EFFECT OF TOPICAL APPLICATION OF HONEY ON ORAL MUCOSA AMONG PATIENTS WITH HEAD AND NECK CANCER UNDERGOING RADIATION THERAPY AT SRI RAMAKRISHNA HOSPITAL, COIMBATORE.

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A Dissertation submitted to
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EFFECT OF TOPICAL APPLICATION OF HONEY ON ORAL MUCOSA AMONG PATIENTS WITH HEAD AND NECK CANCER UNDERGOING RADIATION THERAPY AT SRI RAMAKRISHNA HOSPITAL, COIMBATORE.

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ORAL MUCOSA

EFFECT OF TOPICAL APPLICATION OF HONEY ON ORAL MUCOSA AMONG PATIENTS WITH HEAD AND NECK CANCER UNDERGOING RADIATION THERAPY AT SRI RAMAKRISHNA HOSPITAL, COIMBATORE.

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Abstract

An interventional study was conducted to evaluate the effect of topical application of honey on oral mucosa. Post test with control group design was adopted. Convenient sample of 20 patients with head and neck cancer undergoing radiation therapy were selected. The honey application was done for 5 days and ongoing assessment was done using WHO oral Toxicity Assessment Scale (Cancer, 1979). The data were analysed with descriptive and inferential statistical methods. Hence the study concluded that honey application found to be an effective measures in managing and preventing radiation induced mucositis.
Effect of Topical Application of Honey on Oral Mucosa among Patients with Head and Neck Cancer Undergoing Radiation Therapy at Sri Ramakrishna Hospital, Coimbatore.

Equilibrium is maintained in between the number of new cases and its advancements in therapies. Everybody has the affinity towards the multiple modalities like ayurvedhic, siddha and homeopathy for recovery. But the basic concept is prevention rather than curing the disease after the occurrence. Rapidly emerging technology and dramatically expanding knowledge increase the responsibilities of a health care professional to face a complex health environment.

Nowadays cancer is a unisex disease. World wide 12% of deaths occur due to cancer, which is the third leading cause of death following infection and cardiovascular diseases. Cancer affects people at all ages with the risk for most types increasing with age. Cancer causes 13% of all human deaths in 2007 (7.5 million). In 2008 about 11 million peoples were diagnosed as cancer and 6.2 million peoples die every year (Feeley, 2008).

Cancer commonly occurs as a result of multi factorