of the degree of **Master of Science in Nursing Branch-I Medical Surgical Nursing** under our guidance and supervision during the academic period from 2014 – 2016.

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ABSTRACT

TITLE - A study to assess effectiveness of apitherapy in reducing oral mucositis among head and neck cancer patients undergoing radiation therapy at Rajiv Gandhi Government General Hospital, Chennai.

Oral mucositis is the painful inflammation and ulceration of the oral mucosa, usually as an adverse effect of radiation therapy. It is a major health problem that alters the quality of life and nutritional status of the patients with head and neck cancer undergoing radiation therapy.

Need for the study: As a complementary alternative therapy for oral mucositis, honey has the anti bacterial property and antioxidant property to improve the anatomical and functional abilities. So the investigator felt that it comes within the scope of nursing and wanted to conduct the study to assess the effectiveness of this intervention.

Objectives

- To assess for oral mucositis among patients with head and neck cancer undergoing radiation therapy.
- To assess the effectiveness of apitherapy for the patients with head and neck cancer of experimental group.
- To compare the pre test and post test level of oral mucositis among head and neck cancer patients in experimental group and control group.
- To find the association between post test level of oral mucositis among head and neck cancer patients with selected demographic variables.

Methodology: Research approach-quantitative approach, Research design – experimental design, Sampling technique – simple random sampling (lottery method), Research setting - outpatient department of radiation therapy at Rajiv Gandhi Government General Hospital, Chennai, Study population – head and neck cancer patients undergoing 2^{nd} phase radiation therapy, Tool-demographical data and clinical variables, National Cancer Institute-Cancer Toxicity Criteria (NCI-CTC) scale.

Data collection procedure: After obtaining formal permission from concerned Head of Department and consent from patients study procedure was started. Pre assessment was done and 60 samples were selected. Among 60 patients 30 were assigned to experimental group & 30 control group. Experimental group patients were given 20 ml of pure honey 15 min before and 15 min after radiation therapy to swish for 5 minutes and then swallow it. Simultaneously, routine care given for control group. The procedure continued for 14 days. Then both group patients were evaluated at the end of 3rd phase (after 14 days) with NCI-CTC scale.

Data analysis: The data were analysed with descriptive statistics (frequency and percentage) and inferential statistics (chi square).

Study results: The study revealed the pre test and post test effectiveness, considering experimental group in ulceration **χ2=16.16 (p=0.001)**, Erythema **χ2=28.17 (p=0.001)**, Pain **χ2=29.39 (p=0.001)** and ability to swallow **χ2=15.67 (p=0.001)**, which were statistically significant.

In control group, the pre test and post test effectiveness was assessed which shows ulceration χ2=1.51 (p=0.67), erythema χ2=1.50 (p=0.68), pain χ2=5.22 (p=0.16) and ability to swallow χ2=1.21 (p=0.52) were statistically not significant.

Summary of results: The findings of the study shows that there is significant reduction in the oral mucositis after apitherapy among head and neck cancer patients undergoing radiation therapy in experimental group has been proved.

Conclusion: Antibacterial property and antioxidants in honey significantly reduces oral mucositis. So, in our Nursing practices the nurses can incorporate apitherapy as a part of nursing intervention for the patients receiving radiation therapy and chemotherapy in reducing oral mucositis.

Key words: effectiveness, apitherapy, oral mucositis

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ABBREVIATIONS

WHO	World Health Organization
RT	Radiation Therapy
LLL	Low Level Laser
HNC	Head And Neck Cancer
NCI-CTC	National Cancer Institute – Cancer Toxicity Criteria
CAM	Complementary and Alternative Medical therapy
RCTS	Randomized Controlled Trial Study
No.	Number
X^2	Chi square
H1 H2	Research Hypothesis
F	Frequency
N	Number of samples

CHAPTER I

INTRODUCTION

"A positive attitude may not solve all your problems, but it will annoy enough people to make it worth effort."

- ***Herm Albright***

The concept of perfect positive health cannot become a reality because man will never be so perfectly adapted to his environment that his life will not involve struggles; failures and sufferings. Positive health will therefore, always remain mirages, because everything in our life is subject to change. Health in this context has been described as a potentiality - the ability of an individual to modify him or itself continually in the face of changing conditions of life.

Decades before, Hippocrates said that cancer as a disease has existed all alones with man, Susruta who is the father of surgery explained that cancer as a tumour which would ulcerate and would not cure and sow its seeds in other parts of the body. Twenty-five centuries ago, cancer was called as Karakinos because the swollen blood vessels going and coming from the tumour mass.

Cancer is a disease process that begins when an abnormal cell is transformed by the genetic mutation of the cellular DNA. This abnormal cell forms a clone and begins to proliferate abnormally, ignoring growth regulating signals in environment surrounding the cell. Cancer can occur in all persons irrespective of age, sex, socio economic status culture and geographical area. Different forms of cancer strikes special age, ethnic gender groups which varying frequently and severity.

Cancer is one of the 2nd largest killer diseases next to the heart disease. It is a major health problem that occurs in people of all ethnicities. Cancer incidence is highest in men than women.

There are over 20 million people living with cancer in the world today. The estimate number of cases each year is expected to increase from 2 million in 2000 to 15 million in 2020. The number of cancer deaths annually will increase from about 6 million to l0 million. Cancer has now become the third leading cause of deaths in Asian countries. In India, there are approximately 2.2 million cases of cancer and around 7, 00,000 new cases are being detected each year. Among Indian women cancer in the breast account for nearly 60 percent of all cancers. Several studies reported that head and neck cancer is proportionately on the increase in a metropolitan area of India.

Interest in complementary alternative medicine has grown dramatically over the past several years. According to survey results 80% of patients repeated using some type of complementary alternative medicine, in that 54% took herbal products and 30 % used relaxation techniques.

Apitherapy is a type of complementary and alternative therapy which helps to reduce the degree of oral mucositis as a complication of radiation therapy. Apitherapy or bee therapy , is the product of the common honey bee for therapeutic purposes, which involves the medicinal use of bee stings the venom and it has a strong anti – inflammatory and pain relieve effect, soften scar tissue and to boost the body's immune system. There by symptoms of oral mucositis being reduced.

The goal of cancer treatment to cure, control and palliation are achieved through the use of four treatment modalities include surgery, radiation therapy, chemo therapy and biologic therapy. Among these, surgery and radiation therapy have remained the most commonly used treatment modalities.

1.1. Need for study

Cancer is the leading cause of death around the world. According to **WHO** estimation, that 84 million deaths have taken place due to cancer between 2005 and 2015 without intervention. Low income and medium income countries are harder hit by cancer than the high resource countries. It is essential to address the world's growing cancer burden and to work on effective control measures.

Districts in the central, south, northeast India have the world's highest incidence of cancer associated with tobacco in India. Aizawl district in the northeast state of Mizoram has the world's highest incidence of lower pharynx cancer and tongue cancer in men and also highest incidence in stomach cancer. Madhya Pradesh has the highest incidence of mouth ulcer in the world. Rate of stomach cancer were high among men in Bangalore, Chennai and also detected highest incidence in women in coastal district, Kerala, Karnataka and Goa. Lung cancer is the most common cancer in men in Calcutta, Mumbai and New Delhi.

From the experience of working in various health settings, the investigator observed that almost all the patients undergoing radiation therapy experience complications and side effects like alopecia, oral mucositis, nausea, vomiting and anorexia. Out of these complications oral mucositis is painful and prevents the patient to take adequate nutrition.

The investigator felt that there is a need to do some intervention to reduce the oral mucositis among head and neck cancer patients undergoing radiation therapy. After reviewing related literatures the investigator came to know the Apitherapy has good effect in reducing oral mucositis among head and neck cancer patients undergoing radiation therapy. So the researcher planned to conduct a study by using Apitherapy in reducing the oral mucositis among head and neck cancer patients undergoing radiation therapy.

1.1. Statement of the problem

"A study to evaluate the effectiveness of apitherapy in reducing oral mucositis among head and neck cancer patients undergoing radiation therapy at Rajiv Gandhi Government General Hospital, Chennai."

1.2. Objectives of the study

- To assess for oral mucositis among patients with head and neck cancer undergoing radiation therapy.
- To assess the effectiveness of apitherapy for the patients with head and neck cancer of experimental group.
- To compare the pre test and post test level of oral mucositis among head and neck cancer patients in experimental group and control group.
- To find the association between post test level of oral mucositis among head and neck cancer patients with selected demographic variables.

1.2. Operational definition

- ***effectiveness :*** The extent to which the apitherapy has brought about the significant difference between experimental group and control group which is measured in terms of statistical measurement.
- ***apitherapy*****:** Apitherapy is the use of products of the common honey bee for therapeutic purposes. In this study it refers to administration of 20 ml of pure honey before and after 15 minutes of radiation and 6 hours after the radiation to the experimental group to reduce the inflammation, pain, soften the scar tissue and boost the body's immune system.
- ***oral mucositis:*** Oral mucositis is the painful inflammation and ulceration of the oral mucosa, usually as an adverse effect of radiation therapy.

- ***cancer:*** Cancer is the diseases of a cell. It is characterized by a shift in the control mechanisms of the cell which govern cell survival; proliferation and differentiation such cell multiply excessively and form local tumors that can invade adjacent normal structures.

- ***patient*:** Refers to head and neck cancer patients undergoing 2nd phase radiation therapy.

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

1.3. Assumption

- Antibacterial property and antioxidants in honey may reduce oral mucositis.

1.4. Hypothesis

H1 - There is reduction in oral mucositis after apitherapy among head and neck cancer patients undergoing radiation therapy in experimental group.

1.5. Delimitations

- The study was conducted to time period of four weeks
- Study findings can be generalised and performed at Rajiv Gandhi Government General Hospital, Chennai
- Subjects selected with age group of 25 – 65 years with oral mucositis induced by radiation therapy for head and neck cancer.

CHAPTER - II

REVIEW OF LITERATURE

Oral mucositis is actually a widespread and possible serious consequence of high-dose chemotherapy and radiotherapy treatments frequently becoming evident as erythematic and aching ulcerative abrasions of the mouth and even the throat.

The literature gathered from through review is depicted under the following headings.

2.1 Literature related to radiation induced oral mucositis among head and neck cancer patients undergoing radiation therapy
2.2 Literature related to complementary and alternative therapy in reducing degree of oral mucositis among head and neck cancer patients undergoing radiation therapy
2.3 Literature related to Apitherapy in reducing oral mucositis among head and neck cancer patients undergoing radiation therapy

2.1. Literature related to radiation induced oral mucositis for head and neck cancer patients undergoing radiation therapy

Alison., M. et al (2002) conducted a perspective study on complication of radiation therapy for head and neck cancers, by personal interviews were conducted with 33 individuals who had received radiation therapy for head and neck cancers. Overall, lethargy and weakness, dry mouth, mouth sores and pain, taste changes and sore throat were the most frequently reported side effects. The single most debilitating side effect was oropharyngeal mucositis that was characterized by patients as sore throat and mouth sores and pain both negatively affected the patients to experience significant weight loss. As a conclusion trends toward more aggressive management for oropharyngeal mucositis occurring in patients receiving radiotherapy.

Shanthi Appavu (2006) conducted a descriptive study on Nurses roles in the management and prevention of oral complications related to cancer treatment at International cancer centre, Neyyoor. The findings revealed that the majority of staff (67.5%) reported they give more important to oral mucositis. More than one third of the nurses had also reported that they inspect for local infection (37.5%), Xerostomia (37.5%), functional disabilities (15.0%), taste alteration (20.0%) and abnormal dental development (10.0%). As a conclusion there is a great need to educate not only nurses but relatives and the patients to adopt certain preventive strategies to reduce the prevalence of oral complications related to cancer treatment.

Rubina C. M., et al (2007) conducted an evaluative study of some oral post radiotherapy sequelae in patients treated for head and neck tumors. One hundred patients (24 women, 76 men) ranging in age from 30 to 83 years (mean 59.2 years) were examined. The evaluation protocol included anamnesis, intraoral and extraoral examination, measurement of stimulated salivary flow and salivary PH symptoms reported by the patients included dry mouth (68%), dysphagia (38%) and dysgeusia (30%). The mean salivary PH was 6.97 (± o.714) stimulated salivary flow increased with increasing post radiotherapy time ($P< 0.05$). As a conclusion the prevalence of mucositis was associated with higher radiation doses ($P< 0.05$) and the prevalence of atrophic candiadiasis was related to a longer post treatment period ($P < 0.05$)

Goyal. M et al (2009) conducted prospective study on oral mucositis in morning vs evening irradiated patients. The purpose of the study to evaluate prospectively the severity of acute oral mucositis in head and neck carcinoma patients irradiated in the morning (08.00 – 11.00h) versus late afternoon/evening (15.00–18.00h). The results shows the grades of mucositis were marginally higher in the evening irradiated group than in the morning irradiated group 38%versus26% ($P=0.08$). In conclusion the observed incidence may be because of the existence of circadian rhythm in the cell cycle of normal mucosa.

Murphy., B. A. et al (2009) conducted a prospective, longitudinal, multicenter, non interventional study on mucositis related morbidity and resource utilization in head and neck cancer patients receiving radiation therapy with or without chemotherapy. The objective of this study was to estimate health care resource utilization in head and neck cancer (HNC) patients. Over the course of the treatment, 57 (76%) patients reported severe mouth and throat soreness during the course of therapy despite the use of opoid analgesics in 64 (85%) of the patients. As a conclusion this study demonstrates that mucositis related pain and functional impairment is associated with increased use of costly health resources. Effective treatments to reduce the pain and functional impairment of oral mucositis are needed in this patient population.

2.2. Literature related to complementary and alternative therapy in reducing degree of oral mucositis among head and neck cancer patients undergoing radiation therapy

Nikolettti., S et al (2005) conducted a randomized, controlled, crossover trial study to evaluate the effect on mucositis and to determine patients' perception of the two forms of oral cryotherapy in the outpatient department in Perth, Western Australia. The two main forms of oral cryotherapy were taste of flavored ice and lain ice. Side effects such as nausea, sensitivity and headache were reported more frequently for flavored ice (n=11), compared with plain ice (n=5), and standard care (n=1). As a conclusion both forms oral cryotherapy were effective in reducing the severity of oral mucositis and were more effective than standard care alone. Flavored ice was associated with the highest frequency of side effects

Hong., J.P. et al (2005) conducted a experimental study to evaluate the wound healing effect of human recombinant epidermal growth factor in treatment of radiation induced severe oral mucositis in patients with head and neck malignancies at Asan Medical Center. Patients at who had undergone definitive RT of the head and neck region with or without combined

chemotherapy and who had developed severe oral mucositis were treated with topical rhEGF twice daily for 7 days. The evaluation of response with regard to oral mucositis was performed 1 week later. All patients showed improvements in their oral mucositis after topical treatment with rhEGF in that the Radiation Therapy Group grade was significantly decreases(p=0.0000). As a conclusion this findings suggests that rhEGF is effective and safe for the treatment of radiation-induced mucositis.

Debra., L. (2006) conducted a randomized controlled trial study (RCTS) on a systemic review of evaluating alternative and complementary therapies for cancer related pain. Seven trials reported significant benefit for the following CAM therapies, acupuncture (n=1), support groups (n=2), hypnosis (n=1), relaxation/imagery (n=2), herbal supplement (n=1). Four studies reported to benefit to CAM interventions, music (n=2), massage (n=2) in reducing cancer pain compared with a control arm. As a conclusion, CAM interventions for cancer pain with adequate power, duration was effective.

Alterio., D. et al (2006) conducted a experimental study to assess feasibility, pain relief and toxicity tetracaine based oral gel in the treatment of radiotherapy (RT) induced oral mucositis. 50 patients treated with RT for head and neck cancer with clinical evidence of acute oral mucositis of grade >or=2 were scheduled to receive the tetracaine gel. A questionnaire evaluating the effect of the gel was given to all subjects. The result shows in 38 patients (79.2%) a reduction in oral cavity pain was reported. 34 patients (82.9%) reported no side effects. 71% of patients had any difficulties in gel application. Unpleasant taste of the gel and interference with food taste were noticed in 5(12%) and 16patients (39%) respectively. As a conclusion tetracaine oral gel administration seemed feasible and safe while reducing RT- induced mucositis related oral pain in a sizeable proportion of treated head and neck cancer patients.

Arun Maiya., et al. (2006) conducted a true experimental study on low level heliumneon (He-Ne) laser therapy in the prevention and treatment of radiation induced mucositis in head and neck cancer patients. The study group patients were treated with (He- Ne) laser and control group patients were given oral analgesics, local application of anesthetic 0.9% saline and povidine wash during the course of radiotherapy. The result shows a significant difference in pain and mucositis ($p<0.001$) between the two groups. As a conclusion the low level (He-Ne) laser therapy during radiotherapy treatment was found to be effective in preventing and treating the mucositis in head and neck cancer patients.

Chambers., M. S et al (2006) conducted a double blind study to evaluate the effect of RK-0202 on the incidence of severe oral mucositis in patients being treated with of radiation therapy (RT) for tumors of the head and neck. Oral mucositis was assessed twice weekly throughout RT by trained oral evaluators. The result shows the higher dose of RK- 0202 (10%) successfully attenuated severe oral mucositis. As a conclusion RK-0202 significantly reduce the incidence of severe mucositis in subjects treated with radiotherapy for head and neck cancer and was not associated with significant adverse events.

King-fong et'al (2008) conducted a comparative study to assess the efficacy of 0.2% chlorhexidine gluconate and 0.15% benzydamine hydrochloride oral rinses in alleviating irradiation oropharyngeal mucositis for patients with head and neck cancer. 14 subjects were randomly assigned to chlorhexidine (n=7) or benzydamine (n=7). In result chlorhexidine arm 4 subjects (57%) had grade 2, 3 subjects (71%) had grade 2 and 2 subjects (29%) had grade 3 mucositis. In benzydamine arm 5 subjects (71%) had grade 2, 2 subjects (29%) had grade 3 mucositis ($p> 0.05$). As a conclusion a lessening of severity of oral mucositis, pain, dysphagia for patients with head and neck cancer receiving benzydamine oral rinse.

Madankumar., P.D et al (2008) conducted a comparative study to assess the effect of three alcohol free mouthwashes on radiation induced oral mucositis in patients with head and neck malignancies.80 patients with head and neck malignancies, scheduled to undergo curative radiotherapy were randomly assigned to receive one of the three alcohol free test mouthwashes (0.12% chlorhexidine, 1% povidone iodine or salt/soda). The patients were instructed to rinse their mouth with 10ml of the mouthwash, twice a day, for a period of 6 weeks. Mucositis was assessed by using WHO assessment scale. In results among 76 patients, patients in the povidone iodine group had significantly lower mucositis scores when compared to the control group from the first week of radiotherapy. As a conclusion use of alcohol free povidone iodine mouthwash can reduce the severity and delay the onset of oral mucositis due to antineoplastic radiotherapy.

Ozlem., et al (2009) conducted a multivariate analysis study to evaluate the prevalence of and factors related to the use of complementary and alternative medicine among cancer patients undergoing or following conventional treatment at the Erciyes University Oncology Hospital in Central Anatolia. A total of 268 consecutive cancer patients were enrolled in the study. Overall, 43% of the patients were using or had used complementary/alternative medicine. Nearly half of the patients using complementary/alternative medicine (46.1%) were aiming to fight the disease. Among users, half regarded the method used as effective and 54(50.5%) suggested the use of complementary/alternative medicine to other patients. As a conclusion use of complementary/alternative medicine among cancer patients in this center was modestly high, and the most common method was herbal therapy.

Castro., G. et al (2009) conducted a prospective, randomized, double blind study to evaluate the efficacy of LLL (low level laser therapy) to decrease and delay severe oral mucositis and its impact on RT interruptions. The result shows 73 patients were included, 36 patients received prophylactic LLL mean delivered RT dose (Gray) was higher in patients treated with LLL (69.3 VS

67.8, P=O,O4). As a conclusion LLL therapy was effective in reducing grade 3 or 4 oral mucositis and in reducing RT interruptions in these head and neck cancer patients treated with concurrent radiation therapy which is efficacy and tolerance.

Zanin., J. et al (2010) conducted a study to evaluate quantitatively and qualitatively the effect of a 660-nm diode laser in the prevention and treatment of human oral mucositis in head and neck cancer patients undergoing radiation therapy. 72 patients with head and neck patients divided in to a control group (c; n=36) and a laser group (L; n=36). Laser therapy was performed in combination with radiotherapy and chemotherapy twice a week using a diode laser. Patients in group L usually did not present with oral mucositis ranging from level I to III associated with pain. As a conclusion laser therapy was effective in preventing and treating oral effects induced by radiotherapy and chemotherapy, thus improving the patient's quality of life.

2.3. Studies related to Apitherapy in reducing oral mucositis in head and neck cancer patients undergoing radiation therapy

Ahmad Zakaria., et al (2003) conducted a quasi experimental study on honey treatment for prevention of oral mucositis and gingivitis. Patients consumed 20 ml (one and one- third teaspoon) of pure honey 15 minutes before, 15 minutes after and 6 hr post – treatment. There was significant reduction in the symptomatic grade three-four mucositis among honey treated patients compared with controls i.e. 20% versus 75% ($p < 0.001$). In result the compliance of the honey treated group of patients was better than control. A total of 55% patients treated with topical honey showed no change or a positive gain in body weight compared with a positive gain in body weight compared with only 25% in the control arm($P = 0.05$). As a conclusion honey has potential for the treatment of periodontal diseases, mouth ulcers and other problems of oral health.

Biswal., et 'al (2003) conducted a study on topical application of honey in the management of radiation mucositis. The aim of the study was to evaluate the effect of pure honey on radiation induced mucositis. In this study arm, patients were advised to take 20 ml of pure honey 15 min before, 15 min after and 6 h post radiation therapy. The main result of the study was there was significant reduction of symptomatic grade ¾ mucositis among honey–treated patients compared to controls i,e 20% vs 75% (p 0.00058). The compliance of honey treated group of patients was better than controls. As a conclusion topical application of natural honey is a simple and cost- effective treatment in radiation mucositis.

Apitherapy News (2008) the aim of the study is to evaluate the effect of pure natural honey on radiation induced mucositis. 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. In the study group patients were instructed to take 20 ml of honey 15 minutes before and 15 minutes and six hours after radiation. In control group patients were instructed to rinse with 20 ml of saline before and after radiation. Result shows a significant reduction in mucositis among honey received patients compared with controls (p = o.ooo) occurred. As a conclusion within the limits of this study the results showed the application of natural honey is effective in managing radiation induced mucositis.

Rashad UM et al (2009) conducted an evaluative study on honey as topical prophylaxis against radiochemotherapy induced mucositis in head and neck cancer. 40 patients diagnosed with head and neck cancer were entered into the trial. Patients were evaluated clinically every week to assess development of radiation mucositis. In the results in the treatment group, no patients developed grade four mucositis and only 3 patients (15%) developed grade three mucositis. In the control group 13 patients (65%) developed grade three or four mucositis ($p < 0.05$). As a conclusion this study shows that

prophylactic use of pure natural honey was effective in reducing mucositis resulting from radiochemotherapy in patients with head and neck cancer.

Khanal., et al (2010) conducted a single blind, randomized, controlled clinical trial study on effect of topical honey on limitation of radiation-induced mucositis. The study was carried out to compare the mucositis limiting qualities of honey with lignocaine. The result shows only 1 of 20 patients in the honey group developed intolerable oral mucositis compared with 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). As a conclusion honey applied topically to the oral mucosa of patients undergoing radiation therapy appears to provide a distinct benefit by limiting the severity of mucositis.

Gezawy S.M. AL (2013) did a double blind study on honey as topical prophylaxis against radiotherapy- induced mucositis in head and neck cancer at Assiut University Hospital, Egypt. Enrolled patients were randomized to either the treatment group, receiving concomitant chemotherapy and radiotherapy plus prior topical application of pure natural honey, or the control group, receiving concomitant chemotherapy and radiotherapy without honey. In the result in treatment group, no patients developed grade four mucositis and only three patients (15%) developed grade three mucositis where as in the control group, 13 patients, (65%) developed grade three to four mucositis (p< o.o5). Candida colonization was found in 15% of the treatment and 60% of the control group, either during or after radiotherapy (p= 0.003). Positive cultures for aerobic pathogenic bacteria were observed in 15% percent of the treatment group and 65% of the control group, during or after radiotherapy (p=0.007). As a conclusion this study shows that prophylactic use of pure honey was effective in reducing mucositis resulting from radiotherapy in patients with head and neck cancer.

***Kaur Harinderjeet, et al* (2015)** conducted an experimental study to assess the effectiveness of honey in oral mucositis in Punjab. The findings of the study revealed that the mean pre test grade of oral mucositis of experimental & control group were 2.5±0.93 & 2.26±0.94 respectively. After providing intervention, twice a day for 7 days to experimental group the mean post test grade of oral mucositis of experimental was 1 ± 0.98 and in control group after no any intervention was 2.53 ± 1.04 respectively. It indicated that, there was significant (t cal. 6.0489? t table 1.96 at p? 0.05) difference between pre test and post test grade of oral mucositis of cancer patients in the experimental group than control group. So, it is concluded that topical application of honey is effective for reduction of grade of oral mucositis among cancer patients.

2.2. Conceptual framework

The conceptual framework for this study was direction from Wiedenbach's helping art of clinical nursing theory (1969).

According to Ernestine Wiedenbach's Nursing is a helping service that is rendered with compassion, skill and understanding to those in need for care, counsel and confidence in the area of health. The practice of nursing comprises a wide variety of services each directed toward the attainment of one of its three components.

Step I: Identification of a need for help.

Step II: Ministering the help needed.

Step III: Validation that the need for help was met.

Central purpose

The central purpose is to reduce the degree of oral mucositis among head and neck cancer patients undergoing radiation therapy

Step I- Identification of a need for help

The head and neck cancer patients undergoing 2nd phase of radiation therapy are selected. The general information which comprises assessment of demographic variables for both experimental and control group such as age, sex, religion, education, family monthly income, personal habits, family history of cancer, duration of illness and duration of treatment. Pre assessment of oral mucositis done in both experimental group and control group by NCI-CTC scale.

Step II: Ministering the help needed

In this step ministering to the patient the nurse may give advice or information, make a referral, apply a comfort measures or carry out a therapeutic procedures. The nurse will need to identify the cause and if necessary make an adjustment in the plan of action.

Ministering of help needed it has two component.

- Prescription
- Realities

Prescription

It specifies both the nature of the action that will most likely lead to fulfillment of the nurse's central purpose and the thinking process that determines it.

Prescription - apitherapy is the plan of care to achieve the purpose. This includes in experimental group oral administration of 20 ml of pure honey group before and after 15 minutes radiation treatment advise the patient to swish it for 5 minutes then swallow it, and advise the patient to repeat the same for in their homes after 6 hours of post radiation for 14 days (from 23rd day to 36th day).

Realities

Realities of the situation is the one in which the nurse is to provide nursing care. Realities consist of all factors -physical, physiological, emotional and spiritual that are at play in a situation in which nursing actions occur at any given moment. Wiedenbach's defines the five realities as the agent, the recipient, the goal, the means and the framework.

Agent: Investigator

Recipient: Head and neck cancer patients undergoing Radiation therapy.

Goal: To reduce the degree of oral mucositis among head and neck cancer patients undergoing radiation therapy.

Mean: Apitherapy administration for 14 days in experimental group.

Frame work: Radiation Outpatient department in Rajiv Gandhi Government General Hospital at Chennai.

Step III: Validation that the need for help was met

After help has been ministered the nurse validates that the actions were indeed helpful. Evidence must come from the patient that the purpose of the nursing actions has been fulfilled.

Validating the need for help was met by means of post assessment for both experimental and control group with the NCI-CTC Scale and by observational check list to assess the degree of oral mucositis on the 14th day.

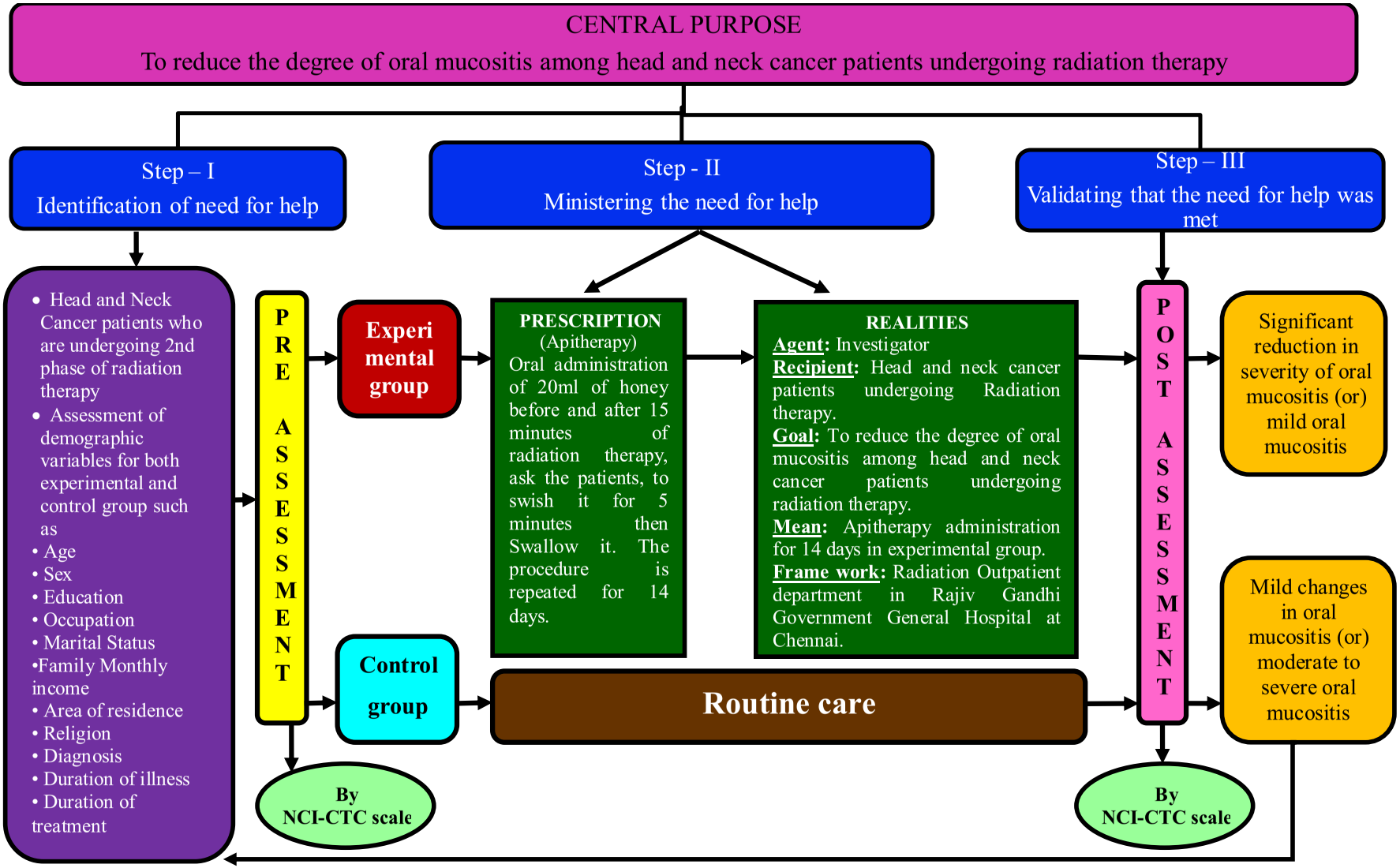


Figure 2.1 MODIFIED WIEDEN BACH'S HELPING ART OF CLINICAL NURSING THEORY (1964)

CHAPTER - III

RESEARCH METHODOLOGY

Research methodology involves the description of research approach, data collection period, study setting, study population, sample size, sampling technique, sample selection criteria, research variables, tools and method of data collection, content validity, ethical consideration, pilot study, reliability and analysis to answer a specific research questions or for testing research hypothesis.

3.1. Research approach

The quantitative approach was used to evaluate the effectiveness of apitherapy in reducing oral mucositis among head and neck cancer patients undergoing radiation therapy.

3.2. Data collection period

The study was conducted for the period of four weeks (from 15.07.15 to 15.08.15)

3.3. Study setting

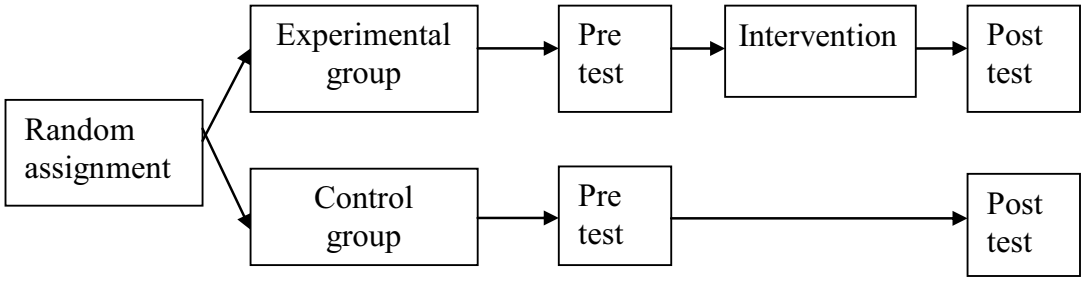
The study was conducted in Outpatient Department of Radiation Therapy at Rajiv Gandhi Government General Hospital, Chennai. It is a major state-owned hospital situated in Chennai with 3,000 beds and is funded & managed by the state government of TamilNadu. Multi specialty services are rendered by the hospital. The hospital is treating about 10,000 to 12,000 outpatients every day.

The department of Radiation Oncology, Barnard Institute of Radiology & Oncology, Madras Medical College was started in 1922. In 1930s, two institutions started their radiotherapy work. One was in England and the other is our department. Hence ours is the first and oldest premier institute in the whole of South East Asia. The Department specializes in providing Radiotherapy treatment to all cancers where indicated in the form of Neo-

adjuvant, Adjuvant, Concurrent & Palliative treatment. In radiation oncology department, inpatient bed strength is 231 beds and outpatient census is 150-170 patients/day. 1n 2015, the inpatient census was 15,956 in which head and neck cancer patients was 7,567.

3.4. Study design

The research design used for this study is experimental design.



3.5. Study population

The target population of the study is head and neck cancer patients undergoing 2nd phase of radiation therapy at Rajiv Gandhi Government General Hospital, Chennai.

3.6. Sample size

Sample size is 60. Among 60 Head and neck cancer patients, 30 were in experimental group and 30 were in control group.

3.7. Sampling criterion

3.7.1. Inclusion criteria

- Both female and male patients undergoing radiation therapy in outpatient department
- Head and neck cancer patients with the age group of 25 – 65yrs
- Head and neck cancer patients undergoing 2nd phase radiation therapy continues for 14 days
- Head and neck cancer Patients who understand, speak Tamil or English
- Head and neck cancer patients who are all willing to participate in this study.

3.7.2. Exclusion criteria

- Head and neck Cancer patients with Diabetes mellitus
- Head and neck Cancer patients who are critically ill

3.8. Sampling technique

Simple random sampling technique (lottery method) was used to select the samples for the study.

3.9. Research variables

Independent Variable

Apitherapy

Dependent Variable

Head and neck cancer Patients with oral mucositis

3.10. Development and description of the tool

After an extensive review of literature and discussion with the experts the following tools are prepared to collect data.

3.10.1. Development of the tool

The tool is developed after extensive review of literature, internet search and discussion with experts and statistician in order to develop guidelines for providing apitherapy and duration of apitherapy. An observation checklist for assessment of radiation therapy induced oral mucositis based on the National Cancer Institute-Cancer Toxicity Criteria (NCI-CTC) was developed.

3.10.2. Description of the tool

The tool consisted of two sections.

Section-A

Demographical and clinical variables of the head and neck cancer patients were age, gender, education, family monthly income, religion, personal habits, family history of cancer, duration of illness, and duration of treatment.

Section-B

Observational Check list & Scoring Key. It consist of 4 items such as

1. Ulceration
2. Erythema
3. Pain
4. Ability to swallow

Each item is categorized as follows,

Ulceration

0 = No Lesion	Score 0	= No Lesion
1 = <1cm^2	Score 1-9	= Mild
2 = 1-3cm^2	Score 10-18	= Moderate
3 = >3cm^2	Score 19- 27	= Severe

Erythema

0 = No Lesion	Score 0	= No Lesion
1 = <1cm^2	Score 1-9	= Mild
2 = 1-3cm^2	Score 10-18	= Moderate
3 = >3cm^2	Score 19- 27	= Severe

Pain

0 = No Pain	Score - 0
1-3 = Mild Pain	Score - 1
4-6 = Moderate Pain	Score – 2
5-9 = Severe Pain	Score - 3
10 = Worst Possible Pain	Score - 4

Ability to swallow

Ability to swallow foods without pain	-Score 3
Ability to swallow with pain	- Score 2
Requires intravenous rehydration	- Score 1
Require parenteral or enteral nutrition	- Score 0

3.10.3. Intervention protocol

Protocol	Experimental group	Control group
Place	Radiation therapy outpatient department	Radiation therapy outpatient department
Dosage	20 ml of honey	Routine care
Duration	5 minutes	-
Frequency	Twice	-
Time	15 minutes before radiation therapy and 15 minutes after radiation therapy.	-
Administered by	Investigator	Self

3.10.4. Content validity

Content validity was determined by experts from Nursing, Medical and Statistician. They suggested certain modifications in tool. After the modifications they agreed this tool to evaluate the effectiveness of apitherapy in reducing oral mucositis among head and neck cancer patients undergoing radiation therapy at Rajiv Gandhi Government General Hospital, Chennai.

3.11. Ethical consideration

The study objectives, intervention & data collection procedure was approved by the Institutional Ethics Committee, Madras medical College, Chennai.

3.12. Pilot study

The pilot study was conducted in Rajiv Gandhi Government General Hospital, Chennai at radiation oncology outpatient department for period of 3 days. Among 10 patients, 5 patients were in experimental group and 5 patients were in control group. The patients were selected using simple random sampling technique. The results showed positive co relation between apitherapy and radiation therapy induced oral mucositis. The study was practically feasible. Pilot study participants were not included in the main study.

3.13. Reliability

After pilot study reliability of the tool was assessed by using Split Half method and its correlation coefficient r –value was 0.83(Ulceration), 0.82 (Erythema), 0.85(pain), 0.79(Ability to swallow). These correlation coefficients are very high and it is good tool to evaluate the effectiveness of Apitherapy in Reducing Oral Mucositis among Head and Neck Cancer Patients Undergoing Radiation Therapy at Rajiv Gandhi Government General Hospital, Chennai.

3.14. Data collection procedure

The investigator obtained permission from the Professor and Head of the Department, Department of Radiation Oncology, Rajiv Gandhi Government General Hospital, Chennai. Rapport was established after a brief introduction about the study and its purpose. Informed consent was obtained from each study participant after giving full information about the study. Anonymity was assured to each participant.

Patients with head and neck cancer who undergo 2nd phase of radiation therapy were selected. Collection of demographic data, clinical variables and assessment of severity of oral mucositis among study participants using NCI-CTC scale. Allocation of samples by simple random sampling (lottery method) to experimental group and control group.

Administration of apitherapy to experimental group for 14days (20ml of honey to swish for 5 minutes, 15 minutes before and after radiation therapy) and routine care to control group. In both group post assessment done at the end of the 3rd phase (on 14th day) by using NCI-CTC scale.

The assessment included examining the oral cavity for, ulceration, erythema, pain and ability to swallow. The investigator followed all ethical principles for collecting the data. The investigator spent 10 to 15 minutes per patient in doing data collection.

3.15. Data entry and analysis

Data were collected and analyzed by using descriptive statistics and inferential statistics.

Descriptive Statistics

- Frequency and Percentage to describe the demographic data and clinical variables of head and neck cancer patients undergoing radiation therapy.

Inferential statistics

- Chi – square test to assess and compare the effectiveness of Apitherapy in reducing oral mucositis.
- Chi – square test to find the association of degree of oral mucositis among head and neck cancer patients undergoing radiation therapy with their selected demographic variables.

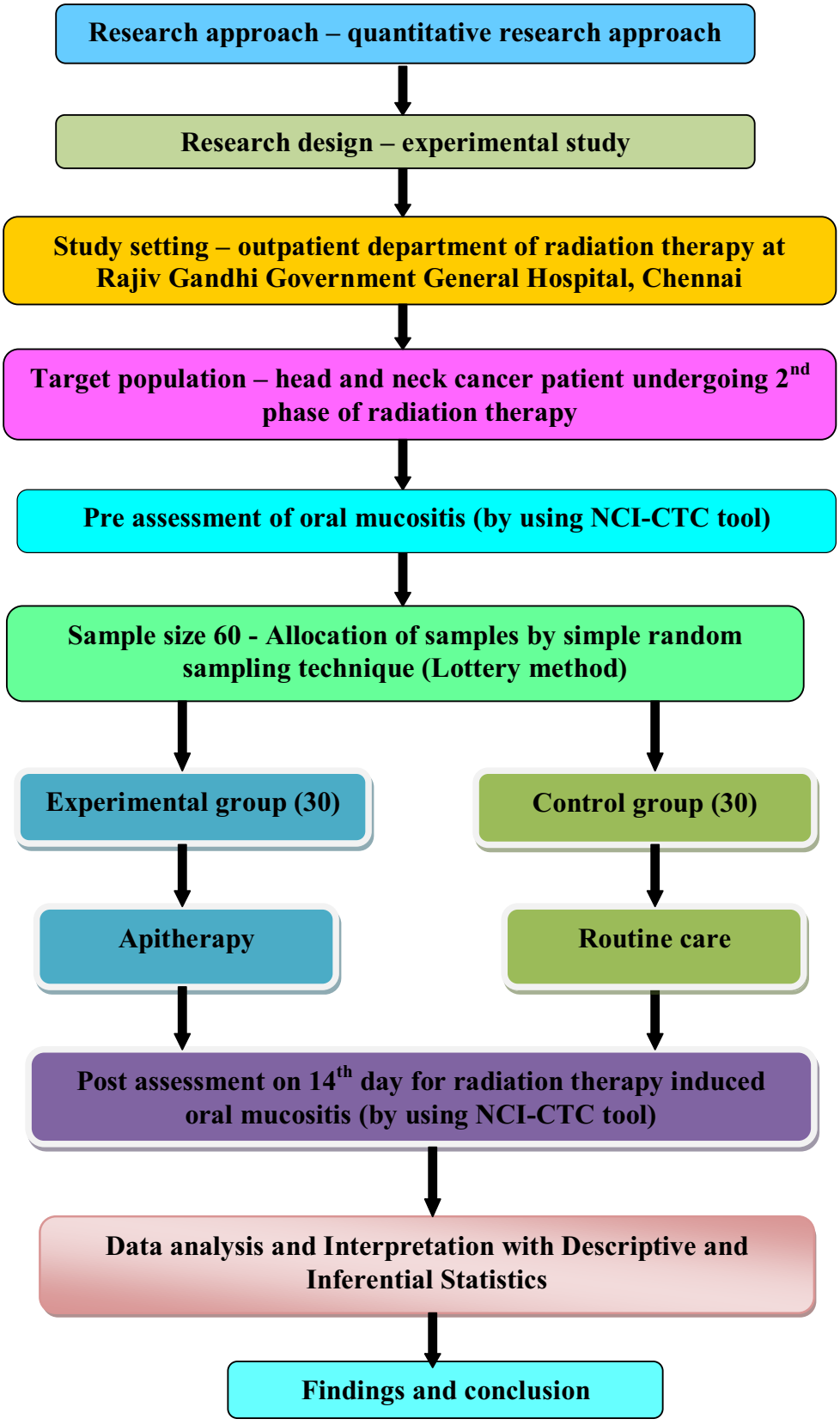


Figure 3.1. Schematic representation of the research study

CHAPTER-IV

DATA ANALYSIS AND INTERPRETATION

"All great truths are simple in final analysis and easily understood: if they are not, they are not great truths"

-Napoleon Hill

This chapter explains the statistical analysis performed in the collected data. Analysis is a method for rending quantitative, meaningful and providing intelligible information. So that the research problem can be studied and tested the relationship between the variables.

Descriptive and inferential statistics were used for analysis of data according the objectives of the study.

ORGANIZATION OF DATA

Section-A: Distribution of Demographic variables of experimental group and control group

Section-B: Assess for oral mucositis of the patients with head and neck cancer of both experimental and control group.

Section-C: Assess effectiveness of apitherapy for the patients with head and neck cancer of experimental group.

Section-D: Compare the pre test and post test level of oral mucositis among head and neck cancer patients in experimental group and control group.

Section-E: Association between post test level of oral mucositis among head and neck cancer patients with selected demographic variables.

Section - A: Distribution of demographical data and clinical variables

Table 4.1 Distribution of demographical data and clinical variables of head and neck cancer patients undergoing radiation therapy

N = 60

S.No	Demographic variables & Clinical variables		Experimental group		Control group		Chi square test
			f	%	f	%	
1.	Age	21 -35 years	3	10.0	4	13.3	χ=0.63 p=0.73
		36 -50 years	12	40.0	14	46.7	
		51 -65 years	15	50.0	12	40.0	
2.	Sex	Male	25	83.3	24	80.0	χ=0.11 p=0.73
		Female	5	16.7	6	20.0	
3.	Religion	Hindu	26	86.7	25	83.3	χ=0.35 p=0.84
		Christian	3	10.0	3	10.0	
		Muslim	1	3.3	2	6.7	
4.	Educational qualification	No formal education	5	16.7	5	16.7	χ=0.44 p=0.93
		Upto Primary level	17	56.7	19	63.3	
		Upto middle school level	7	23.3	5	16.7	
		Higher secondary level	1	3.3	1	3.3	
5.	Income per month	< Rs.5,000	8	26.7	13	43.3	χ=1.90 p=0.38
		Rs.5,001 - 10,000	20	66.6	15	50.0	
		Rs.10,001 - 15,000	2	6.7	2	6.7	
6.	Personal habits	Smoking	3	10.0	5	16.7	χ=2.56 p=0.63
		Alcohol	1	3.3	2	6.7	
		Smoking and alcohol	17	56.7	11	36.6	
		Other tobacco products	4	13.3	5	16.7	
		No habit of tobacco or alcohol abuse	5	16.7	7	23.3	
7.	Family history of cancer	Yes	1	3.3	2	6.7	χ=0.35 p=0.55
		No	29	96.7	28	93.3	
8.	Duration of illness	0 - 3 months	23	76.6	18	60.0	χ=2.27 p=0.32
		4 - 6 months	5	16.7	10	33.3	
		>12 months	2	6.7	2	6.7	
9.	Duration of treatment	0 -1 months	26	86.7	25	83.3	χ=0.13 p=0.71
		1 - 6 months	4	13.3	5	16.7	

* **Significant** at **$p \leq 0.05$**

** **Highly significant at $p \leq 0.001$**

*** **Very highly significant at $p \leq 0.0001$**

Table 4.1 shows demographical data and clinical variables of head and neck cancer patients with oral mucositis who participated in the study.

Regarding **age**,

Majority of the subjects were between 51-65 years of age in experimental group (50%) and control group (40%).

Regarding **gender**,

Males were majority (83.3%) in experimental group and control group (80%).

Regarding **religion**,

Hindus were majority affected in both experimental group (86.7%) and control group (83.3%).

Regarding **educational status**,

Majority were primary school (56.7%) in experimental group and (63.3%) in control group.

Regarding **family monthly income,**

Majority were earning (Rs.5001-1000), in experimental group (66.6%) and control group (50%).

Regarding **personal habits**,

Majority were alcoholic and smoking in experimental group (56.7%) and in control group (36.6%).

According **family history of cancer,** majority does not have family history of cancer, in experimental group (96.7%) and control group (93.3%).

According to **duration of illness** majority were 0-3 months in experimental group (76.6%) and in control group (60%).

According to **duration of treatment** majority are 0-1 month in experimental group (86.7%) and in control group (83.3%).

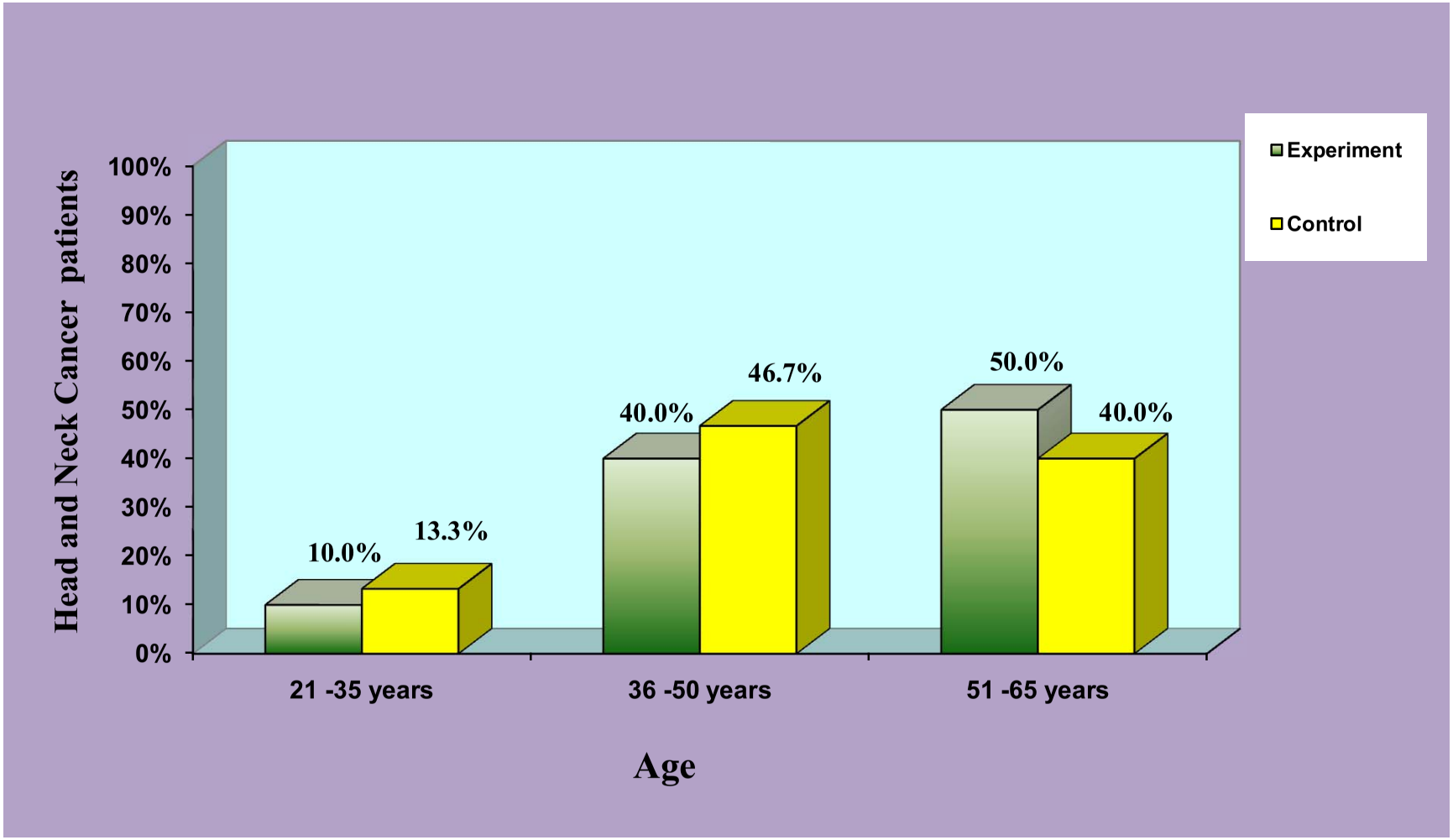


Figure 4.1 Age wise distribution of head and neck cancer patients

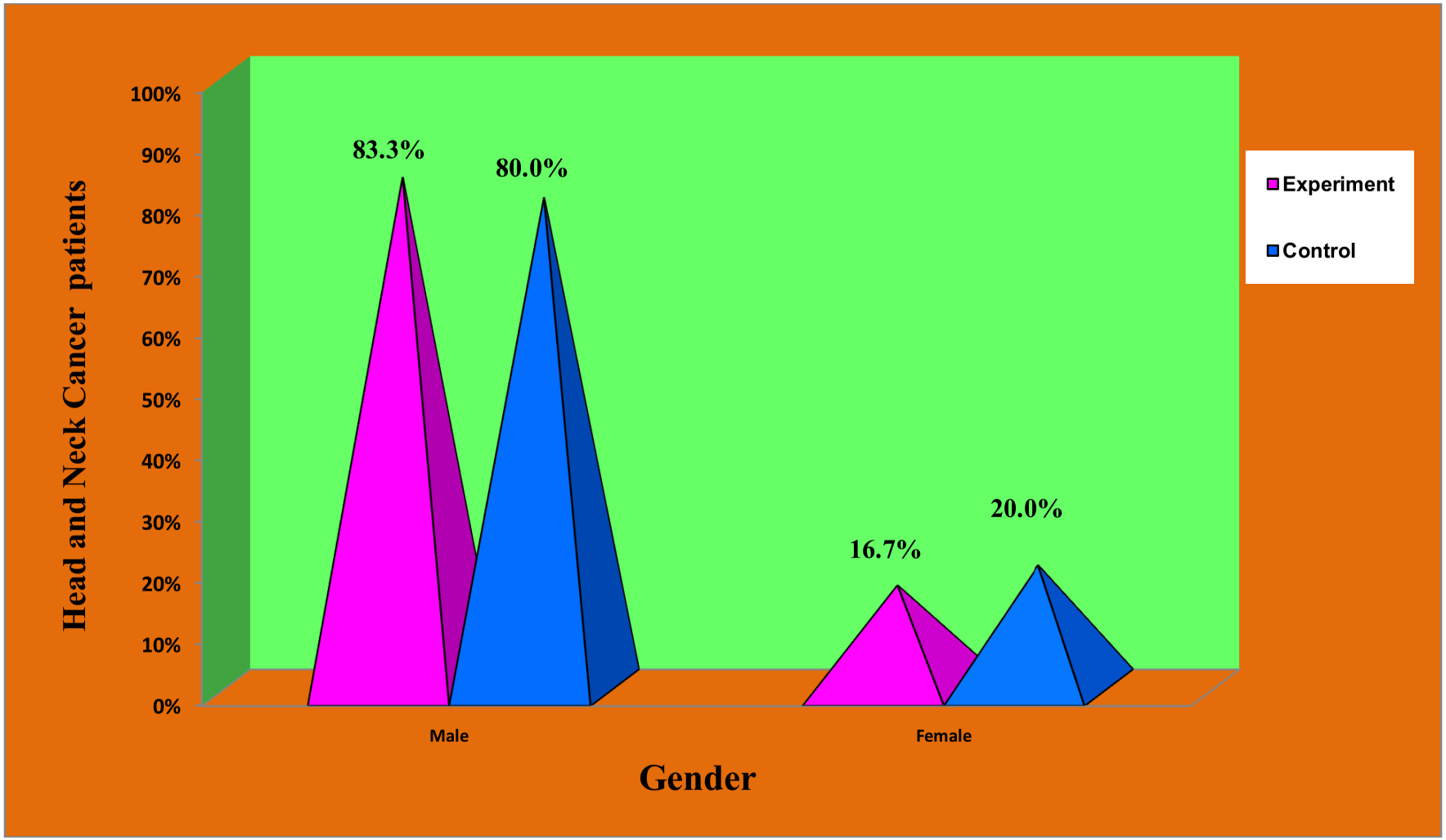


Figure 4.2 Gender wise distribution of head and neck cancer patients

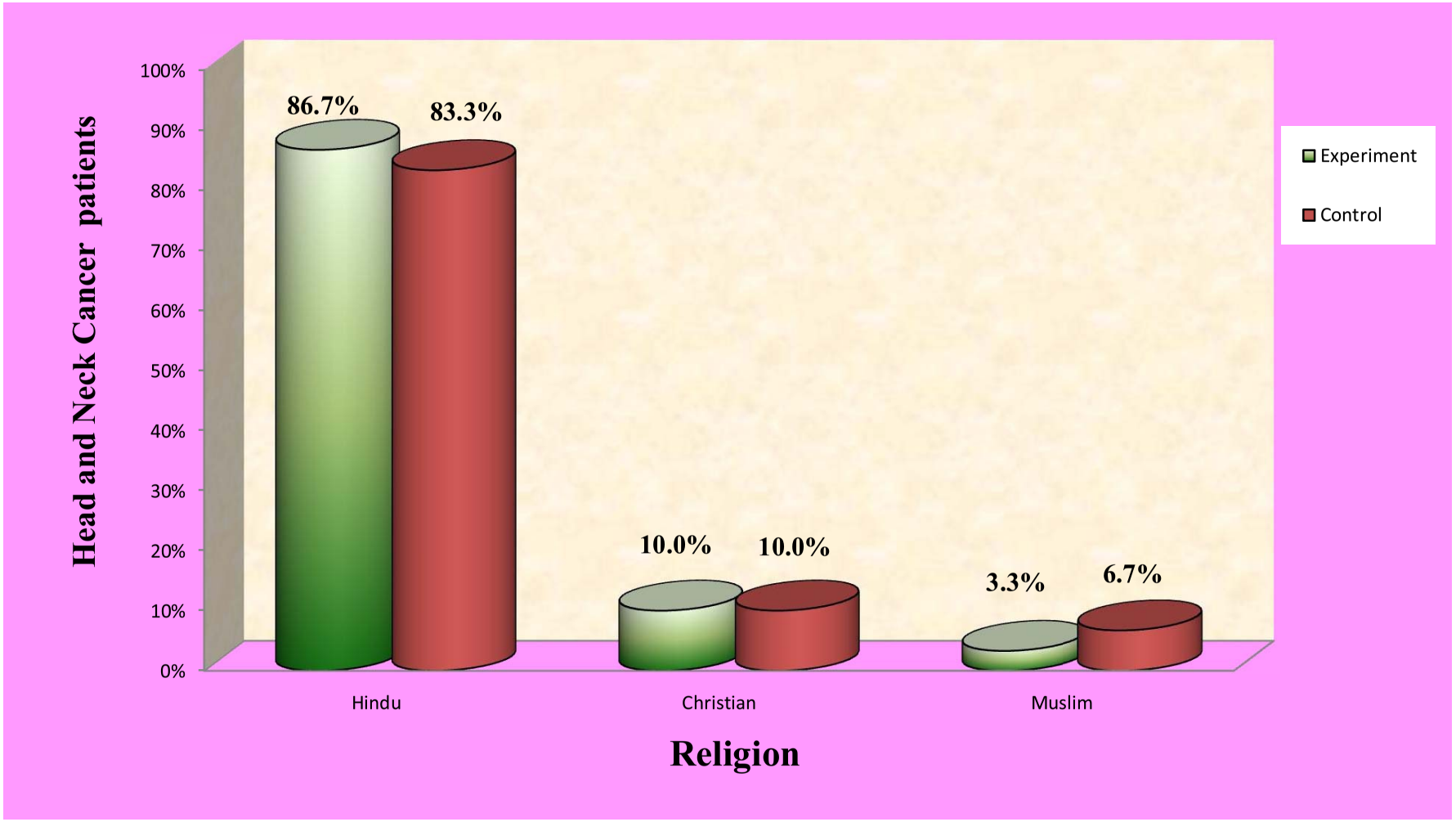


Figure 4.3 Religion wise distribution of head and neck cancer patients

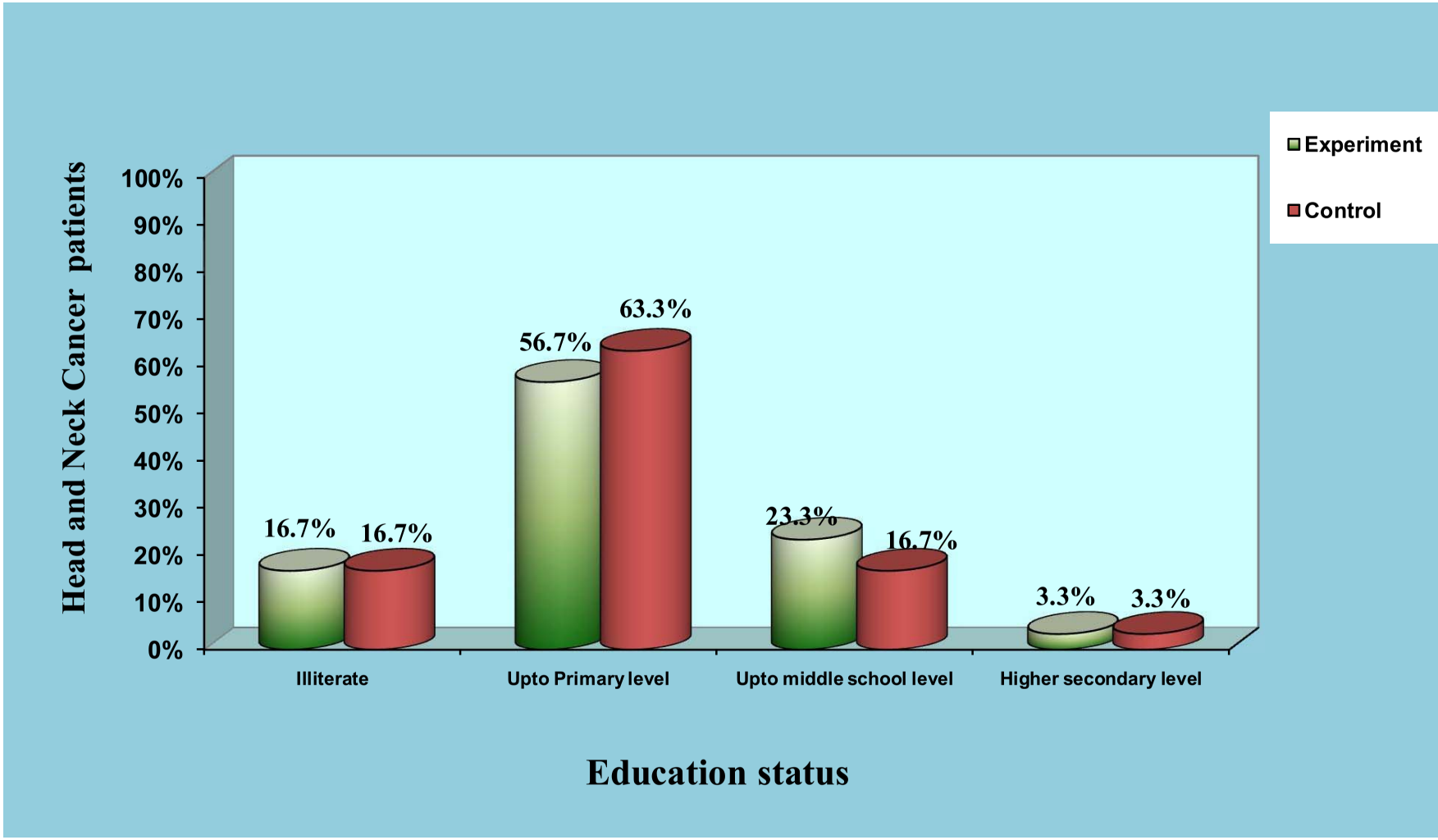


Figure 4.4 Educational status wise distribution of head and neck cancer patients

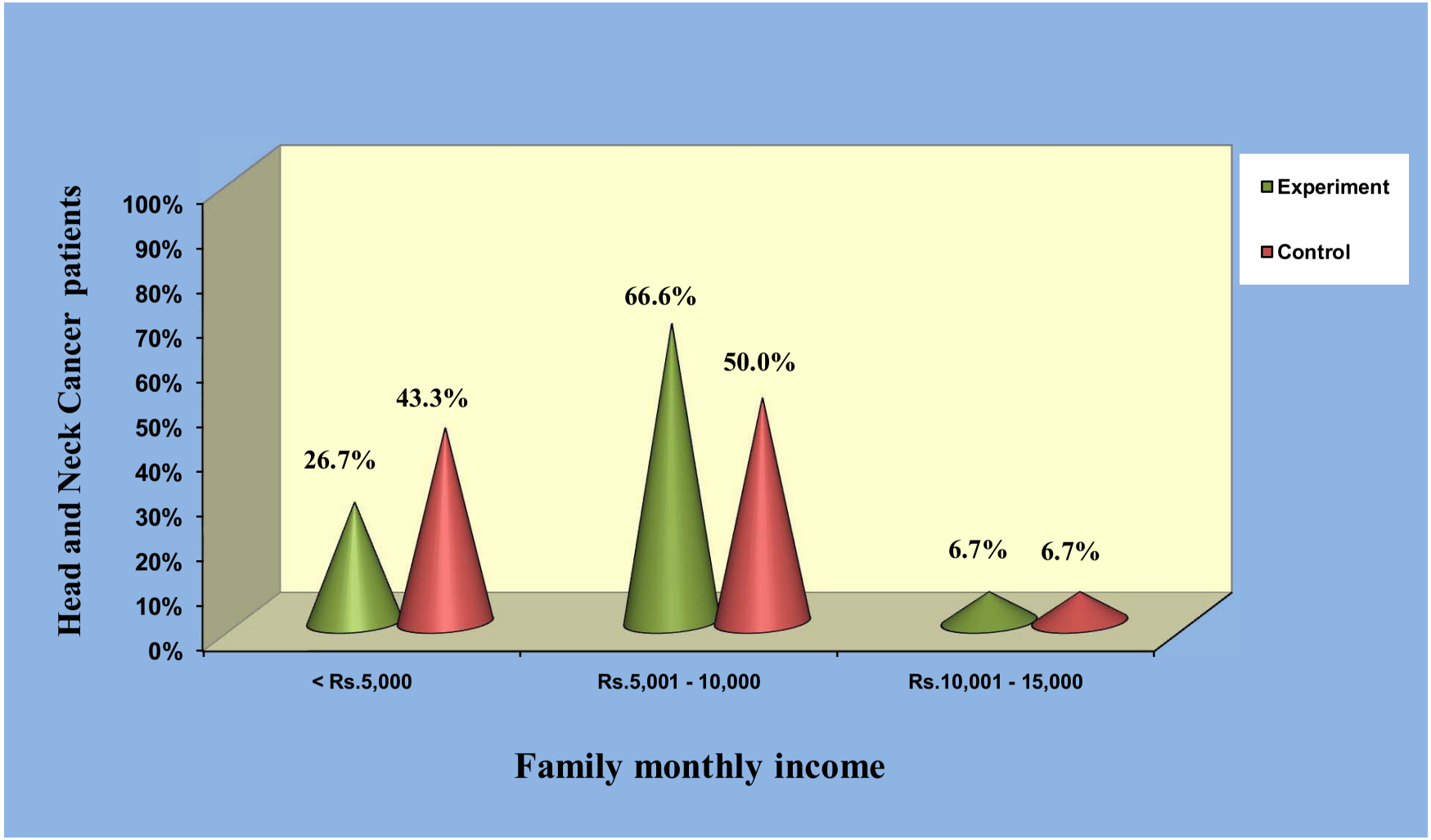


Figure 4.5 Family monthly income wise distribution of head and neck cancer patients

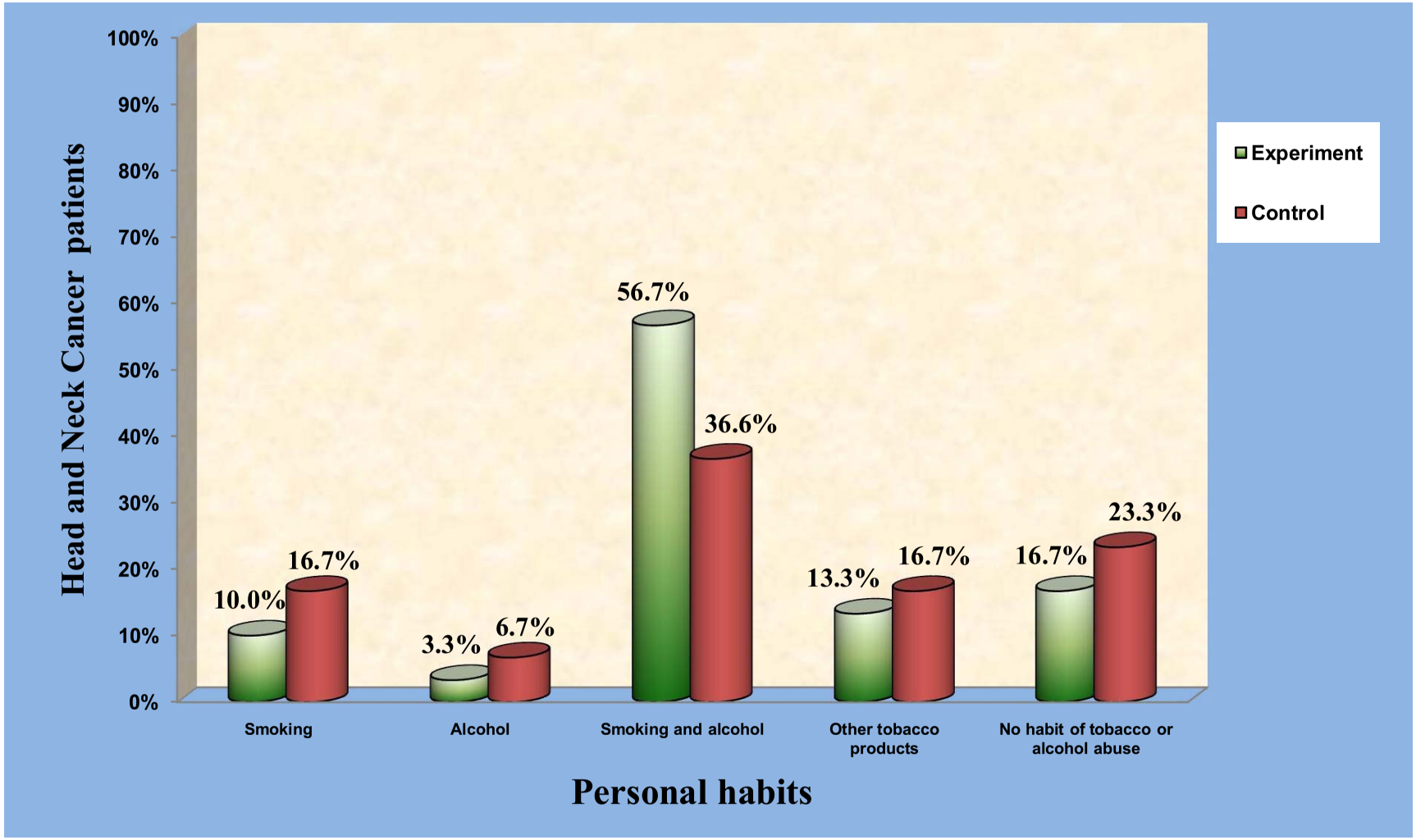


Figure 4.6 Personal habits wise distribution of head and neck cancer patients

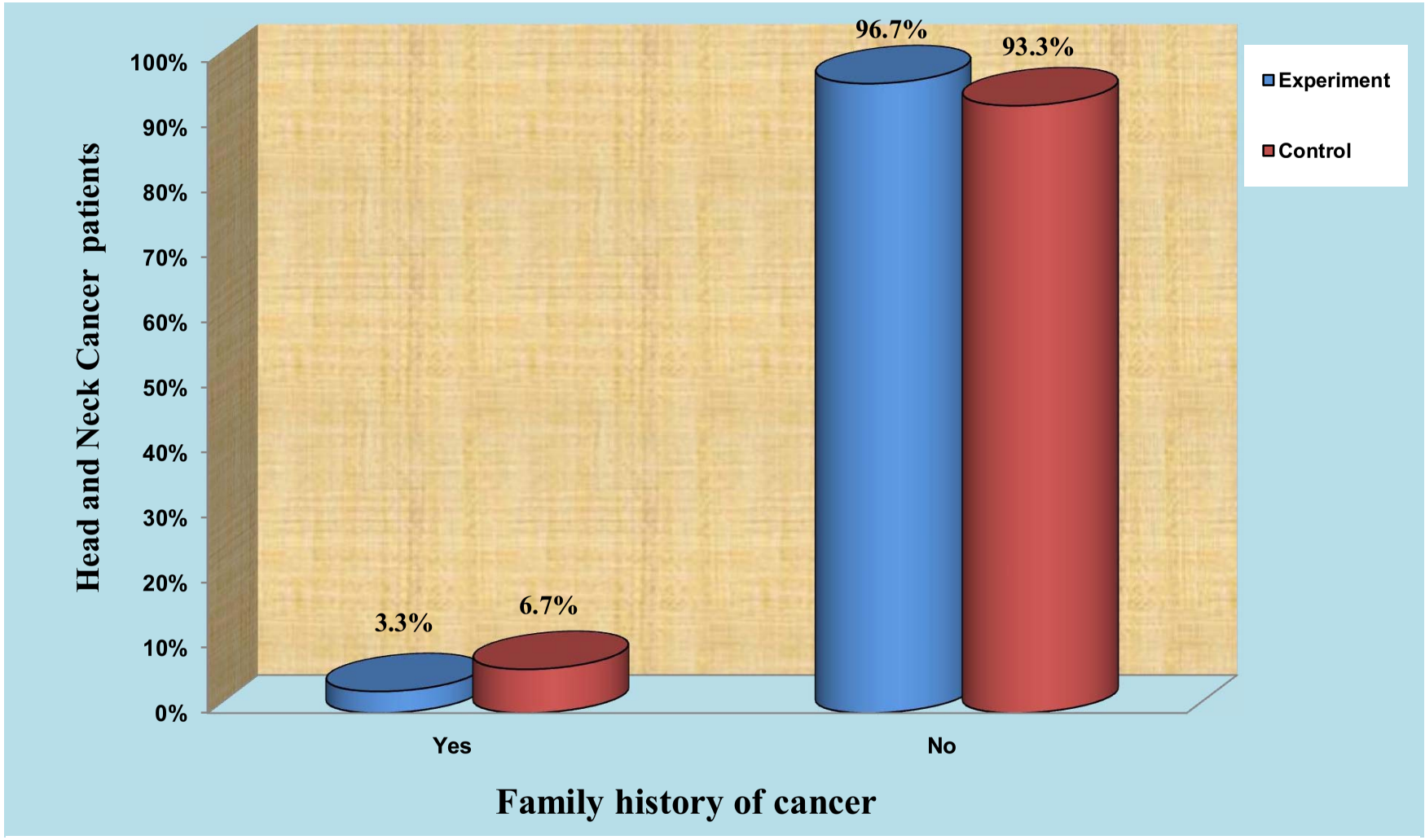


Figure 4.7 Family history of cancer among head and neck cancer patients

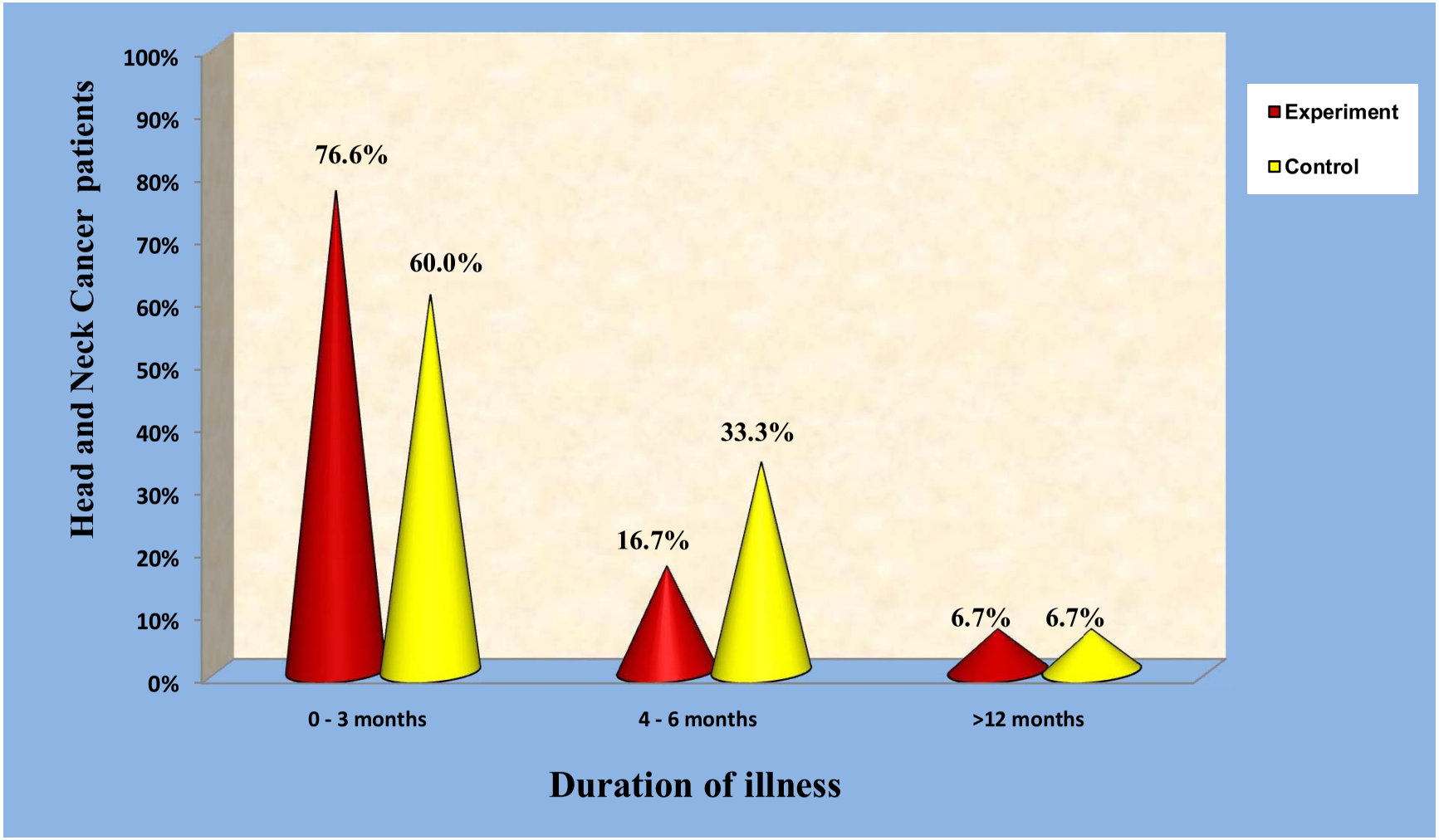


Figure 4.8 Duration of illness of head and neck cancer patients

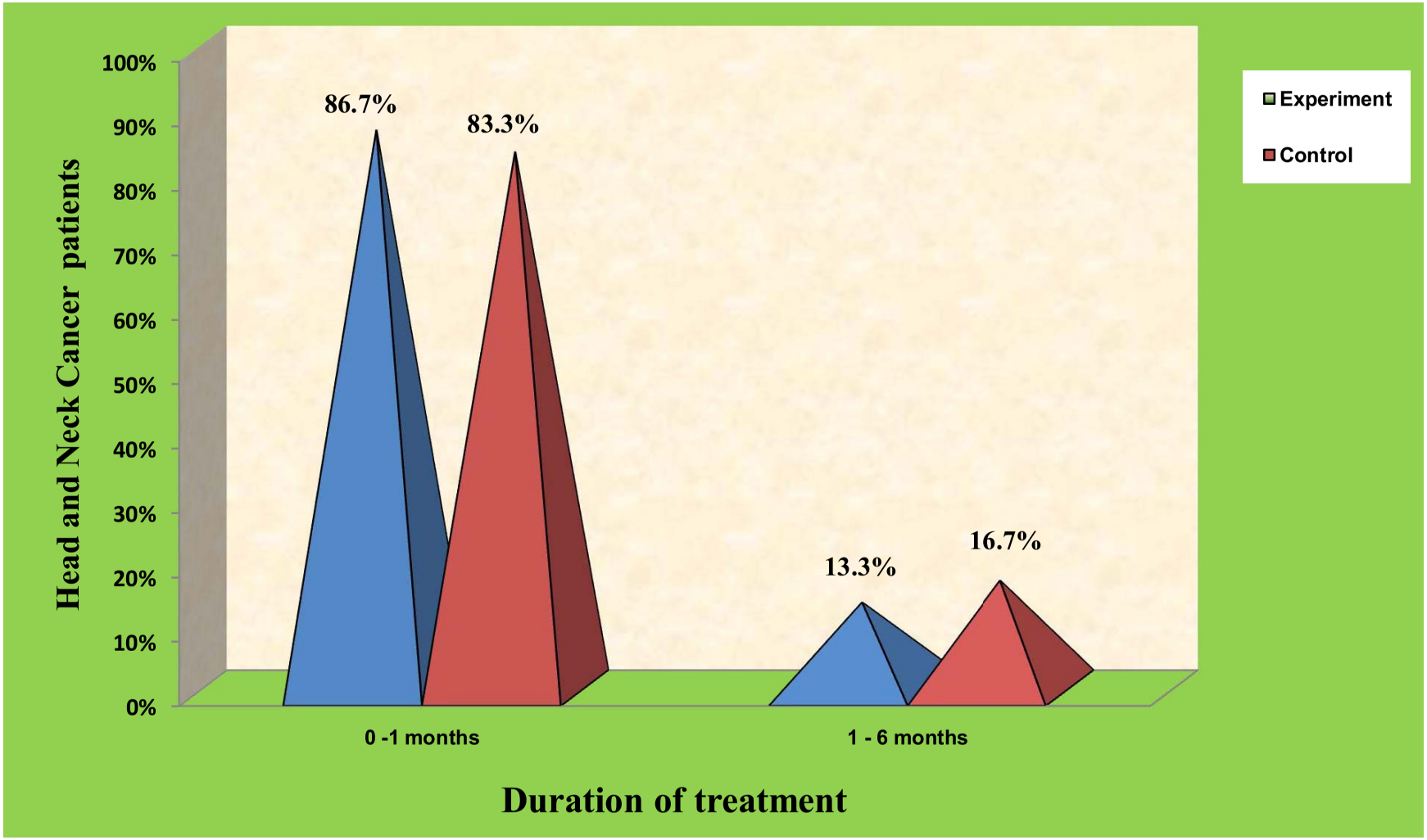


Figure 4.9 Duration of treatment wise distribution of head and neck cancer

Section-B: Assess for oral mucositis of the patients with head and neck cancer of both experimental and control group.

Table 4.2 Pre test level of oral mucositis (ulceration, erythema, pain and ability to swallow)

S.No	Items of oral mucositis	Experimental group		Control group		Chi square test
		f	%	f	%	
1.	**Ulceration**					
	No lesion	1	3.3	2	6.7	$\chi 2=1.36$ p=0.71
	Mild	9	30.0	9	30.0	
	Moderate	17	56.7	18	60.0	
	Severe	3	10.0	1	3.3	
	Total	**30**	**100.0**	**30**	**100.0**	
2	**Erythema**					$\chi 2=1.01$ p=0.80
	No lesion	1	3.3	2	6.7	
	Mild	8	26.7	10	33.3	
	Moderate	19	63.3	17	56.7	
	Severe	2	6.7	1	3.3	
	Total	**30**	**100.0**	**30**	**100.0**	
3.	**Pain**					$\chi 2=2.53$ p=0.28
	No pain	0	0.0	0	0.0	
	Mild	13	43.3	17	56.6	
	Moderate	11	36.7	11	36.7	
	Severe	6	20.0	2	6.7	
	Total	**30**	**100.0**	**30**	**100.0**	
4.	**Ability to swallow**					$\chi 2=1.51$ p=0.46
	Able to swallow foods without pain	3	10.0	2	6.7	
	Able to swallow with pain	22	73.3	25	83.3	
	Requires intravenous rehydration	5	16.7	3	10.0	
	Total	**30**	**100.0**	**30**	**100.0**	

* **Significant** at **$p \leq 0.05$**

** **Highly significant at $p \leq 0.001$**

*** **Very highly significant at $p \leq 0.0001$**

Table 4.2 shows that prevalence of ulceration, erythema, pain and ability to swallow in oral mucositis was equally distributed in both experimental group and control group.

In **ulceration** - Among experimental group (30 patients), 1(3.3%) did not have any lesion, 9(30.0%) had mild score, 17(56.7%) had moderate score and 3(10.0%) had severe ulceration score. Among control group (30 patients), 2(6.7%) did not have any lesion, 9(30.0%) had mild score, 18(60.0%) had moderate score and 1(3.3%) had severe ulceration score.

In **Erythema** - Among experimental group (30 patients), 1(3.3%) patients did not have any lesion, 8(26.7%) had mild score, 19(63.3%) had moderate score and 2(6.7%) had severe erythema score. Among control group, 2(6.7%) did not have any lesion, 10(33.3%) had mild score, 17(56.7%) had moderate score and 1(3.3%) had severe Erythema score.

In **pain** - Among experimental group, 13(43.3%) patients had mild score, 11(36.7%) had moderate score and 6(20.0%) had severe pain score. Among control group, 17(56.7%) had mild score, 11(36.7%) had moderate score and 2(6.7%) had severe pain score.

In **ability to swallow -** Among experimental group, 3(10.0%) patients were able to swallow foods without pain, 22(73.3%) were able to swallow with pain, and 5(16.7%) were requiring intravenous rehydration. Among control group, 2(6.7%) were able to swallow foods without pain, 25(83.3%) were able to swallow with pain, and 3(10.0%) were requiring intravenous rehydration.

Section-C: Assess effectiveness of apitherapy for the patients with head and neck cancer of experimental group.

Table 4.3 Post test level of oral mucositis (ulceration, erythema, pain and ability to swallow)

S.No	Items of oral mucositis	Experimental group		Control group		Chi square test
		f	%	f	%	
1.	**Ulceration**					**$\chi 2=8.16$ p=0.02***
	No lesion	9	30.0	3	10.0	
	Mild	15	50.0	11	36.7	
	Moderate	6	20.0	16	53.3	
	Severe	0	0.0	0	0.0	
	Total	**30**	**100.0**	**30**	**100.0**	
2.	**Erythema**					**$\chi 2=16.52$ p=0.001*** **
	No lesion	13	43.3	3	10.0	
	Mild	15	50.0	12	40.0	
	Moderate	2	6.7	15	50.0	
	Severe	0	0.0	0	0.0	
	Total	**30**	**100.0**	**30**	**100.0**	
3.	**Pain**					**$\chi 2=15.94$ p=0.001*** **
	No pain	17	56.7	3	10.0	
	Mild	11	36.7	18	60.0	
	Moderate	2	6.7	9	30.0	
	Severe	0	0.0	0	0.0	
	Total	**30**	**100.0**	**30**	**100.0**	
4.	**Ability to swallow**					**$\chi 2=13.49$ p=0.001*** **
	Able to swallow without pain	16	53.3	3	10.0	
	Able to swallow with pain	14	46.7	26	86.7	
	Requires intravenous rehydration	0	0.0	1	3.3	
	Total	**30**	**100.0**	**30**	**100.0**	

* **Significant** at **$p \leq 0.05$**

** **Highly significant at $p \leq 0.001$**

*** **Very highly significant at $p \leq 0.0001$**

Table 4.3 shows effectiveness of apitherapy by comparing the post test level of oral mucositis among experimental group and control group.

In **Ulceration -** Among experimental group, 9(30.0%) patients did not have any lesion, 15(50.0%) had mild score, and 6(20.0%) had moderate score. Among control group, 3(10.0%) did not have any lesion, 11(36.7%) had mild score, and 16(53.3%) had moderate score.

In **Erythema** - among experimental group, 13(43.3%) patients did not have any lesion, 15(50.0%) had mild score, and 2(6.7%) had moderate score. Among control, 3(10.0%) did not have any lesion, 12(40.0%) had mild score, and 15(50.0%) had moderate score.

In **Pain -** among experimental, 17(56.7%) patients did not have any pain, 11(36.7%) had mild pain score, and 2(6.6%) had moderate pain score. Among control group, 3(10%) did not have any pain, 18(60.0%) had mild pain score, and 9(30.0%) had moderate score.

In **Ability to swallow -** among experimental group, 16(53.3%) were able to swallow foods without pain, 14(46.7%0 were able to swallow with pain. Among control group, 3(10%) were able to swallow foods without pain, 26(86.7%) were able to swallow with pain, and 1(3.3%) were requiring intravenous rehydration.

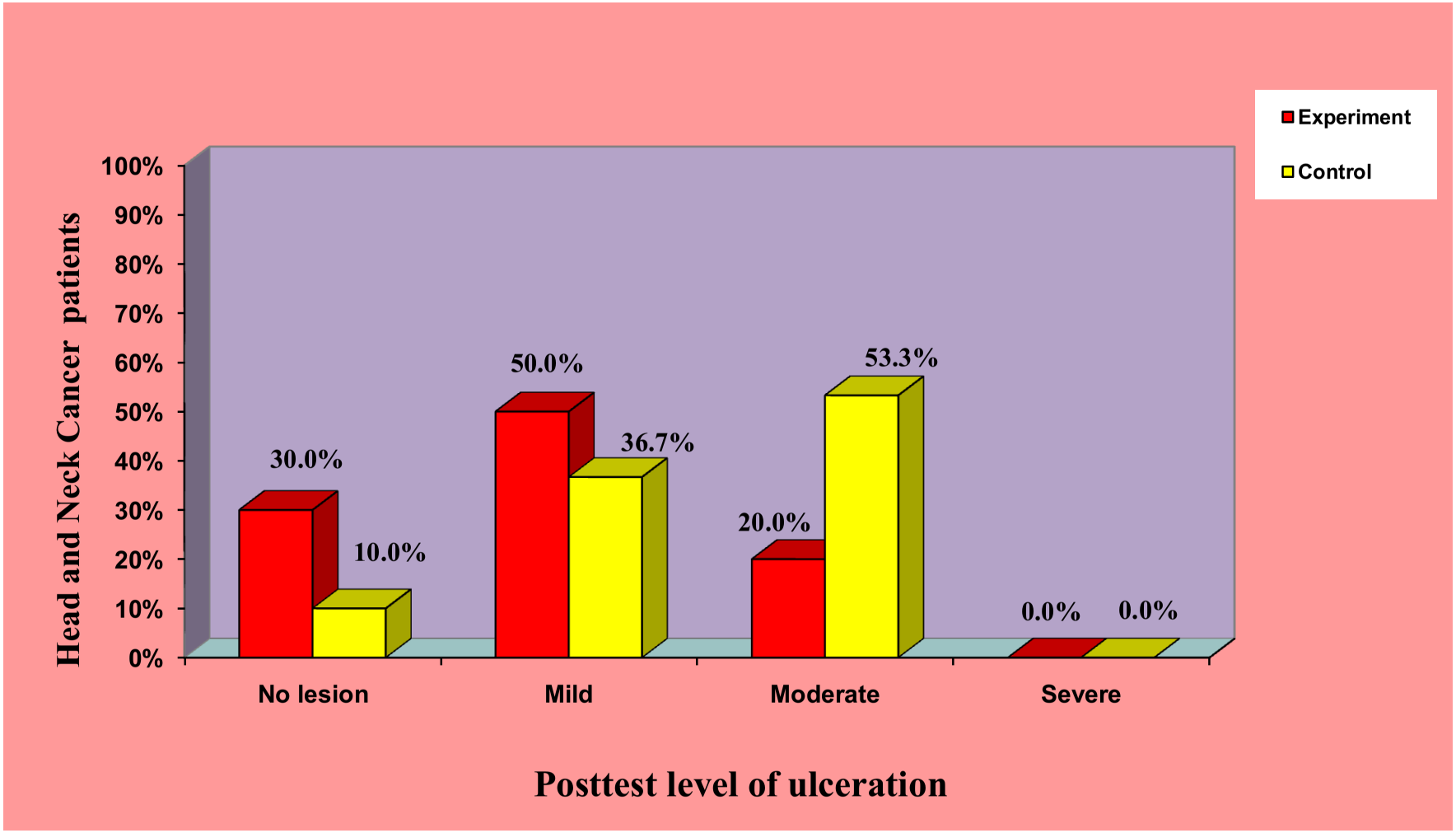


Figure 4.10 Comparison of post test level of ulceration of head and neck cancer patients

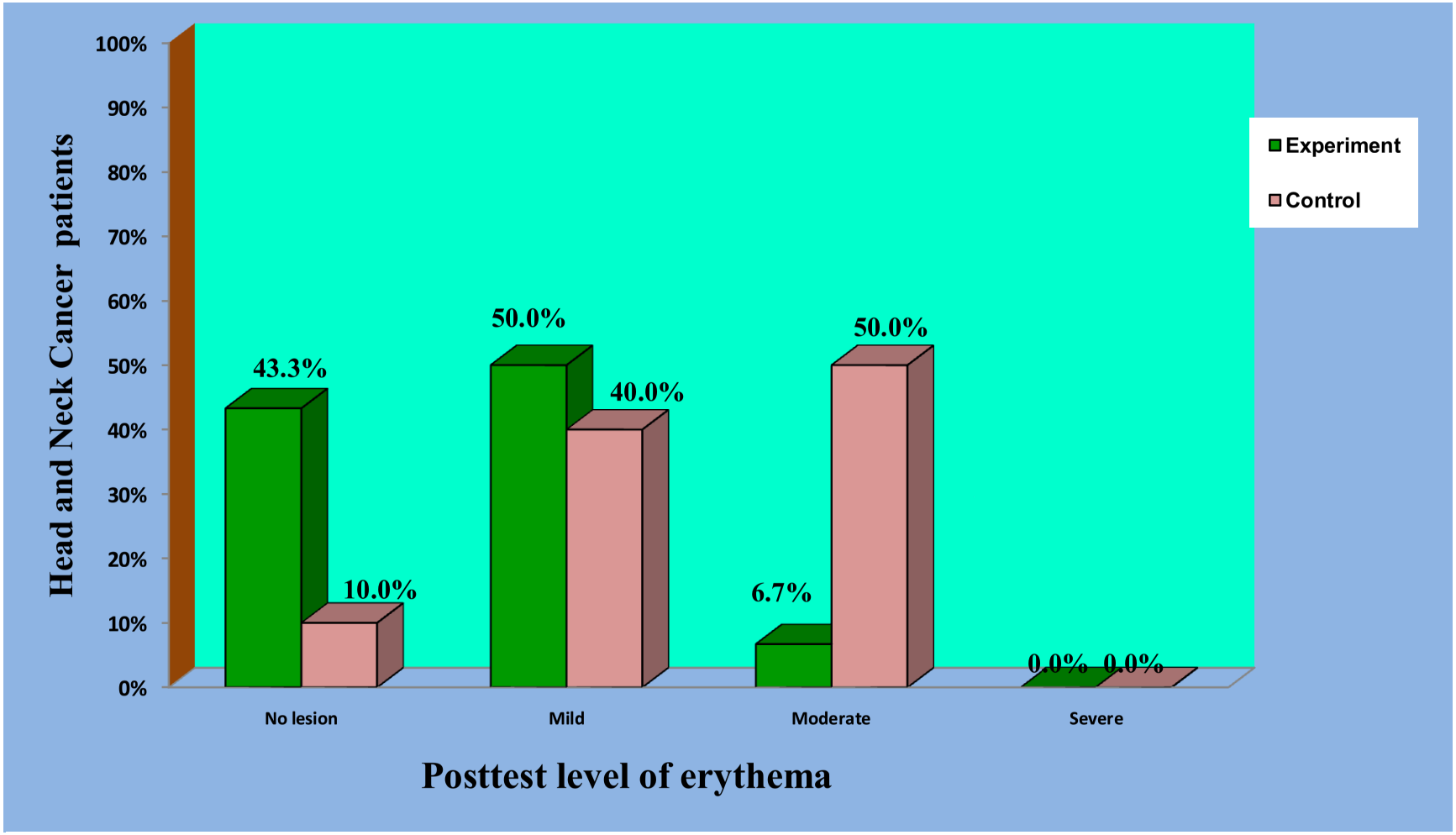


Fig4.11 Comparison of post test level of erythema of head and neck cancer patients

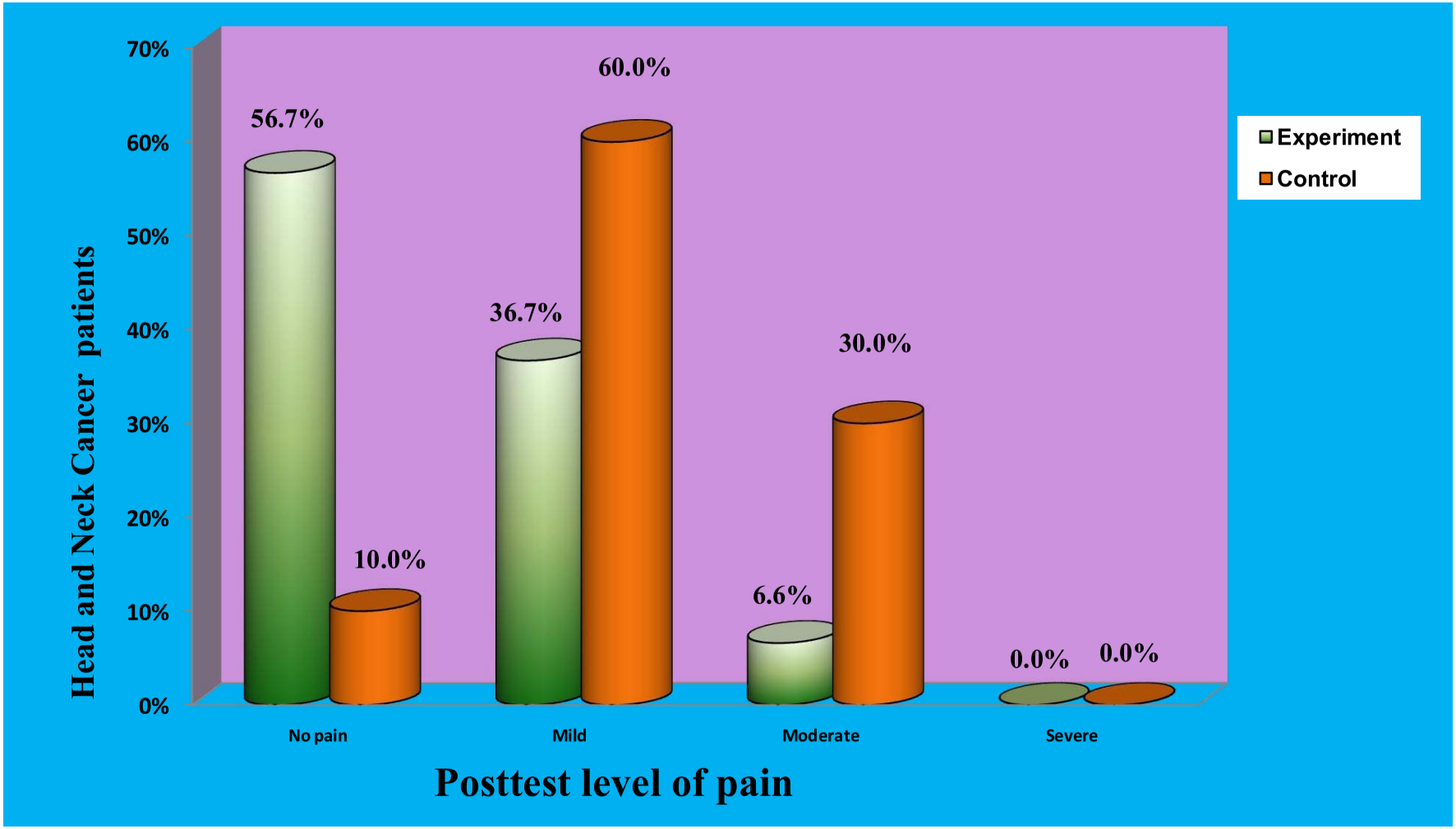


Figure 4.12 Comparison of post test level of pain of head and neck cancer patients

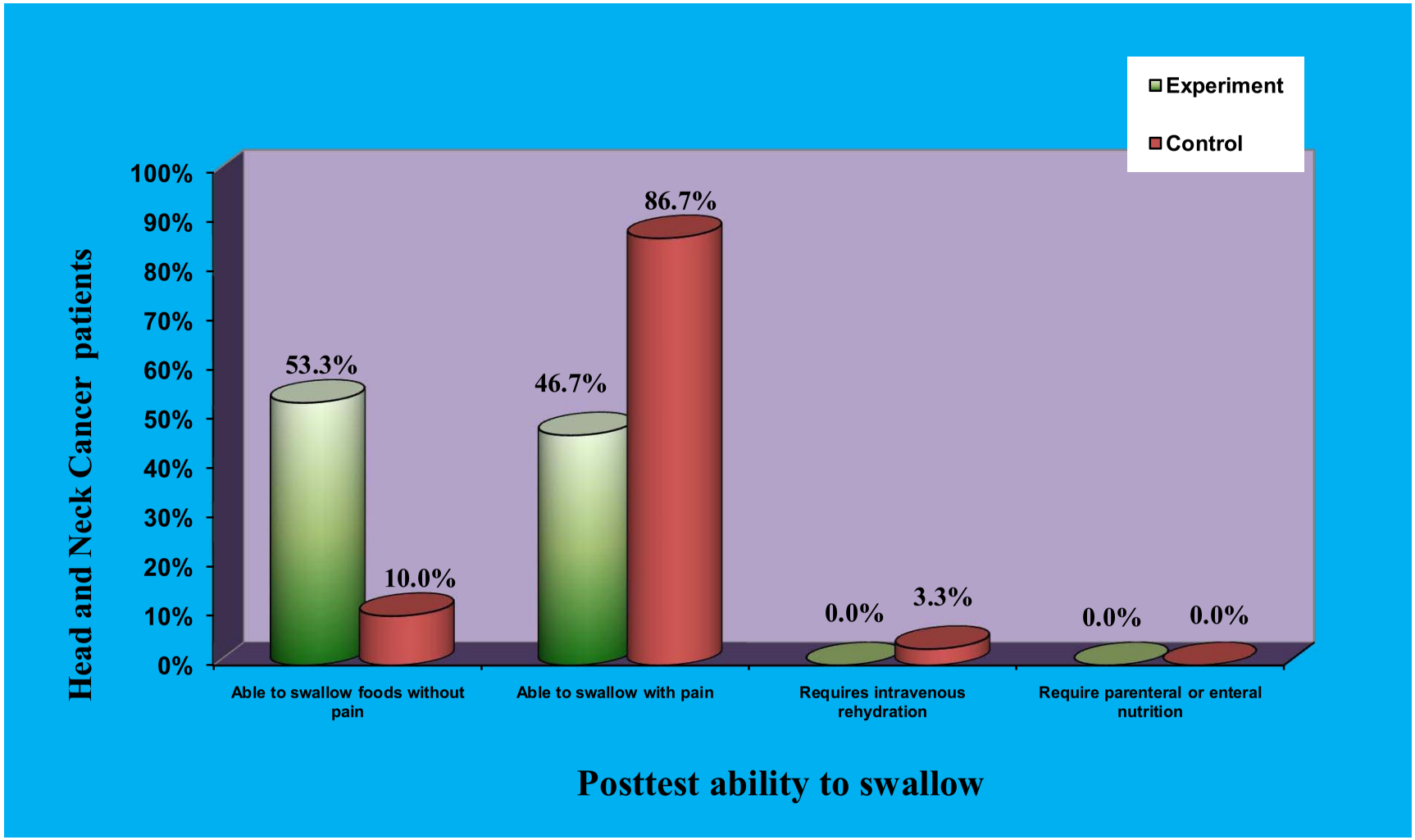


Figure 4.13 Comparison of post test ability to swallow of head and neck cancer patients

Section-D: Compare the pre test and post test level of oral mucositis among head and neck cancer patients in experimental group and control group.

Table 4.4 Pre test and post test level of oral mucositis (ulceration, erythema, pain and ability to swallow) in experimental group

S.No	Items of oral mucositis	Pre test		Post test		Chi square test
		f	%	f	%	
1.	**Ulceration**					**χ^2=16.16 p=0.001****
	No lesion	1	3.3	9	30.0	
	Mild	9	30.0	15	50.0	
	Moderate	17	56.7	6	20.0	
	Severe	3	10.0	0	0.0	
	Total	**30**	**100.0**	**30**	**100.0**	
2.	**Erythema**					**χ^2=28.17 p=0.001*****
	No lesion	1	3.3	13	43.3	
	Mild	8	26.7	15	50.0	
	Moderate	19	63.3	2	6.7	
	Severe	2	6.7	0	0.0	
	Total	**30**	**100.0**	**30**	**100.0**	
3.	**Pain**					**χ^2=29.39 p=0.001*****
	No pain	0	0.0	17	56.7	
	Mild	13	43.3	11	36.7	
	Moderate	11	36.7	2	6.6	
	Severe	6	20.0	0	0.0	
	Total	**30**	**100.0**	**30**	**100.0**	
4.	**Ability to swallow**					**χ^2=15.67 p=0.001*****
	Able to swallow without pain	3	10.0	16	53.3	
	Able to swallow with pain	22	73.3	14	46.7	
	Requires intravenous rehydration	5	16.7	0	0.0	
	Total	**30**	**100.0**	**30**	**100.0**	

*** Significant $p \leq 0.01$**

**** Highly significant $p \leq 0.001$**

***** Very highly significant $p \leq 0.001$**

Table 4.4 shows level of oral mucositis among patients in experimental group before and after apitherapy

In experimental group (30 patients),

On assessing pre test level of ulceration, 1(3.3%) did not have any lesion, 9(30.0%) had mild score, 17(56.7%) had moderate score and 3(10.0%) had severe ulceration score. In post test level of ulceration, 9(30.0%) did not have any lesion, 15(50.0%) had mild score, 6(20.0%) had moderate score. Hence post test level of **ulceration (p=0.001**)** was highly significant

In pre test level of erythema, 1(3.3%) did not have any lesion, 8(26.7%) had mild score, 19(63.3%) had moderate score and 2(6.7%) had severe erythema score. In post test level of erythema, 13(43.3%) did not have any lesion, 15(50.0%) had mild score, 2(6.7%) had moderate score. Hence post test level of **erythema (p=0.001***)** was very highly significant.

In pre test level of pain, 13(43.3%) had mild score, 11(36.7%) had moderate score and 6(20.0%) had severe pain score. In post test level of pain, 17(56.7%) did not have any lesion, 11(36.7%) had mild score, 2(6.6%) had moderate score. Hence post test level of **pain (p=0.001***)** was very highly significant.

In pre test level of ability to swallow, 3(10.0%) were able to swallow foods without pain, 22(73.3%) were able to swallow with pain, and 5(16.7%) were requiring intravenous rehydration. In post test level of ability to swallow, 16(53.3%) were able to swallow foods without pain, 14(46.7%) were able to swallow with pain. Hence post test level of **ability to swallow (p=0.001***)** was very highly significant.

Table 4.5 Pre test and post test level of oral mucositis (ulceration, erythema, pain and ability to swallow) in control group

S.No	Items of oral mucositis	Pre test		Post test		Chi square test
		f	%	f	%	
1.	**Ulceration**					
	No lesion	2	6.7	3	10.0	
	Mild	9	30.0	11	36.7	$\chi 2=1.51$
	Moderate	18	60.0	16	53.3	$p=0.67$
	Severe	1	3.3	0	0.0	
	Total	**30**	**100.0**	**30**	**100.0**	
2.	**Erythema**					
	No lesion	2	6.7	3	10.0	
	Mild	10	33.3	12	40.0	$\chi 2=1.50$
	Moderate	17	56.7	15	50.0	$p=0.68$
	Severe	1	3.3	0	0.0	
	Total	**30**	**100.0**	**30**	**100.0**	
3.	**Pain**					
	No pain	0	0.0	3	10.0	
	Mild	17	56.6	18	60.0	$\chi 2=5.22$
	Moderate	11	36.7	9	30.0	$p=0.16$
	Severe	2	6.7	0	0.0	
	Total	**30**	**100.0**	**30**	**100.0**	
4.	**Ability to swallow**					
	Able to swallow foods without pain	2	6.7	3	10.0	
	Able to swallow with pain	25	83.3	26	86.7	$\chi 2=1.21$
	Requires intravenous rehydration	3	10.0	1	3.3	$p=0.52$
	Total	**30**	**100.0**	**30**	**100.0**	

* **Significant** at $\mathbf{p \leq 0.05}$

The above table represents the pre test and post test levels of oral mucositis among control group in which there was no significant change in ulceration, erythema, pain and ability to swallow.

Section-E: Association between post test level of oral mucositis among head and neck cancer patients with selected demographic variables.

Table 4.6 Association between post test level of ulceration and patients demographic variables (experimental group)

S.No	Demographic variables		Post test level of Ulceration						Total	Chi square test
			No lesion		Mild		Moderate			
			f	%	f	%	f	%		
1.	Age	21 -35 years	0	0.0	1	33.3	2	66.7	3	**χ2=10.53 p=0.03***
		36 -50 years	2	16.7	6	50.0	4	33.3	12	
		51 -65 years	7	46.7	8	53.3	0	0.0	15	
2.	Sex	Male	9	36.0	12	48.0	4	16.0	25	χ2=3.12 p=0.21
		Female	0	0	3	60.0	2	40.0	5	
3.	Religion	Hindu	9	34.6	12	46.2	5	19.2	26	χ2=7.26 p=0.12
		Christian	0	0	3	100	0	0	3	
		Muslim	0	0	0	00	1	100	1	
4.	Educational qualification	No formal education	1	20.0	3	60.0	1	20.0	5	χ2=2.63 p=0.25
		Upto Primary level	5	29.4	9	52.9	3	17.6	17	
		Upto middle school level	3	42.9	2	28.6	2	28.6	7	
		Higher secondary level	0	0	1	100	0	0	1	
5.	Income per month	< Rs.5,000	3	37.5	3	37.5	2	25.0	8	χ2=2.35 p=0.67
		Rs.5,001 - 10,000	6	30.0	11	55.0	3	15.0	20	
		Rs.10,001 - 15,000	0	0.0	1	50.0	1	50.0	2	
6.	Personal habits	Smoking	1	33.3	2	66.7	0	0.0	3	χ2=9.86 p=0.27
		Alcohol	0	0.0	1	100	0	0.0	1	
		Smoking and alcohol	8	47.1	7	41.2	2	11.8	17	
		Other tobacco products	0	0.0	2	50.0	2	50.0	4	
		No habit of tobacco or alcohol abuse	0	0.0	3	60.0	2	40.0	5	
7.	Family history of cancer	Yes	1	100	0	0.0	0	0.0	1	χ2=1.41 p=0.29
		No	8	27.6	15	51.7	6	20.7	29	
8.	Duration of illness	0 - 3 months	7	30.4	13	56.5	3	13.0	23	**χ2=10.62 p=0.03***
		4 - 6 months	2	40.0	2	40.0	1	20.0	5	
		>12 months	0	50.0	0	0.0	2	100	2	
9.	Duration of treatment	0 -1 months	9	34.6	13	50.0	4	15.4	26	χ2=3.46 p=0.18
		1 - 6 months	0	0.0	2	50.0	2	50.0	4	

*** Significant $p \leq 0.05$**

Table 4.6 shows the association between post test level of oral mucositis (ulceration) after apitherapy among head and neck cancer patients undergoing radiation therapy with selected demographic variables in experimental group.

Demographic variables - Elders and less duration of illness patients among experimental group have association with post test level of ulceration. Statistical significance was calculated using chi square test.

Gender, religion, educational qualification, income per month, personal habits, family history of cancer, and duration of treatment does not have significance with degree of oral mucositis (post test level of ulceration).

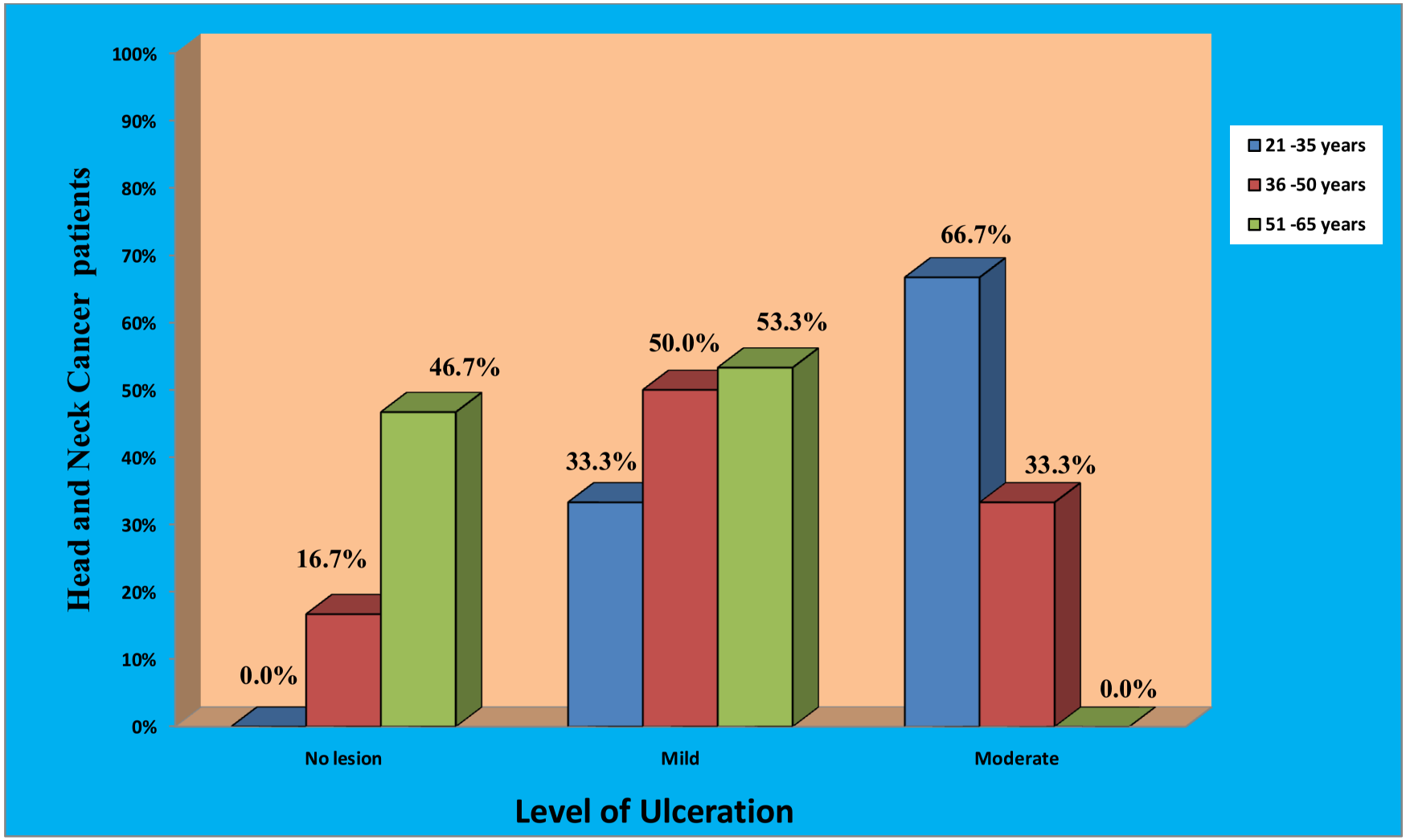


Figure 4.14 Association between post test level of Ulceration and patients' age (experimental group)

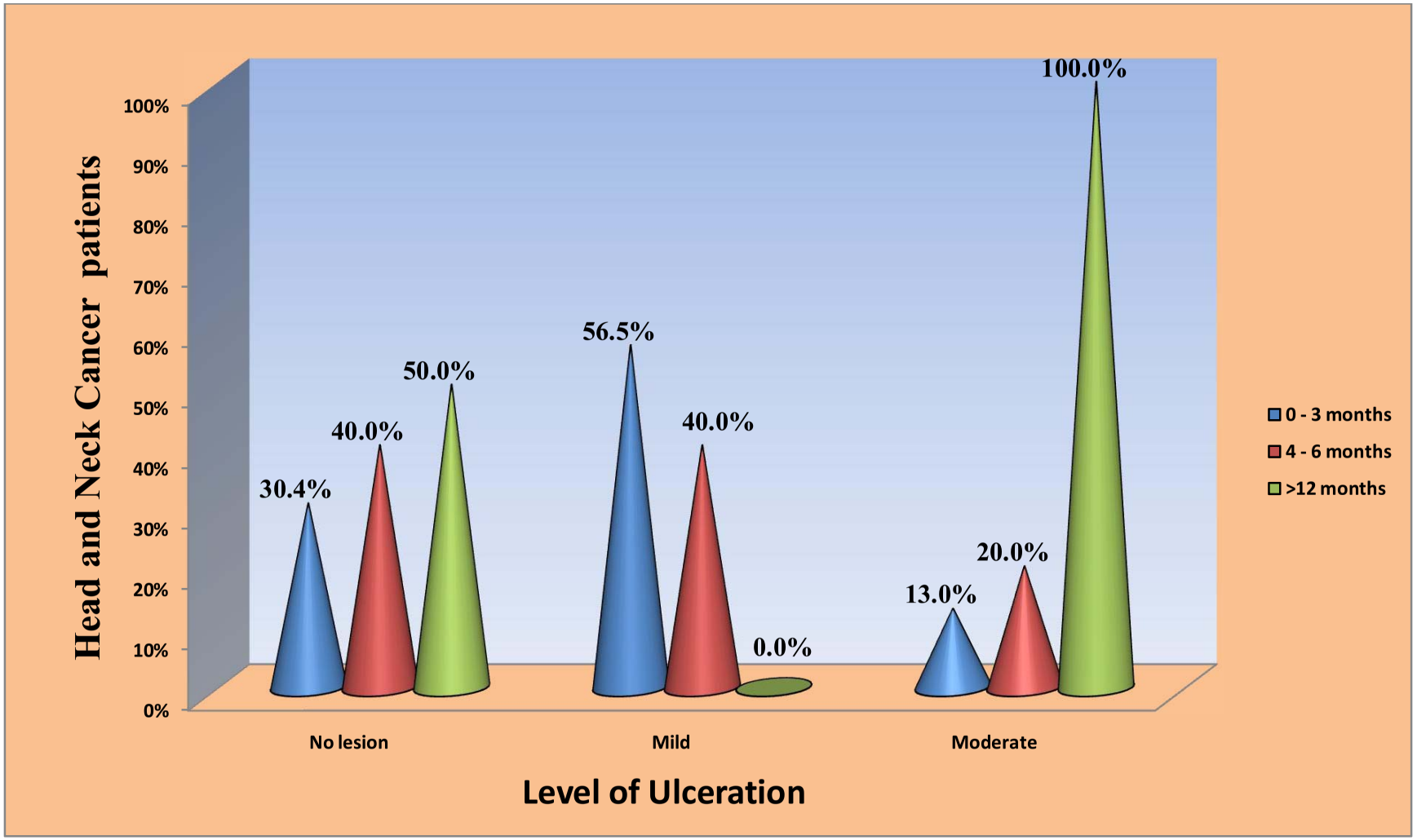


Figure 4.15 Association between post test level of Ulceration and duration of illness (experimental group)

Table 4.7 Association between post test level of ulceration and patients demographic variables (control group)

S.No	Demographic variables		Post test level of Ulceration						Total	Chi square test
			No lesion		Mild		Moderate			
			f	%	f	%	f	%		
1.	Age	21 -35 years	0	0	1	25.0	3	75.0	4	$\chi 2=1.97$ p=0.74
		36 -50 years	1	7.1	5	35.7	8	57.1	14	
		51 -65 years	2	16.7	5	41.7	5	41.7	12	
2.	Sex	Male	2	8.3	9	37.5	13	54.2	24	$\chi 2=0.37$ p=0.83
		Female	1	16.7	2	33.3	3	50.0	6	
3.	Religion	Hindu	3	12.0	9	36.0	13	52.0	25	$\chi 2=0.82$ p=0.93
		Christian	0	0	1	33.3	2	66.7	3	
		Muslim	0	0	1	50.0	1	50.0	2	
4.	Educational qualification	No formal education	0	0	1	20.0	4	80.0	5	$\chi 2=8.61$ p=0.19
		Upto Primary level	1	5.3	9	47.4	9	47.4	19	
		Upto middle school level	2	40.0	1	20.0	2	40.0	5	
		Higher secondary level	0	0	0	0	1	100	1	
5.	Income per month	< Rs.5,000	1	7.7	3	23.1	9	69.2	13	$\chi 2=2.71$ p=0.61
		Rs.5,001 - 10,000	2	13.3	7	46.7	6	40.0	15	
		Rs.10,001 - 15,000	0	0	1	50.0	1	50.0	2	
6.	Personal habits	Smoking	0	0	4	80.0	1	20.0	5	$\chi 2=11.56$ p=0.17
		Alcohol	0	0	1	50.0	1	50.0	2	
		Smoking and alcohol	0	0	2	18.2	9	81.8	11	
		Other tobacco products	1	20.0	2	40.0	2	40.0	5	
		No habit of tobacco or alcohol abuse	2	28.6	2	28.6	3	42.9	7	
7.	Family history of cancer	Yes	0	0	1	50.0	1	50.0	2	$\chi 2=0.32$ p=0.85
		No	3	10.7	10	35.7	15	53.6	28	
8.	Duration of illness	0 - 3 months	2	11.1	7	38.9	9	50.0	18	$\chi 2=1.88$ p=0.76
		4 - 6 months	1	10.0	4	40.0	5	50.0	10	
		>12 months	0	0	0	0	2	100	2	
9.	Duration of treatment	0 -1 months	3	12.0	7	28.0	15	60.0	25	$\chi 2=4.92$ p=0.09
		1 - 6 months	0	0	4	80.0	1	20.0	5	

* **Significant** at **$p \leq 0.05$**

The above table shows that there was no between post test level of oral mucositis (ulceration) among head and neck cancer patients undergoing radiation therapy with selected demographic variables in control group.

Table 4.8 Association between post test level of erythema and patients demographic variables (experimental group)

S.No	Demographic variables		Post test level of Erythema						Total	Chi square test
			No lesion		Mild		Moderate			
			f	%	f	%	f	%		
1.	Age	21 -35 years	2	66.7	1	33.3	0	0	3	$\chi2$=1.30 p=0.86
		36 -50 years	4	33.3	7	58.3	1	8.3	12	
		51 -65 years	7	46.7	7	46.7	1	6.7	15	
2.	Sex	Male	10	40.0	13	52.0	2	8.0	25	$\chi2$=0.90 p=0.63
		Female	3	60.0	2	40.0	0	0	5	
3.	Religion	Hindu	12	46.2	12	46.2	2	7.7	26	$\chi2$=4.47 p=0.34
		Christian	0	0	3	100.0	0	0	3	
		Muslim	1	100	0	0	0	0	1	
4.	Educational qualification	No formal education	3	60.0	1	20.0	1	20.0	5	$\chi2$=7.23 p=0.30
		Upto Primary level	6	35.3	11	64.7	0	0	17	
		Upto middle school level	4	57.1	2	28.6	1	14.3	7	
		Higher secondary level	0	0	1	100.0	0	0	1	
5.	Income per month	< Rs.5,000	4	50.0	2	25.0	2	25.0	8	$\chi2$=7.05 p=0.13
		Rs.5,001 - 10,000	8	40.0	12	60.0	0	0	20	
		Rs.10,001 - 15,000	1	50.0	1	50.0	0	0	2	
6.	Personal habits	Smoking	1	33.3	2	66.7	0	0	3	$\chi2$=3.20 p=0.92
		Alcohol	0	0	1	100.0	0	0	1	
		Smoking and alcohol	7	41.2	8	47.1	2	11.8	17	
		Other tobacco products	2	50.0	2	50.0	0	0	4	
		No habit of tobacco or alcohol abuse	3	60.0	2	40.0	0	0	5	
7.	Family history of cancer	Yes	0	0.0	0	0.0	1	100	1	$\chi2$=1.45 p=0.20
		No	13	44.8	15	51.7	1	3.4	29	
8.	Duration of illness	0 - 3 months	11	47.8	12	52.2	0	0.0	23	**$\chi2$=9.60 p=0.05***
		4 - 6 months	2	40.0	2	40.0	1	20.0	5	
		>12 months	0	0.0	1	50.0	1	50.0	2	
9.	Duration of treatment	0 -1 months	13	50.0	12	46.1	1	3.9	26	**$\chi2$=6.63 p=0.05***
		1 - 6 months	0	0.0	3	75.0	1	25.0	4	

*** Significant $p \leq 0.05$**

Table 4.8 shows the association between post test level of oral mucositis (erythema) after apitherapy among head and neck cancer patients undergoing radiation therapy with selected demographic variables in experimental group

Demographic variables - less duration of illness and less duration of treatment patients among experimental group have association with post test level of erythema. Statistical significance was calculated using chi square test.

Age, sex, religion, educational qualification, income per month, personal habits, and family history of cancer does not have significance with degree of oral mucositis (post test level of erythema).

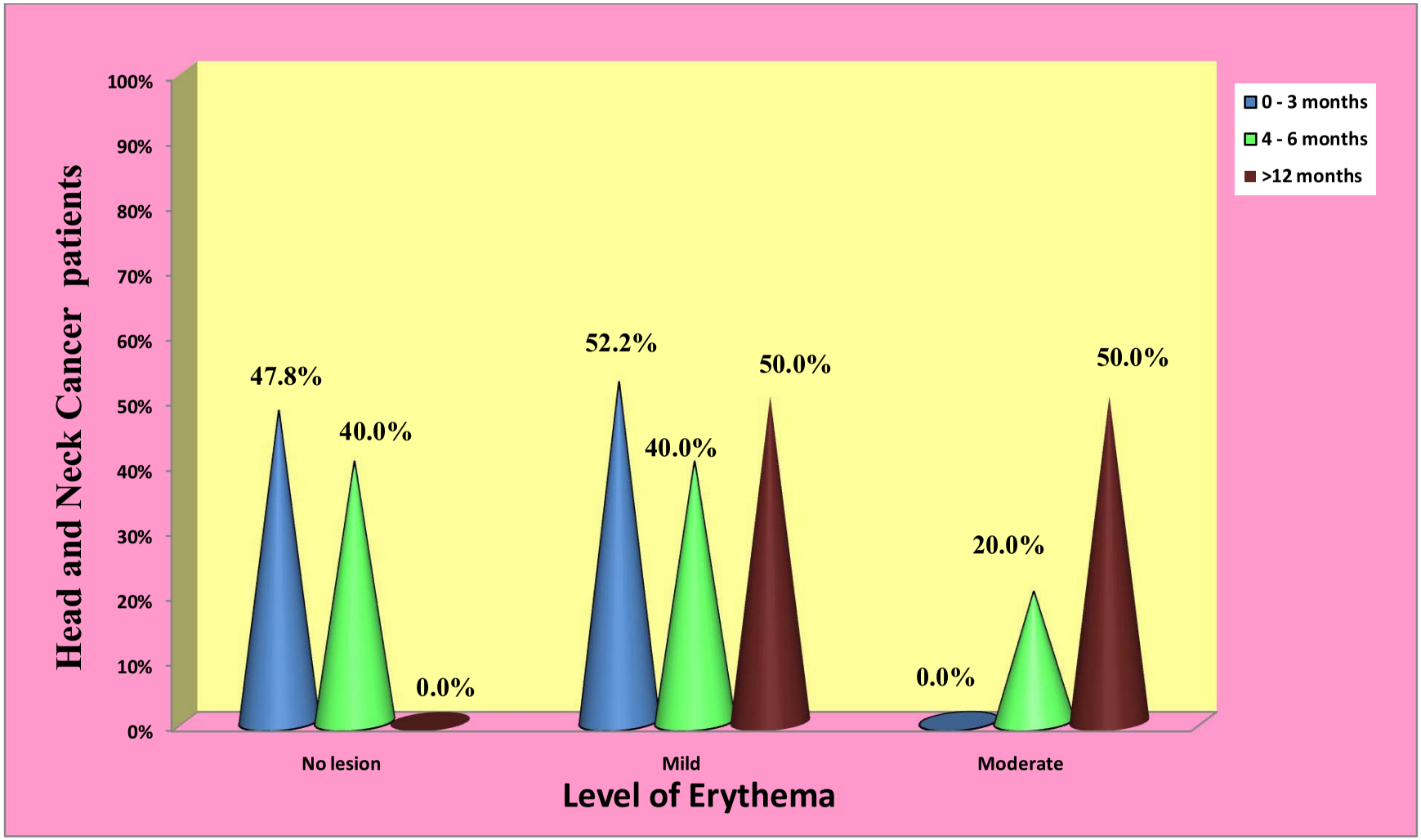


Figure 4.16 Association between post test level of Erythema and duration of illness (experimental group)

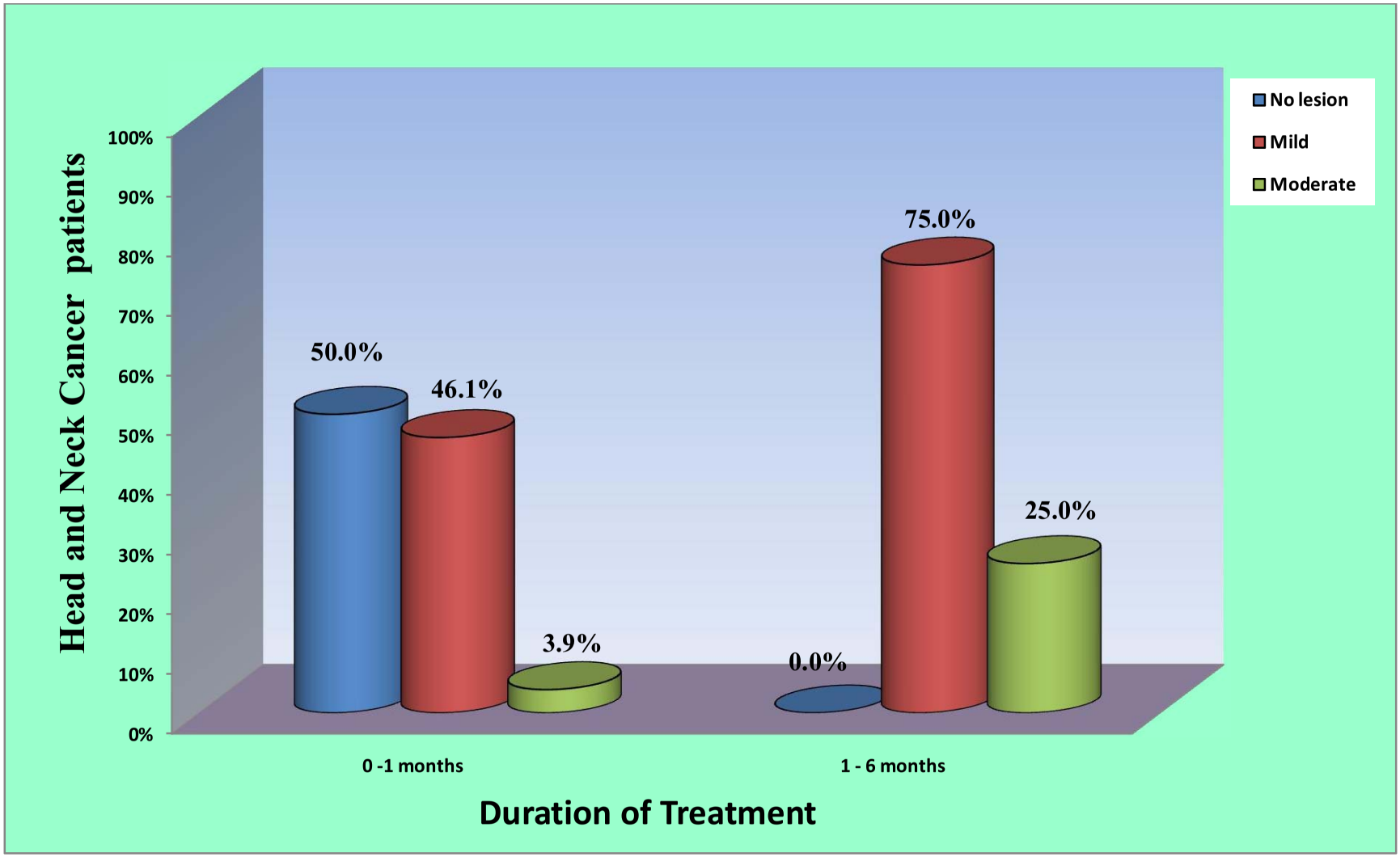


Figure 4.17 Association between post test level of Erythema and duration of treatment (experimental group)

Table 4.9 Association between level of erythema and patients demographic variables (control)

S.No	Demographic variables		Post test level of Erythema						Total	Chi square test
			No lesion		Mild		Moderate			
			f	%	f	%	f	%		
1.	Age	21 -35 years	1	25.0	1	25.0	2	50.0	4	$\chi 2$=3.97 p=0.40
		36 -50 years	1	7.1	4	28.6	9	64.3	14	
		51 -65 years	1	8.3	7	58.3	4	33.3	12	
2.	Sex	Male	3	12.5	9	37.5	12	50.0	24	$\chi 2$=0.93 p=0.62
		Female	0	0	3	50.0	3	50.0	6	
3.	Religion	Hindu	2	8.0	11	44.0	12	48.0	25	$\chi 2$=3.47 p=0.48
		Christian	1	33.3	0	0	2	66.7	3	
		Muslim	0	0	1	50.0	1	50.0	2	
4.	Educational qualification	No formal education	0	0	2	40.0	3	60.0	5	$\chi 2$=3.41 p=0.75
		Upto Primary level	3	15.8	7	36.8	9	47.4	19	
		Upto middle school level	0	0	3	60.0	2	40.0	5	
		Higher secondary level	0	0	0	0	1	100	1	
5.	Income per month	< Rs.5,000	1	7.7	6	46.2	6	46.2	13	$\chi 2$=0.84 p=0.91
		Rs.5,001 - 10,000	2	13.3	5	33.3	8	53.3	15	
		Rs.10,001 - 15,000	0	0	1	50.0	1	50.0	2	
6.	Personal habits	Smoking	0	0	3	60.0	2	40.0	5	$\chi 2$=9.66 p=0.28
		Alcohol	1	50.0	0	0	1	50.0	2	
		Smoking and alcohol	0	0	3	27.3	8	72.7	11	
		Other tobacco products	1	20.0	2	40.0	2	40.0	5	
		No habit of tobacco or alcohol abuse	1	14.3	4	57.1	2	28.6	7	
7.	Family history of cancer	Yes	0	0	0	0	2	100	2	$\chi 2$=2.14 p=0.33
		No	3	10.7	12	42.9	13	46.4	28	
8.	Duration of illness	0 - 3 months	3	16.7	6	33.3	9	50.0	18	$\chi 2$=5.20 p=0.26
		4 - 6 months	0	0	6	60.0	4	40.0	10	
		>12 months	0	0			2	100	2	
9.	Duration of treatment	0 -1 months	3	12.0	9	36.0	13	52.0	25	$\chi 2$=1.32 p=0.52
		1 - 6 months	0	0	3	60.0	2	40.0	5	

* **Significant** at **$p \leq 0.05$**

The above table shows that there was no association between post test level of oral mucositis (erythema) among head and neck cancer patients undergoing radiation therapy with selected demographic variables in control group.

Table 4.10 Association between post test level of pain and patients demographic variables (Experimental group)

S.No	Demographic variables		Post test level of Pain						Total	Chi square test
			No pain		Mild		Moderate			
			f	%	f	%	f	%		
1.	Age	21 -35 years	1	33.3	0	0.0	2	66.7	3	**$\chi 2=20.37$ p=0.01***
		36 -50 years	6	50.0	6	50.0	0	0.0	12	
		51 -65 years	10	66.7	5	33.3	0	0.0	15	
2.	Sex	Male	16	64.0	8	32.0	1	4.0	25	$\chi 2=3.91$ p=0.14
		Female	1	20.0	3	60.0	1	20.0	5	
3.	Religion	Hindu	14	53.8	10	38.5	2	7.7	26	$\chi 2=1.12$ p=0.89
		Christian	2	66.7	1	33.3	0	0.0	3	
		Muslim	1	100	0	0.0	0	0.0	1	
4.	Educational qualification	No formal education	3	60.0	2	40.0	0	0	5	$\chi 2=3.01$ p=0.89
		Upto Primary level	8	47.1	7	41.2	2	11.8	17	
		Upto middle school level	5	71.4	2	28.6	0	0	7	
		Higher secondary level	1	100	0	0	0	0	1	
5.	Income per month	< Rs.5,000	3	37.5	4	50.0	1	12.5	8	$\chi 2=2.91$ p=0.56
		Rs.5,001 - 10,000	12	60.0	7	35.0	1	5.0	20	
		Rs.10,001 - 15,000	2	100	0	0	0	0	2	
6.	Personal habits	Smoking	3	100	0	0.0	0	0.0	3	$\chi 2=12.16$ p=0.14
		Alcohol	0	0.0	1	100	0	0.0	1	
		Smoking and alcohol	12	70.6	5	29.4	0	0.0	17	
		Other tobacco products	1	25.0	2	50.0	1	25.0	4	
		No habit of tobacco or alcohol abuse	1	20.0	3	60.0	1	20.0	5	
7.	Family history of cancer	Yes	0	0.0	1	100	0	0.0	1	$\chi 2=1.78$ p=0.40
		No	17	58.6	10	34.5	2	6.9	29	
8.	Duration of illness	0 - 3 months	15	65.2	7	30.4	1	4.3	23	**$\chi 2=10.37$ p=0.05***
		4 - 6 months	2	40.0	3	60.0	0	0.0	5	
		>12 months	0	0.0	1	50.0	1	50.0	2	
9.	Duration of treatment	0 -1 months	16	61.5	8	30.8	2	7.7	26	$\chi 2=2.94$ p=0.21
		1 - 6 months	1	25.0	3	75.0	0	0.0	4	

*** Significant $p \leq 0.05$**

Table 4.10 shows the association between post test level of oral mucositis (pain) after apitherapy among head and neck cancer patients undergoing radiation therapy with selected demographic variables.

Demographic variables - Less duration of illness and elder patients among experimental group have association with post test level of pain.

Sex, religion, educational qualification, income per month, personal habits, family history of cancer and duration of treatment does not have significance with degree of oral mucositis (post test level of pain).

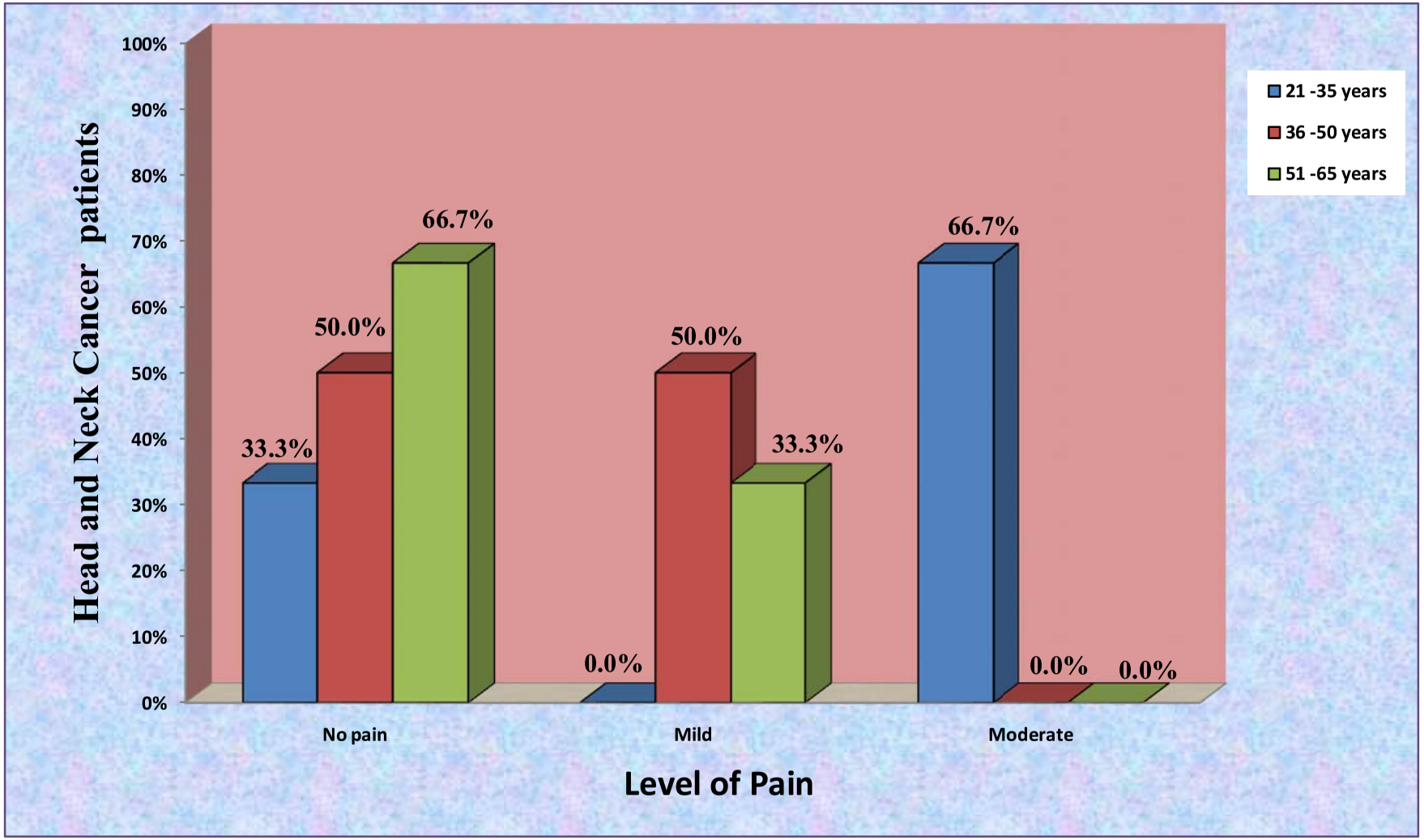


Figure 4.18 Association between post test level of Pain and patients age (experimental group)

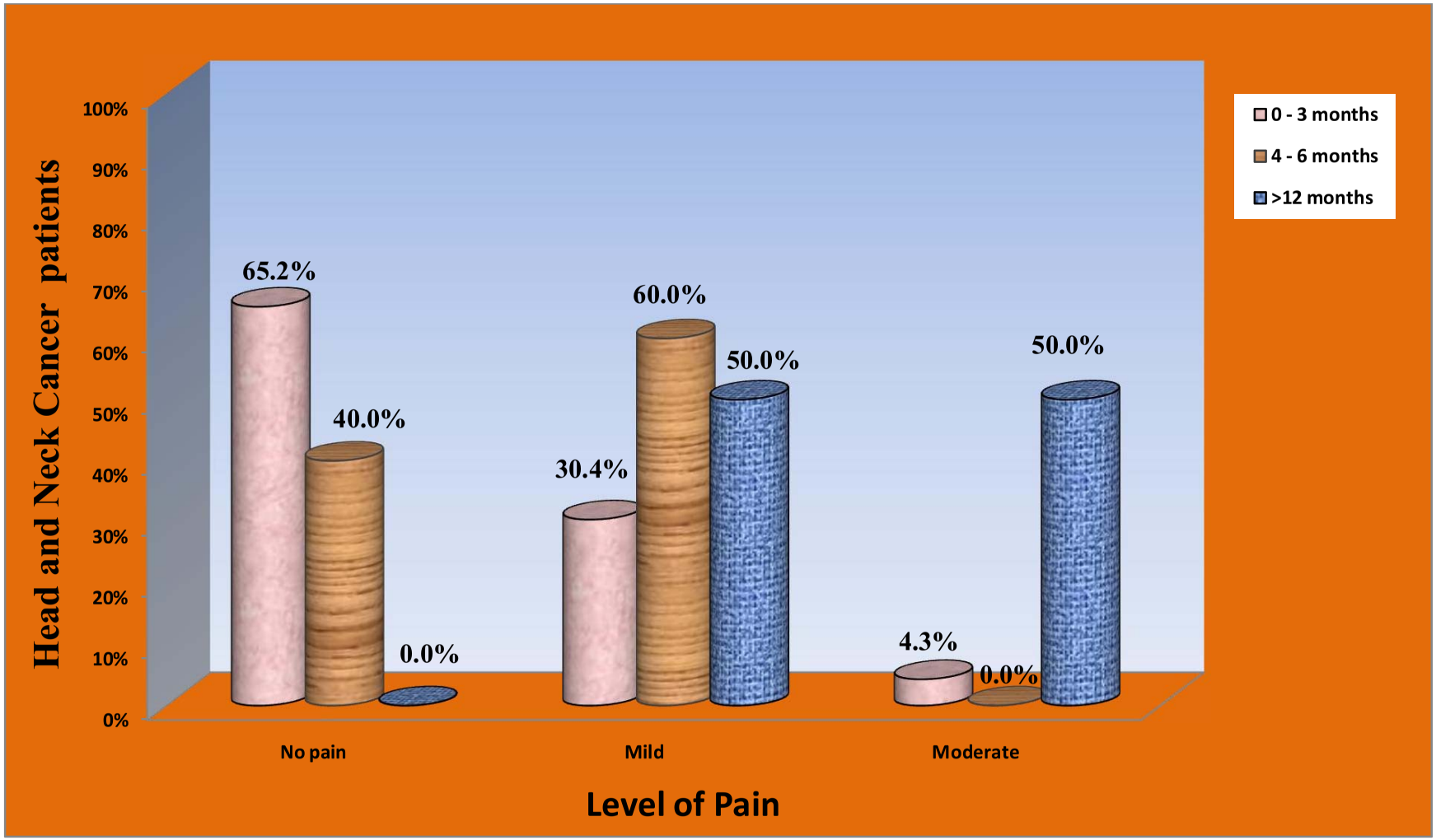


Figure 4.19 Association between post test level of Pain and duration of illness (experimental group)

Table 4.11 Association between level of pain and patients demographic variables (control group)

S.No	Demographic variables		Post test level of Pain						Total	Chi square test
			No pain		Mild		Moderate			
			f	%	f	%	f	%		
1.	Age	21 -35 years	0	0	2	50.0	2	50.0	4	$\chi2$=6.01 p=0.19
		36 -50 years	0	0	9	64.3	5	35.7	14	
		51 -65 years	3	25.0	7	58.3	2	16.7	12	
2.	Sex	Male	1	4.2	15	62.5	8	33.3	24	$\chi2$=4.65 p=0.10
		Female	2	33.3	3	50.0	1	16.7	6	
3.	Religion	Hindu	3	12.0	16	64.0	6	24.0	25	$\chi2$=2.97 p=0.56
		Christian	0	0	1	33.3	2	66.7	3	
		Muslim	0	0	1	50.0	1	50.0	2	
4.	Educational qualification	No formal education	2	40.0	2	40.0	1	20.0	5	$\chi2$=11.21 p=0.08
		Upto Primary level	0	0	15	78.9	4	21.1	19	
		Upto middle school level	1	20.0	1	20.0	3	60.0	5	
		Higher secondary level	0	0	0	0	1	100	1	
5.	Income per month	< Rs.5,000	0	0	10	76.9	3	23.1	13	$\chi2$=4.62 p=0.36
		Rs.5,001 - 10,000	3	20.0	7	46.7	5	33.3	15	
		Rs.10,001 - 15,000	0	0	1	50.0	1	50.0	2	
6.	Personal habits	Smoking	1	20.0	4	80.0	0	0	5	$\chi2$=7.35 p=0.48
		Alcohol	0	0	1	50.0	1	50.0	2	
		Smoking and alcohol	0	0	7	63.6	4	36.4	11	
		Other tobacco products	0	0	3	60.0	2	40.0	5	
		No habit of tobacco or alcohol abuse	2	28.6	3	42.9	2	28.6	7	
7.	Family history of cancer	Yes	0	0	1	50.0	1	50.0	2	$\chi2$=0.53 p=0.76
		No	3	10.7	17	60.7	8	28.6	28	
8.	Duration of illness	0 - 3 months	1	5.6	12	66.7	5	27.8	18	$\chi2$=5.22 p=0.25
		4 - 6 months	0	0	6	60.0	4	40.0	10	
		>12 months	2	100	0	0	0	0	2	
9.	Duration of treatment	0 -1 months	3	12.0	14	56.0	8	32.0	25	$\chi2$=1.20 p=0.54
		1 - 6 months	0	0	4	80.0	1	20.0	5	

* **Significant** at $\mathbf{p \leq 0.05}$

The above table shows that there was no association between post test level of oral mucositis (pain) after apitherapy among head and neck cancer patients undergoing radiation therapy with selected demographic variables in control group.

Table 4.12 Association between post test level of ability to swallow and patients demographic variables (Experimental group)

S.No	Demographic variables		Post test level of ability to swallow				Total	Chi square test
			Able to swallow without pain		Able to swallow with pain			
			f	%	f	%		
1.	Age	21 -35 years	2	66.7	1	33.3	3	$\chi 2=0.60$ p=0.74
		36 -50 years	7	58.3	5	41.7	12	
		51 -65 years	7	46.7	8	53.3	15	
2.	Sex	Male	16	64.0	9	36.0	25	**$\chi 2=9.52$ p=0.05***
		Female	0	00.0	5	100.0	5	
3.	Religion	Hindu	15	57.7	11	42.3	26	$\chi 2=4.50$ p=0.10
		Christian	0	0	3	100.0	3	
		Muslim	1	100	0	0	1	
4.	Educational qualification	No formal education	1	20.0	4	80.0	5	$\chi 2=4.51$ p=0.21
		Upto Primary level	10	58.8	7	41.2	17	
		Upto middle school level	5	71.4	2	28.6	7	
		Higher secondary level	0	0	1	100.0	1	
5.	Income per month	< Rs.5,000	3	37.5	5	62.5	8	$\chi 2=1.17$ p=0.57
		Rs.5,001 - 10,000	12	60.0	8	40.0	20	
		Rs.10,001 - 15,000	1	50.0	1	50.0	2	
6.	Personal habits	Smoking	2	66.7	1	33.3	3	$\chi 2=2.94$ p=0.56
		Alcohol			1	100.0	1	
		Smoking and alcohol	10	58.8	7	41.2	17	
		Other tobacco products	1	25.0	3	75.0	4	
		No habit of tobacco or alcohol abuse	3	60.0	2	40.0	5	
7.	Family history of cancer	Yes	1	100	0	0	1	$\chi 2=0.90$ p=0.34
		No	15	51.7	14	48.3	29	
8.	Duration of illness	0 - 3 months	15	65.2	8	34.8	23	**$\chi 2=5.84$ p=0.05***
		4 - 6 months	1	20.0	4	80.0	5	
		>12 months	0	0.0	2	100.0	2	
9.	Duration of treatment	0 -1 months	13	50.0	13	50.0	26	$\chi 2=0.87$ p=0.35
		1 - 6 months	3	75.0	1	25.0	4	

*** Significant p≤0.05**

Table 4.12 shows the association between post test level of oral mucositis (ability to swallow) after apitherapy among head and neck cancer patients undergoing radiation therapy with selected demographic variables in experimental group.

Demographic variables - male and less duration of illness patients among experimental group have association with post test level of ability to swallow.

Age, religion, educational qualification, income per month, personal habits, family history of cancer and duration of treatment does not have significance with degree of oral mucositis (post test level of ability to swallow).

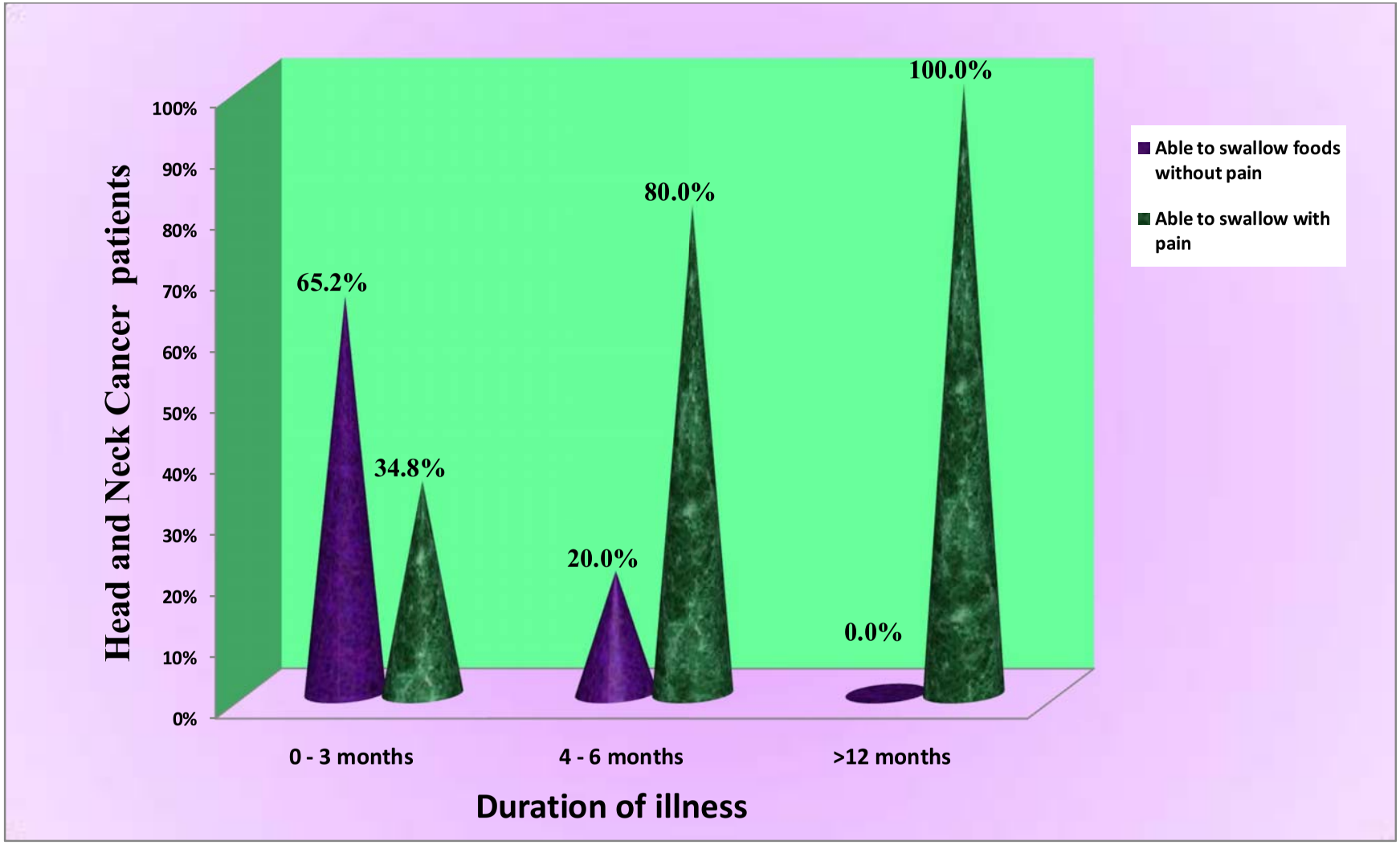


Figure 4.20 Association between post test level of ability to swallow and Duration of illness (experimental group)

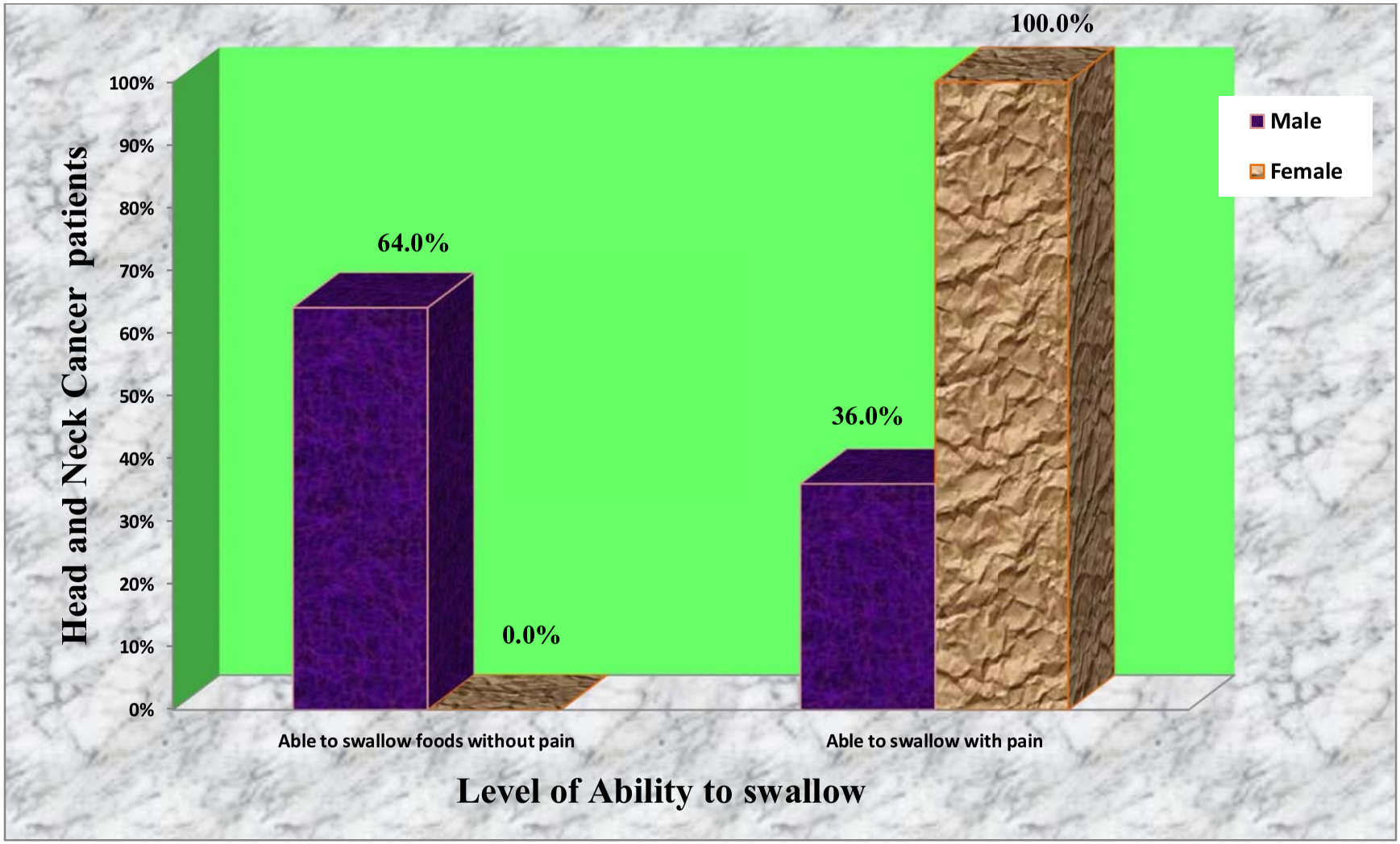


Figure 4.21 Association between post test level of ability to swallow and patient gender (experimental group)

Table 4.13 Association between level of ability to swallow and patients demographic variables(control group)

S.No	Demographic variables		Post test level of Ability to swallow						Total	Chi square test
			swallow without pain		swallow with pain		Requires intravenous rehydration			
			n	%	n	%	n	%		
1.	Age in years	21 -35 years	1	25.0	3	75.0	0	0	4	$\chi 2=2.68$ p=0.61
		36 -50 years	1	7.1	13	92.9	0	0	14	
		51 -65 years	1	8.3	10	83.3	1	8.3	12	
2.	Sex	Male	1	4.2	22	91.7	1	4.2	24	$\chi 2=4.67$ p=0.10
		Female	2	33.3	4	66.7	0	0	6	
3.	Religion	Hindu	3	12.0	21	84.0	1	4.0	25	$\chi 2=0.92$ p=0.92
		Christian	0	0	3	100	0	0	3	
		Muslim	0	0	2	100	0	0	2	
4.	Educational qualification	No formal education	0	0	5	100	0	0	5	$\chi 2=2.67$ p=0.85
		Upto Primary level	3	15.8	15	78.9	1	5.3	19	
		Upto middle school level	0	0	5	100	0	0	5	
		Higher secondary level	0	0	1	100	0	0	1	
5.	Income per month	< Rs.5,000	2	15.4	10	76.9	1	7.7	13	$\chi 2=2.31$ p=0.68
		Rs.5,001 - 10,000	1	6.7	14	93.3	0	0	15	
		Rs.10,001 - 15,000	0	0	2	100	0	0	2	
6.	Personal habits	Smoking	1	20.0	4	80.0	0	0	5	$\chi 2=6.45$ p=0.60
		Alcohol	0	0	2	100	0	0	2	
		Smoking and alcohol	1	9.1	10	90.9	0	0	11	
		Other tobacco products	0	0	4	80.0	1	20.0	5	
		No habit of tobacco or alcohol abuse	1	14.3	6	85.7	0	0	7	
7.	Family history of cancer	Yes	0	0	2	100	0	0	2	$\chi 2=0.33$ p=0.84
		No	3	10.7	24	85.7	1	3.6	28	
8.	Duration of illness	0 - 3 months	3	16.7	14	77.8	1	5.6	18	$\chi 2=3.07$ p=0.54
		4 - 6 months	0	0	10	100	0	0	10	
		>12 months	0	0	2	100	0	0	2	
9.	Duration of treatment	0 -1 months	3	12.0	21	84.0	1	4.0	25	$\chi 2=0.92$ p=0.63
		1 - 6 months	0	0	5	100	0	0	5	

* **Significant** at $\mathbf{p \leq 0.05}$

The above table shows the no association between post test level of oral mucositis (ability to swallow) among head and neck cancer patients undergoing radiation therapy with selected demographic variables in control group.

CHAPTER - V

SUMMARY OF RESULTS

This chapter deals with the summary of discussion on the findings of the study interpreted from statistical analysis. The findings are discussed in relation to the objectives, need for the study, related literature review and conceptual frame work.

Demographic and clinical variables of head and neck cancer patients

The demographic variables of head and neck cancer patients with oral mucositis those who participated in the study were explained. Regarding the age, majority of the subjects were between 51-65 years of age in experimental group (50%) and control group (40%).

Regarding gender, males were majority (83.3%) in experimental group and control group (80%).

Regarding religion, Hindus were majority affected in both experimental group (86.7%) and control group (83.3%).

Regarding educational status, majority primary school (56.7%) in experimental group and (63.3%) in control group.

According to family monthly income was (Rs.5001-1000) majority in experimental group (66.6%) and control group (50%).

According to personal habits majority were alcoholism and smoking in experimental group (56.7%) and in control group (36.6%).

According to family history of cancer majority does not have family history of cancer, in experimental group (96.7%) and control group (93.3%).

According to duration of illness majority were 0-3 months in experimental group (76.6%) and in control group (60%).

According to duration of treatment majority were 0-1 month in experimental group (86.7%) and in control group (83.3%).

Level of oral mucositis of the patients with head and neck cancer of experimental group and control group before apitherapy.

In **ulceration** - Among experimental group, 1(3.3%) patients did not have any lesion, 9(30.0%) had mild score, 17(56.7%) had moderate score and 3(10.0%) had severe ulceration score.

Among control group, 2(6.7%) did not have any lesion, 9(30.0%) had mild score, 18(60.0%) had moderate score and 1(3.3%) had severe ulceration score.

In **Erythema** - Among experimental group, 1(3.3%) patients did not have any lesion, 8(26.7%) had mild score, 19(63.3%) had moderate score and 2(6.7%) had severe erythema score.

Among control group, 2(6.7%) did not have any lesion, 10(33.3%) had mild score, 17(56.7%) had moderate score and 1(3.3%) had severe Erythema score.

In **pain** - Among experimental group, 13(43.3%) patients had mild score, 11(36.7%) had moderate score and 6(20.0%) had severe pain score.

Among control group, 17(56.7%) had mild score, 11(36.7%) had moderate score and 2(6.7%) had severe pain score.

In **ability to swallow -** Among experimental group, 3(10.0%) patients were able to swallow foods without pain, 22(73.3%) were able to swallow with pain, and 5(16.7%) were requiring intravenous rehydration.

Among control group, 2(6.7%) were able to swallow foods without pain, 25(83.3%) were able to swallow with pain, and 3(10.0%) were requiring intravenous rehydration.

So, there was equal distribution of subjects among experimental group and control group. It was confirmed using chi square.

Effectiveness of apitherapy for the patients with head and neck cancer of experimental group.

Effectiveness of apitherapy was assessed by comparing the post test level of experimental group with the control group.

In **Ulceration -** Among experimental group, 9(30.0%) patients did not have any lesion, 15(50.0%) had mild score, and 6(20.0%) had moderate score. Among control group, 3(10.0%) did not have any lesion, 11(36.7%) had mild score, and 16(53.3%) had moderate score.

In **Erythema** - among experimental group, 13(43.3%) patients did not have any lesion, 15(50.0%) had mild score, and 2(6.7%) had moderate score. Among control, 3(10.0%) did not have any lesion, 12(40.0%) had mild score, and 15(50.0%) had moderate score.

In **Pain -** among experimental, 17(56.7%) patients did not have any pain, 11(36.7%) had mild score, and 2(6.6%) had moderate pain score. Among control group, 3(10%) did not have any pain, 18(60.0%) had mild score, and 9(30.0%) had moderate score.

In **Ability to swallow -** among experimental group, 16(53.3%) were able to swallow foods without pain, 14(46.7%0 were able to swallow with pain. Among control group, 3(10%) were able to swallow foods without pain, 26(86.7%) were able to swallow with pain, and 1(3.3%) were requiring intravenous rehydration.

Hence, ***there was statistically significant reduction in oral mucositis among patients in experimental group after apitherapy. (p=0.02 for ulceration, p=0.001 for erythema, p=0.001 for pain and p=0.001 for ability to swallow)***

Compare the pre test and post test level of oral mucositis among head and neck cancer patients in experimental group and control group.

Using chi square the effectiveness of apitherapy between experimental group and control group was assessed.

In experimental group (30 patients),

In pre test level of ulceration, 1(3.3%) did not have any lesion, 9(30.0%) had mild score, 17(56.7%) had moderate score and 3(10.0%) had severe ulceration score. In post test level of ulceration, 9(30.0%) did not have any lesion, 15(50.0%) had mild score, 6(20.0%) had moderate score. Hence post test level of **ulceration (p=0.001**)** was highly significant

In pre test level of erythema, 1(3.3%) did not have any lesion, 8(26.7%) had mild score, 19(63.3%) had moderate score and 2(6.7%) had severe erythema score. In post test level of erythema, 13(43.3%) did not have any lesion, 15(50.0%) had mild score, 2(6.7%) had moderate score. Hence post test level of **erythema (p=0.001***)** was very highly significant.

In pre test level of pain, 13(43.3%) had mild score, 11(36.7%) had moderate score and 6(20.0%) had severe pain score. In post test level of pain, 17(56.7%) did not have any lesion, 11(36.7%) had mild score, 2(6.6%) had moderate score. Hence post test level of **pain (p=0.001***)** was very highly significant.

In pre test level of ability to swallow, 3(10.0%) were able to swallow foods without pain, 22(73.3%) were able to swallow with pain, and 5(16.7%) were requiring intravenous rehydration. In post test level of ability to swallow, 16(53.3%) were able to swallow foods without pain, 14(46.7%) were able to swallow with pain. Hence post test level of **ability to swallow (p=0.001***)** was very highly significant.

In control group, the pre test and post test effectiveness was assessed which shows ulceration (p=0.67), erythema (p=0.68), pain (p=0.16) and ability to swallow (p=0.52) were statistically not significant.

Association between post test level of oral mucositis among head and neck cancer patients with selected demographic variables.

Association between demographic variables and their post test **level of ulceration** in experimental group showed that elders and less duration of illness were closely associated ($\chi 2$=10.53 **p=0.03*** & $\chi 2$=10.62 **p=0.03***). None of the variables were associated with their level of ulceration in control group.

Association between demographic variables and their post test **level of erythema** in experimental group showed that less duration of illness and less duration of treatment were closely associated ($\chi 2$=9.60 **p=0.05*** & $\chi 2$=6.63 **p=0.05***). None of the variables were associated with their level of erythema in control group.

Association between demographic variables and their post test **level of pain** in experimental group showed that elders and less duration of illness were closely associated ($\chi 2$=20.37 **p=0.01*** & $\chi 2$=10.37 **p=0.05***). None of the variables were associated with their level of pain in control group.

Association between demographic variables and their post test **level of ability to swallow** in experimental group showed that male and less duration of illness were closely associated ($\chi 2$=9.52**p=0.05*** & $\chi 2$=5.84**p=0.05*).** None of the variables were associated with their level of ability to swallow in control group.

CHAPTER - VI

DISCUSSION

This chapter presents the interpretation of the statistical findings with other co related similar studies from literature reviewed

The aim of the study was to evaluate the effectiveness of apitherapy in reducing oral mucositis among head and neck cancer patients undergoing radiation therapy. A sample consist of 60 head and neck cancer patients undergoing radiation therapy who met the inclusion criteria were selected for the study by using simple random sampling method. Apitherapy given from 23rd day to 36th day (about 14 days) to the experimental group and routine care to control group. Pre test & Post test done by using NCI-CTC scale.

Objective 1: To assess for oral mucositis among patients with head and neck cancer.

In **ulceration**, the difference between experimental group and control group was small ($\chi 2=1.36$ $p=0.71$) & it was not significant. In **Erythema**, the difference between experimental group and control group was small ($\chi 2=1.01$ $p=0.80$) & it was not significant.

In **pain**, the difference between experimental group and control group was small ($\chi 2=2.53$ $p=0.28$) & it was not significant. In **ability to swallow**, the difference between experimental group and control group was small ($\chi 2=1.51$ $p=0.46$) & it was not significant.

So, there was equal distribution of subjects among experimental group and control group.

Objective 2: To assess effectiveness of apitherapy for the patients with head and neck cancer of experimental group.

Effectiveness of apitherapy was assessed by comparing the post test level of experimental group with the control group.

In **Ulceration -**9(30.0%) of patients in experimental group and 3(10.0%) in control group did not have any lesion of ulceration. The difference between experimental and control group after apitherapy was statistically significant **(p=0.02*)**

In **Erythema** - 13(43.3%) of patients in experimental group and 3(10.0%) in control group did not have any lesion of erythema. The difference between experimental and control group after apitherapy was statistically significant **(p=0.001***)**

In **Pain -** 17(56.7%) of patients in experimental group and 3(10.0%) in control group did not have any pain. The difference between experimental and control group after apitherapy was statistically significant **(p=0.001***)**

In **Ability to swallow -** 16(53.3%) of patients in experimental group and 3(10.0%) in control group were able to swallow without pain. The difference between experimental and control group after apitherapy was statistically significant **(p=0.001***)**

There was statistically significant reduction in oral mucositis among head and neck cancer patients in experimental group after apitherapy. Hence hypothesis (H1) has been accepted.

This finding is consistent with the findings of **Rashad UM et 'al (2009)** conducted a cohort study on honey as topical prophylaxis against radiochemotherapy induced mucositis in head and neck cancer. The aim of the study was to evaluate the efficacy of pure natural honey as against radiochemotherapy induced mucositis. In the results in the treatment group, no patients developed grade four mucositis and only 3 patients (15%) developed grade three mucositis. In the control group 13 patients (65%) developed grade three or four mucositis ($p< 0.05$). As a conclusion this study shows that prophylactic use of pure natural honey was effective in reducing mucositis resulting from radiochemotherapy in patients with head and neck cancer.

Objective 3: To compare the pre test and post test level of oral mucositis among head and neck cancer patients in experimental group and control group.

In experimental group, on comparing the pre test and post test level of oral mucositis there was significant reduction in level of **ulceration** ($\chi 2$=16.16 **p=0.001****), level of **erythema** ($\chi 2$=28.17 **p=0.001*****), level of **pain** ($\chi 2$=29.39 **p=0.001*****) and level of **ability to swallow** ($\chi 2$=15.67 **p=0.001*****).

In control group, on comparing the pre test and post test level of oral mucositis there was no significant reduction in level of ulceration ($\chi 2$=1.51 p=0.67), level of erythema ($\chi 2$=1.50 p=0.68), level of pain ($\chi 2$=5.22 p=0.16), level of ability to swallow ($\chi 2$=1.21 p=0.52).

On comparing the pre test and post test level of oral mucositis among head and neck cancer patients in experimental group and control group, ***there was statistically significant reduction in oral mucositis after apitherapy in experimental group than control group.***

This finding is consistent with the findings of **Biswa Mohan Biswal et 'al (2003)** conducted an experimental study to evaluate the effect of pure honey on radiation induced mucositis. The main result of the study was there was significant reduction of symptomatic grade 3 mucositis among honey – treated patients compared to controls. i.e. 20% versus 75% (p 0.00058). As a conclusion topical application of natural honey is a simple and cost- effective treatment in radiation mucositis.

Objective 4: To find the association between post test level of oral mucositis among head and neck cancer patients with selected demographic variables.

Association between demographic variables and their post test **level of ulceration** in experimental group showed that elders and less duration of illness were closely associated ($\chi 2=10.53$ **p=0.03*** & $\chi 2=10.62$ **p=0.03***). None of the variables were associated with their level of ulceration in control group.

Association between demographic variables and their post test **level of erythema** in experimental group showed that less duration of illness and less duration of treatment were closely associated ($\chi 2=9.60$ **p=0.05*** & $\chi 2=6.63$ **p=0.05***). None of the variables were associated with their level of erythema in control group.

Association between demographic variables and their post test **level of pain** in experimental group showed that elders and less duration of illness were closely associated ($\chi 2=20.37$ **p=0.01*** & $\chi 2=10.37$ **p=0.05***). None of the variables were associated with their level of pain in control group.

Association between demographic variables and their post test **level of ability to swallow** in experimental group showed that male and less duration of illness were closely associated ($\chi 2=9.52$ **p=0.05*** & $\chi 2=5.84$ **p=0.05*).** None of the variables were associated with their level of ability to swallow in control group.

Hence there was statistically significant association between the effectiveness of apitherapy and selected demographical variables in reducing oral mucositis among head and neck cancer patients.

CHAPTER-VII

CONCLUSION AND RECOMMENDATION

This chapter deals with the conclusions drawn and recommendations. It clarifies the limitations of the study. The implications and recommendations are given for different areas of nursing such as practice, education, research and administration in the health care delivery system.

7.1. Implications

The implication had drawn from the present study is a vital concern in the field of health team including the professional nurse practitioners, nurse administrators, nurse educators and researchers.

Implications for Nursing Practice

- The nurses can develop the skill in providing necessary care to head and neck cancer patients in reducing oral mucositis by using apitherapy, as it help to reduce the degree of oral mucositis among head and neck cancer patients undergoing radiation therapy.
- Apitherapy technique can be practiced in hospital settings as a evidence based practice in reducing the degree of oral mucositis among head and neck cancer patients undergoing radiation therapy
- The findings will help the nursing profession to assess the effectiveness of apitherapy and could implement the apitherapy technique for head and neck cancer patients undergoing radiation therapy.

Implications for Nursing Education

- The nurse educator can provide in–service education to nursing personnel to update their knowledge about the apitherapy and its benefits to the head and neck cancer patients.
- Nursing students should be educated on apitherapy technique in reducing degree oral mucositis among head and neck cancer patients.

- ❖ The findings will help the student nurses to identify the apitherapy technique, and to be motivated in participating to reduce the degree of oral mucositis among head and neck cancer patients.
- ❖ The nurse educator can include Apitherapy technique as a means of non–pharmacological therapy in the curriculum, which can be adopted by the students and the nursing personals.

Implications for Nursing Administration

- ❖ The nurse administrator should conduct in–service education to disseminate the research findings through continuous nursing education to all nurses.
- ❖ Pamphlets, leaflet about apitherapy technique can be made available to nursing staff in the cancer wards and to nurse educators in nursing educational institution.
- ❖ Clinical nurses and nurse educators should be given education to update their knowledge on apitherapy technique.
- ❖ The findings will help the nurse administrator to take up an important role in implementing apitherapy technique in hospital settings.

Implications for Nursing Research

- ❖ The findings of this study will help to motivate the nurses to conduct research about apitherapy technique in future.
- ❖ This study is the foundation to conduct study on larger population to strongly prove the efficacy of apitherapy technique on reducing oral mucositis among head and neck cancer patients undergoing radiation therapy.
- ❖ The findings can be utilized for further research in head and neck cancer with oral mucositis.

7.2. Limitations

- The study was confined to small samples in a single setting, which limits the study.
- Data collection period was only four weeks.
- The study was limited to only 25 to 65 years old subjects.
- The study was limited to only one hospital.

7.3. Recommendations for further study

- A comparative study can also be done between the effectiveness of various non – pharmacological measures on reducing oral mucositis
- A comparative study can be conducted to evaluate the apitherapy practice in various cancer settings.
- The effect of apitherapy can be assessed in combination with other non pharmacological agents and various oral rinses for the good parturient outcome.
- The study can be conducted in a larger population and various age groups.

Conclusion

From the study conducted it is concluded that honey has good effect on oral mucositis in healing. Presence of antibacterial property and antioxidants in honey provokes adequate wound healing and also improves immune system. In addition to antibacterial activity, honey is known to possess strong antioxidant capacity, which acts in modulating free radical production, thus protecting cell components from their harmful action. Honey helps in earlier healing of wounds and promotes healthy living among cancer patients. Such cost effective interventions in hospital practices are highly recommended.

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APPENDIX-A

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. SONIA.M,
M.Sc., (Nursing),
College of Nursing
Madras Medical College,
Chennai – 600 003.

Dear Mrs. SONIA.M,

The Institutional Ethics Committee has considered your request and approved your study titled **A STUDY TO ASSESS THE EFFECTIVENESS OF APITHERAPY IN REDUCING ORAL MUCOSITIS AMONG HEAD AND NECK CANCER PATIENTS UNDERGOING RADIATION THERAPY AT RAJIV GANDHI GOVERNMENT GENERAL HOSPITAL, CHENNAI. No.31102014.**

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

1. Dr.C.Rajendran, M.D.,	: Chairperson
2. Dr.R.Vimala, M.D., Dean, MMC, Ch-3	: Deputy Chairperson
3. Prof.B.Kalaiselvi, M.D., Vice-Principal, MMC, Ch-3	: Member Secretary
4. Prof.R.Nandhini, M.D., Inst.of Pharmacology, MMC	: Member
5. Prof.K.Ramadevi, Director i/c, Inst.of Biochemistry, MMC	: Member
6. Prof.Saraswathy, M.D., Director, Pathology, MMC, Ch-3	: Member
7. Prof.S.G.Sivachidambaram, M.D., Director i/c, Inst.of Internal Medicine, MMC	: Member
8. Dr.Raghumani, M.S., Professor 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 Secretary, Ethics Committee

APPENDIX-B

CERTIFICATE FOR CONTENT VALIDITY

This is to certify that a tool prepared by **Ms.Sonia.M** , studying M.Sc.Nursing II year, College of Nursing, Madras Medical College, undertaking a Research study on **"A STUDY TO ASSESS THE EFFECTIVENESS OF APITHERAPY IN REDUCING ORAL MUCOSITIS AMONG HEAD AND NECK CANCER PATIENTS UNDERGOING RADIATION THERAPY AT RAJIV GANDHI GOVERNMENT GENERAL HOSPITAL, CHENNAI-03"**, has been validated by me and is found to be valid upto date and she can proceed with this tool to conduct the main study.

SIGNATURE WITH SEAL

N.V. 10.7.2012

Name :

Designation :

Date :

Place :

Dr. N.V. KALAIYARASI, MD,RT,DCH.,
REG. No: 39598
ADDITIONAL PROFESSOR
DEPT. OF RADIATION ONCOLOGY
RAJIV GANDHI GOVT. GENERAL HOSPITAL,
MMC, CHENNAI-3

CERTIFICATE FOR CONTENT VALIDITY

This is to certify that a tool prepared by **Ms.Sonia.M** , studying M.Sc.Nursing II year, College of Nursing, Madras Medical College, undertaking a Research study on **"A STUDY TO ASSESS THE EFFECTIVENESS OF APITHERAPY IN REDUCING ORAL MUCOSITIS AMONG HEAD AND NECK CANCER PATIENTS UNDERGOING RADIATION THERAPY AT RAJIV GANDHI GOVERNMENT GENERAL HOSPITAL, CHENNAI-03",** has been validated by me and is found to be valid upto date and she can proceed with this tool to conduct the main study.

PRINCIPAL
MADHA COLLEGE OF NURSING
MADHA NAGAR, KUNDRATHUR,
CHENNAI - 600 069
PHONE : 24780736

SIGNATURE WITH SEAL

Name : DR. TAMILARASI. B

Designation : PRINCIPAL

Date : 15.07.2015

Place : CHENNAI.

MADHA COLLEGE OF NURSING
15 JUL 2015
CHENNAI - 600 069

APPENDIX-C

From

Sonia.M,
M.Sc.,(N) II Year,
College of Nursing,
Madras Medical College,
Chennai - 03.

To

The Head of the Department & Professor,
Department of Radiation Oncology,
Rajiv Gandhi Government General Hospital,
Chennai - 03.

Through

The proper channel

Respected Sir /Madam,

Sub: Permission for conducting Research study at Department of Radiation oncology, Rajiv Gandhi Government General Hospital – requested –regarding

I, Sonia.M, M.Sc (N) II year student, College of Nursing, Madras Medical College, Chennai in partial fulfillment of M.Sc., Nursing course ,have a plan to conduct Research study on topic mentioned below at Department of Radiation Oncology, Rajiv Gandhi Government General Hospital ,Chennai -600 003.The period is from 06.07.2015 to 31.08.2015. I assure that I will not interfere with the routine treatment and routine activity of the department.

The topic is **"A STUDY TO ASSESS THE EFFECTIVENESS OF APITHERAPY IN REDUCING ORAL MUCOSITIS AMONG HEAD AND NECK CANCER PATIENTS UNDERGOING RADIATION THERAPY AT RAJIV GANDHI GOVERNMENT GENERAL HOSPITAL,CHENNAI-03".**

Forwarded
09/07/15

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

Thanking you

Yours sincerely,

(Sonia.M)

Date: 09.07.15
Place: Chennai - 03

Dr. N.V. KALAIYARASI, MD.,RT.DCH.,
REG. No: 39598
ADDITIONAL PROFESSOR
DEPT. OF RADIATION ONCOLOGY
RAJIV GANDHI GOVT. GENERAL HOSPITAL
MMC, CHENNAI-3

PRINCIPAL
COLLEGE OF NURSING
MADRAS MEDICAL COLLEGE
CHENNAI - 600 003

LETTER SEEKING PERMISSION FOR CONTENT VALIDITY

From

Sonia.M,
M.Sc (Nursing) II year,
College of Nursing,
Madras Medical College,
Chennai - 03.

To

The Head of the Department & Professor,
Department of Radiation Oncology,
Rajiv Gandhi Government General Hospital,
Chennai - 03.

Through Proper Channel,
Respected Sir/Madam,

Sub: Requisition for expert opinion on suggestion for content validity of the tools.

I, **Ms. Sonia.M,** studying M.Sc. Nursing II year, College of Nursing, Madras Medical College, Chennai-03 affiliated to Dr.M.G.R Medical University, Chennai. As a partial fulfillment of the requirement in the M.Sc Nursing Programme, I have to complete my dissertation and the topic I have selected is titled, **"A STUDY TO ASSESS THE EFFECTIVENESS OF APITHERAPY IN REDUCING ORAL MUCOSITIS AMONG HEAD AND NECK CANCER PATIENTS UNDERGOING RADIATION THERAPY AT RAJIV GANDHI GOVERNMENT GENERAL HOSPITAL, CHENNAI -03".**

Herewith, I have enclosed the tool for content validity and for your expert opinion and valuable suggestions.

Forwarded
09/7/15

Thanking you

Yours sincerely,

M. Sonia

(Sonia.M)

Enclosures

1. Statement and objectives of the study
2. Blue print of the tools
3. Content validity certificate

PRINCIPAL
COLLEGE OF NURSING
MADRAS MEDICAL COLLEGE
CHENNAI - 600 003

N.V.K 10/7/2015

Dr. N.V. KALAIYARASI, MD,RT,DCH.
REG. No: 39598
ADDITIONAL PROFESSOR
DEPT. OF RADIATION ONCOLOGY
RAJIV GANDHI GOVT. GENERAL HOSPITAL,
MMC, CHENNAI-3

APPENDIX-D

STUDY TOOL (SECTION-A: DEMOGRAPHIC INFORMATION)

1. Name of the patient : _____
2. Sex
   a. Male □
   b. Female □

3. Age in years
   a. 21 to 35 □
   b. 36 to 50 □
   c. 51 to 65 □

4. Religion
   a. Hindu □
   b. Christian □
   c. Muslim □
   d. Others □

5. Educational qualification
   a. Illiterate □
   b. Upto Primary level □
   c. Upto middle school level □
   d. Higher secondary level □

6. Total income per month
   a. <5,000 rupees/month □
   b. 5,001 – 10,000 rupees/month □
   c. 10,001 – 15,000 rupees/month □
   d. >15,000 rupees/ month □

7. Personal habits
    a. Smoking □
    b. Alcohol □
    c. Smoking and alcohol □
    d. Other tobacco products □
    e. No habit of tobacco or alcohol abuse □

8. Family history of cancer
    a. Yes □
    b. No □
    c. Not known □

9. Duration of illness
    a. 0 to 3 months □
    b. 4 -6 months □
    c. 7 – 12 months □
    d. More than 12 months □

10. Duration of treatment
    a. 0 -1 months □
    b. 1 to 6 months □
    c. More than 6 months □

SECTION-B National Cancer Institute – Cancer Toxicity Criteria

Observational Checklist & Scoring Key

It consist of 4 items such as

5. Ulceration
6. Erythema
7. Pain
8. Ability to swallow

Each item is categorized as follows,

Ulceration

0 = No Lesion	Score 0	= No Lesion
1 = <1cm^2	Score 1-9	= Mild
2 = 1-3cm^2	Score 10-18	= Moderate
3 = >3cm^2	Score 19- 27	= Severe

Erythema

0 = No Lesion	Score 0	= No Lesion
1 = <1cm^2	Score 1-9	= Mild
2 = 1-3cm^2	Score 10-18	= Moderate
3 = >3cm^2	Score 19- 27	= Severe

Pain

0 = No Pain

1-3 = Mild Pain

4-6 = Moderate Pain

5-9 = Severe Pain

10 = Worst Possible Pain

Ability to swallow

Ability to swallow foods without pain	-score 3
Ability to swallow with pain	- score 2
Requires intravenous rehydration	- score 1
Require parenteral or enteral nutrition	- score 0

1. ULCERATION

LOCATION	ULCERATION			
UPPER LIP	0	1	2	3
LOWER LIP	0	1	2	3
LEFT CHEEK	0	1	2	3
RIGHT VENTRAL AND LATERAL TONGUE	0	1	2	3
LEFT VENTRAL AND LATERAL TONGUE	0	1	2	3
FLOOR OF THE MOUTH	0	1	2	3
SOFT PALATE / FAUCES	0	1	2	3
HARD PALATE	0	1	2	3
Sub Total				
Total				

0 = No Lesion
1 = <1cm^2
2 = 1-3cm^2
3 = >3cm^2

Score 0 = No Lesion
Score 1-9 = Mild
Score 10-18 = Moderate
Score 19- 27 = Severe

Inference

a) No lesion
b) Mild
c) Moderate
d) Severe

2. **ERYTHEMA**

LOCATION	**ULCERATION**			
UPPER LIP	0	1	2	3
LOWER LIP	0	1	2	3
LEFT CHEEK	0	1	2	3
RIGHT VENTRAL AND LATERAL TONGUE	0	1	2	3
LEFT VENTRAL AND LATERAL TONGUE	0	1	2	3
FLOOR OF THE MOUTH	0	1	2	3
SOFT PALATE / FAUCES	0	1	2	3
HARD PALATE	0	1	2	3
Sub Total				
Total				

0 = No Lesion
1 = <1cm^2
2 = 1-3cm^2
3 = >3cm^2

Score 0 = No Lesion
Score 1-9 = Mild
Score 10-18 = Moderate
Score 19- 27 = Severe

Inference

a) No lesion
b) Mild
c) Moderate
d) Severe

3. PAIN

No pain	Mild			Moderate			severe			Worst pain
0	1	2	3	4	5	6	7	8	9	10

a) 0 = no pain Score 0
b) 1-3 = mild pain Score 1
c) 4-6 = moderate pain Score 2
d) 7-9 = severe pain Score 3
e) 10 = worst possible pain Score 4

4. ABILITY TO SWALLOW

a) Able to swallow foods without pain -score 3
b) Able to swallow with pain - score 2
c) Requires intravenous rehydration - score 1
d) Require parenteral or enteral nutrition - score 0

பகுதி - 1: சமுதாயகாரணிகள்

1. தனி நபர் பெயர்

2. பாலினம்

அ. ஆண் ☐

ஆ. பெண் ☐

3. வயது

அ.21 முதல் 35 ☐

ஆ.36 முதல் 50 ☐

இ.51 முதல் 65 ☐

4. மதம்

அ. இந்து ☐

ஆ. கிறிஸ்துவர் ☐

இ. முஸ்லிம் ☐

ஈ. மற்றவை ☐

5. கல்வி தகுதி

அ. முறை சாரா கல்வி ☐

ஆ. அடிப்படைக்கல்வி ☐

இ. மேல்நிலை கல்வி ☐

ஈ. கல்லூரி படிப்பு ☐

6. குடும்பம் மாத வருமானம்

அ. ரூ. 5,000க்கும் குறைவாக ☐

ஆ. ரூ. 5,001 - 10,000 ☐

இ. ரூ.10,001 - 15,000 ☐

ஈ. ரூ.15,000 க்கும் மேல் ☐

7. தனிபட்ட பழக்கம்

அ. புகை பிடித்தல் ☐

ஆ. மது அருந்துதல் ☐

இ. புகை பிடித்தல் மற்றும் மது அருந்துதல் ☐

ஈ. மற்ற புகையிலை பழக்கம் ☐

உ. புகை பிடித்தல் மற்றும் மது அருந்துதல் பழக்கம் இல்லை ☐

8. குடும்பத்தில் யாராவது புற்று நோயால் பதிக்கபட்டுள்ளார்களா?

அ. ஆம் ☐

ஆ. இல்லை ☐

இ. தெரியவில்லை ☐

9. நோய் காலம்

அ. 0 முதல் 3 மாதம் ☐

ஆ. 4 முதல் 6 மாதம் ☐

இ. 7 முதல் 12 மாதம் ☐

ஈ. 1 வருடத்திற்கு மேல் ☐

10. சிகிச்சை காலம்

அ. 0 முதல் 1 மாதம் ☐

ஆ. 1 முதல் 6 மாதம் ☐

இ. 6 மாதங்களுக்கு மேல் ☐

APITHERAPY PROCEDURE

DEFINITION:

Apitherapy or bee therapy is the use of products of the common honey bee for therapeutic purposes.

PURPOSE:

- To promote healing.
- To reduce the level of pain.
- To improve body's immune system.

PREPARTION OF THE PATIENT:

- Explain the procedure to the patient.

ARTICLES:

- Honey
- Ounce glass

PROCEDURE:

- Explain procedure to the subjects.
- Obtain consent from the subjects.
- Make the subject comfortable position.
- Ask the subject to swish with water.
- Pre assessment of oral mucositis.
- Apitherapy (20ml) of honey orally given to the patients before 15minutes and after 15 minutes of radiation therapy, ask the patient to swish 20 ml of honey for 5 minutes then swallow it.
- Do the procedure gently.
- Repeat the procedure until end of 3rd phase.
- Post assessment of oral mucositis.

HONEY RELATED INFORMATION

INTRODUCTION

Honey is one of nature's wonder. it is nectar gathered from the blossoms of many flowers by bees. It is then taken in to the beehive and changed by the worker bees. Worker bees remove the liquid from the nectar. The finished product is heavy syrup with 12 to 20 percent moisture and 80 to 85 percent sugar. It is a good source of quick energy for the human body.

DEFINITION

The definition of honey stipulates a pure product that does not allow for the addition of any other substance. This includes water or other sweeteners.

THE CONTENTS OF HONEY

- Sugar like fructose, glucose, sucrose, maltose, lactose and other disaccharides and trisaccharides
- Proteins, fats, vitamins, minerals, enzymes and amino acids
- Volatile aromatic substances
- Ashes and water etc

THE HONEY ANALYSIS

- Fructose : 38.2%
- Glucose : 31.3%
- Sucrose : 1.3%
- Maltose : 7.1%
- Water : 17.2%
- Higher sugar : 1.5%
- Ash : 0.2%
- Other/undetermined : 3.2%

NURTITIONAL VALUE PER 100g (3.5oZ)

- Energy : 1,272 KJ (304 K cal)
- Carbohydrate : 82.4 g
- Sugars : 82.12 g
- Dietary fiber : 0.2 g
- Fat : 0 g
- Protein : 0.3 g
- Water : 17.10 g
- Riboflavin (vit.B2) : 0.038 mg (3%)
- Niacin (vit.B3) : 0.121 mg (1%)
- Pantothenic acid (B5) : 0.068 mg (1%)
- Vitamin B6 : 0.024 mg (2%)
- Vitamin C : 0.5 mg (1%)
- Calcium : 6 mg (1%)
- Iron : 0.42 mg (3%)
- Magnesium : 2 mg (1%)
- Phosphorus : 4 mg (1%)
- Potassium : 52 mg (1%)
- Sodium : 4 mg (0%)
- Zinc : 0.22 mg (2%)

BENEFITS OF HONEY

- The most common use of honey as a microbial agent it as a dressing for wounds, burns and skin ulcers. This application has a long history in traditional medicine, additionally the use of honey reduces odors, reduces swelling, and reduces scarring, it also prevents the dressing from sticking to the healing wound.
- The honey has antibacterial properties has been established for over a century, but in many cultures it has been used as a medicine. It is now less established that honey inhibits a broad spectrum of bacterial and fungal species.

- Honey has powerful antimicrobial properties, which can soothe your raw tissue. Pour a teaspoon of honey into a large serving spoon and then top off the spoon with lemon juice. Swallow the concoction (without water) every few hours until symptoms clear up. Some people add a pinch of black or red pepper to increase blood circulation to the throat
- Honey is useful for the skin diseases. It can be applied externally for wounds, sores and burns. It is also believed to minizing disfiguring scar.
- Honey is useful in providing energy to the body.
- As it contains sugars which are quickly absorbed by the digestive system and converted in to energy. This can be used as instant energizer.
- As it is hygroscopic, it speeds up healing tissue and dries it up.
- Honey act as a sedative and it very useful in bed wetting disorders.
- Honey is very good antioxidant which restores the damaged skin and gives soft, young looks.
- Honey has antibacterial properties due to its acidic nature and enzymatically produced hydrogen peroxide.
- Constant use of honey strengthens the white blood corpuscles to fight bacterial and viral diseases.

PRECAUTIONS TO BE TAKEN BEFORE USING HONEY

- Honey should not be mixed with hot foods
- Honey should not be heated
- Honey should not be consumed when working in hot environment where you are exposed to more heat
- Honey should never be mixed with rain water, hot and spicy foods, and fermented beverages like whisky, rum, brandy, ghee and mustard.
- Honey includes nectar of various flowers of which some may be poisonous. Poison has hot or Ushant qualities. When honey is mixed with hot and spicy foods the poisonous properties get enhanced and cause imbalance of health status.

APPENDIX - E

INFORMED CONSENT

Title of the study : "A study to assess the effectiveness of apitherapy in reducing oral mucositis among head and neck cancer patients undergoing radiation therapy at Rajiv Gandhi Government General Hospital, Chennai".

Investigator : Sonia.M

Name of Participant :

Age/sex :

Date :

Name of the institution : Rajiv Gandhi Government General Hospital, Chennai-3

- I _____ have read/it has been read for me, the information in this form. I was free to ask any questions and they have been answered. I am over 20 yrs of age and exercising my free power of choice, hereby give my consent to be included as a participant in the study.
- I have read and understood this consent form and the information provided to me.
- I have had the consent document explained in detail to me & been explained about the nature of my study.
- My rights and responsibilities have been explained to me by the investigator.
- I agree to cooperate with the investigator & I have not participated in any research study at any time.
- I am aware of the fact that I can opt out of the study at any time without having to give any reason
- I hereby give permission to the investigators to release the information obtained from me as a result of participation in this study to the regulatory authorities, government agencies and Institutional ethics committee.
- I understand that they are publically presented; my identity will be kept confidential.
- I am aware that I have any question during this study; I should contact the concerned investigator.

Signature of Investigator
Date:

Signature of Participant
Date:

ஆராய்ச்சி ஒப்புதல் படிவம்

ஆராய்ச்சி தலைப்பு **:கதிர் இயக்க சிகிச்சையின் போது தலை மற்றும் கழுத்து புற்று நோயாளிகளுக்கு ஏற்படும் வாய்புண்ணை குறைக்க தேன் தடவுதல் பற்றிய ஆய்வு**

ஆய்வாளர் பெயர் : சோனியா.ம

பங்கேற்பாளர் பெயர் :

தேதி :

வயது/பால் :

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

ஆய்வாளர் கையொப்பம் பங்கேற்பாளர் கையொப்பம்

தேதி தேதி

INFORMATION TO PARTICIPANTS

Title of the study: "A study to assess the effectiveness of apitherapy in reducing oral mucositis among head and neck cancer patients undergoing radiation therapy at Rajiv Gandhi Government General Hospital, Chennai."

Name of the Participant : **Age/sex :**

Date :

Investigator : Sonia.M

Name of the institution : Rajiv Gandhi Government General Hospital, Chennai-3

Enrollment No :

You are invited to take part in this study. The information in this document is meant to help you decide whether or not to take part. Please feel free to ask if you have any queries or concerns. You are being asked to co-operate in this study being conducted in Rajiv Gandhi Government General Hospital, Chennai-3.

What is the Purpose of the Research (explain briefly)

This research is conducted to evaluate the effectiveness of Apitherapy among head and neck cancer patients undergoing radiation therapy in Rajiv Gandhi Government General Hospital, Chennai-3. We have obtained permission from the Institutional Ethics Committee.

Study Procedure

- The study will be conducted after obtaining approval from Institutional Ethics Committee.
- Patients with head and neck cancer on radiation therapy will be explained about the study procedures and purpose.
- Informed consent will be obtained from those who are willing to participate.
- Those who fulfill the inclusion criteria will be enrolled and randomized to either experimental or control group.
- Pre test assessment of oral mucosa will be done by National Cancer Institute – Cancer Toxicity Criteria (NCI-CTC) scale for both groups.
- The experimental group will receive oral application of apitherapy before radiation therapy, 15mins and 6 hrs after radiation therapy for 3 cycles. At

the end of 3 cycles the oral mucosa will be evaluated for mucositis by National Cancer Institute – Cancer Toxicity Criteria (NCI-CTC) scale.

- The control group will undergo oral mucosa examination for 3 cycles.

Possible Risks to you

No risks involved.

Possible Benefits to you

After finishing this study, investigator will provide information that apitherapy is effective in reducing oral mucositis among head and neck cancer patients undergoing radiation therapy.

Possible benefits to other people

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

Confidentiality of the information obtained from you

You have the right to confidentiality regarding the privacy of your personal details. Your privacy in the study will be maintained throughout the study in the event of any publication or presentation resulting from the research, no personally identifiable information will be shared. The information from this study, if published in scientific journals or presented at scientific meetings, will not reveal your identity.

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

Your decisions not to participate in this research study will not affect your activity of daily living, medical care or your relationship with investigator or the institution.

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 from this study at any time during course of the study without giving any reasons.

However, it is advisable that you talk to the research team prior to stopping the treatment.

Signature of Investigator Signature of Participant

Date: Date:

ஆராய்ச்சி தகவல் தாள்

ஆராய்ச்சி தலைப்பு :கதிர் இயக்க சிகிச்சையின் போது தலை மற்றும் கழுத்து புற்று நோயாளிகளுக்கு ஏற்படும் வாய்புண் குறைக்க தேன் தடவுதல் பற்றிய ஆய்வு

ஆய்வாளர் பெயர் : சோனியா.ம

பங்கேற்பாளர் பெயர் :

தேதி :

வயது/பால் :

பங்கேற்பாளர் எண் :

ஆய்வாளர் மேற்கொள்ளும் ஆராய்ச்சியில் பங்கேற்க யாருடைய கட்டாயமுமின்றி முழுமனதுடனும் சம்மதிக்கலாம். இதில் பங்கேற்பதன் நோக்கம். இந்த ஆராய்ச்சியில் தகவல்களை தெரிந்து கொள்வதற்காகவும். அதனை பயன்படுத்துவதற்காக மட்டும் தான்.

இந்த ஆராய்ச்சியின் நோக்கம்,கதிர் இயக்க சிகிச்சையின் போது தலை மற்றும் கழுத்து புற்று நோயாளிகளுக்கு ஏற்படும் வாய்புண் குறைக்க தேன் உபயோகபடுதலாம் என்பதே ஆகும்.

ஆராய்ச்சி மேற்க்கொள்ளும் முறை

இந்த ஆராய்ச்சியில் கதிர் இயக்க சிகிச்சை பெரும் தலை மற்றும் கழுத்து புற்று நோயாளிகளுக்கு ஏற்படும் வாய் புண்ணை குறைக்க 15 நிமிடம் கதிர் இயக்க சிகிச்சைக்கு முன்னும் 6 மணி நேரம் பின்னும் வாய் உட்புரதில் தேன் தடவ வேண்டும்.

இதனால் ஆய்வாளருக்கான பயன்

இந்த ஆய்விற்க்குபின் கதிர் இயக்க சிகிச்சை பெரும் தலை மற்றும் கழுத்து புற்று நோயாளிகளுக்கு ஏற்படும் வாய் புண்ணை குறைவதை அறியலாம்.

இதனால் பங்கேற்பாளருக்கான பயன்

இந்த ஆய்வு கதிர் இயக்க சிகிச்சை பெரும் தலை மற்றும் கழுத்து புற்று நோயாளிகளுக்கு ஏற்படும் வாய் புண்ணை குறைக்கும். ஆராய்ச்சியில் பங்கேற்கவில்லை என்றாலும், உங்களின் சராசரி வாழ்கைமுறை, மருத்துவரின் ஆலோசனை மற்றும் சிகிச்சை முறையில் எந்த வித மாற்றமும் ஏற்படாது என்பதை தெரிவிக்கிறேன்.

இந்த ஆராய்ச்சியல் பங்கேற்க விருப்பம் இல்லை என்றால் உங்களின் முழுமனதுடன் நீங்கள் இந்த ஆராய்ச்சியில் இருந்து விலகி கொள்ளலாம் என்பதை தெரிவிக்கிறேன்.

இந்த ஆராய்ச்சியில் உங்களின் மருத்துவதகவல்களை பாதுகாப்பாக வைத்துகொள்கிறேன் என்பதை தெரிவிக்கிறேன்.

இந்த ஆராய்ச்சியின் தகவல்களை வெளியிடும் போது, உங்களை பற்றிய அடையாளங்கள் வெளிவராது என்பதை உறுதி கூறுகிறேன்.

ஆய்வாளர் கையொப்பம் பங்கேற்பாளர் கையொப்பம்

தேதி தேதி

APPENDIX-F
CODING SHEET – EXPERIMENTAL GROUP

Sample number	Sex	Age in years	Religion	Educational qualification	Income per month	Personal habits	Family history	Duration of illness	Duration of treatment	Ulceration		Erythema		Pain		Ability to swallow	
										pre test	post test	pre test	post test	pre test	post test	pre test	post test
1	a	b	a	c	b	c	b	d	a	c	b	c	b	c	b	b	b
2	b	b	a	b	b	e	b	b	b	c	b	c	b	d	b	b	a
3	a	b	a	b	b	e	b	a	b	c	b	c	b	c	b	b	a
4	a	c	a	b	b	c	b	a	a	c	b	c	b	d	b	b	a
5	a	c	a	a	a	c	b	b	a	d	b	d	b	d	b	d	b
6	a	b	a	a	a	c	b	a	a	c	b	c	b	d	b	c	a
7	a	c	a	b	a	c	b	a	a	c	b	c	b	c	a	b	a
8	a	a	a	b	a	d	b	a	a	d	b	d	b	d	b	c	b
9	a	b	a	b	b	c	b	b	b	c	b	c	b	c	a	b	a
10	a	b	a	c	c	c	b	a	a	c	b	b	b	b	a	b	a
11	b	a	a	b	b	e	b	a	a	c	b	b	b	b	a	b	a
12	b	b	a	a	a	e	b	b	b	d	b	d	b	d	b	c	b
13	a	b	a	c	b	d	b	a	a	c	b	c	b	c	a	b	a
14	b	c	a	a	a	e	b	a	a	c	b	c	b	c	a	b	a
15	a	c	a	b	b	c	b	a	a	c	b	c	b	c	b	a	a
16	a	c	a	a	a	a	b	a	a	c	b	b	a	b	a	b	a
17	a	b	b	d	c	c	b	b	a	c	b	c	b	b	a	b	a
18	b	b	b	b	b	b	b	a	a	c	b	c	b	c	b	b	a
19	a	c	b	b	b	c	b	a	a	c	b	c	b	b	a	b	a
20	a	c	a	b	b	c	b	a	a	c	b	c	b	c	a	b	a
21	a	c	a	b	a	d	b	a	a	c	b	c	b	c	b	b	a
22	a	c	a	a	b	c	b	a	a	c	b	c	b	b	a	a	a
23	a	c	a	b	b	d	b	a	a	c	b	c	b	c	b	b	a
24	a	a	a	b	b	a	b	a	a	c	b	c	b	b	a	b	a
25	a	c	a	c	b	c	b	a	a	b	b	b	a	b	a	a	a
26	a	b	a	b	b	a	b	a	a	b	b	b	b	b	a	a	a
27	a	c	a	b	b	c	b	a	a	a	a	a	a	a	a	a	a
28	a	c	a	b	b	c	b	a	a	b	a	b	a	b	a	a	a
29	a	c	a	c	b	c	b	a	a	b	a	b	a	b	a	a	a
30	a	b	a	c	b	c	b	a	a	b	b	b	b	b	a	a	a

CODING SHEET – CONTROL GROUP

Sample number	Sex	Age in years	Religion	Educational qualification	Income per month	Personal habits	Family history	Duration of illness	Duration of treatment	Ulceration		Erythema		Pain		Ability to swallow	
										Pre test	Post test	Pre test	Post test	Pre test	Post test	Pre test	Post test
1	a	c	a	c	c	e	b	b	b	b	b	b	b	a	b	a	b
2	a	b	a	c	b	e	b	b	a	a	b	b	c	a	c	a	b
3	a	a	a	b	a	c	a	b	a	c	c	c	c	c	c	a	b
4	a	b	c	b	a	d	c	b	a	b	c	b	c	c	c	b	b
5	a	b	b	d	c	c	b	a	a	c	c	c	c	c	c	b	b
6	a	c	a	b	a	c	b	b	a	b	c	b	c	c	b	a	b
7	a	b	a	b	b	d	b	a	a	b	c	b	c	b	c	a	b
8	a	b	a	b	a	c	b	b	a	c	c	c	c	c	b	b	b
9	a	b	a	b	a	c	b	a	a	c	c	c	c	b	c	a	b
10	b	b	a	b	a	e	b	a	a	c	c	c	c	b	c	a	b
11	a	b	a	a	a	c	c	a	a	c	c	c	c	c	b	a	b
12	a	a	a	b	a	c	b	a	a	b	c	b	c	a	b	a	b
13	a	c	a	b	a	d	b	a	a	a	b	a	b	a	b	a	b
14	a	c	a	a	a	a	b	b	b	b	c	b	c	a	b	a	b
15	a	b	a	b	a	a	b	b	b	b	c	b	c	a	b	a	b
16	a	a	b	b	b	e	b	a	a	b	c	b	c	a	b	a	b
17	b	b	c	b	b	d	b	a	a	b	c	b	c	a	b	a	b
18	a	b	a	b	b	b	b	a	a	b	c	b	c	a	b	a	b
19	a	c	a	b	b	c	b	a	a	b	c	b	c	a	b	a	b
20	a	b	a	b	b	c	b	b	b	b	c	b	c	a	b	a	b
21	a	b	a	b	a	a	b	a	a	b	b	b	b	a	b	a	b
22	a	c	a	b	b	d	a	a	a	b	b	b	c	a	b	a	b
23	b	c	a	b	b	a	b	a	a	b	b	b	b	b	b	a	b
24	b	c	a	a	a	e	b	a	a	b	b	b	c	b	b	a	b
25	b	c	a	a	a	e	b	a	a	c	c	c	c	b	b	a	b
26	a	c	a	a	a	a	b	a	a	c	c	c	c	b	b	a	b
27	a	c	a	b	b	c	b	a	a	c	c	c	c	b	c	a	b
28	a	a	a	c	b	c	b	b	b	c	c	c	c	b	c	a	b
29	a	b	b	c	b	b	b	a	a	c	c	c	c	b	c	a	b
30	b	c	a	a	a	e	b	a	a	c	c	b	c	b	c	a	b

APPENDIX-G

CERTIFICATE OF ENGLISH EDITING

To whom so ever it may concern

This is to certify that the dissertation work ""**A STUDY TO ASSESS THE EFFECTIVENESS OF APITHERAPY IN REDUCING ORAL MUCOSITIS AMONG HEAD AND NECK CANCER PATIENTS UNDERGOING RADIATION THERAPY AT RAJIV GANDHI GOVERNMENT GENERAL HOSPITAL, CHENNAI-3.**" done by Mrs.Sonia.M. M.Sc (N) II year College of Nursing, Madras Medical College, Chennai-03 is edited for English language appropriateness.

SIGNATURE : 19/1/16

DESIGNATION : (N. RAMESH BABU)

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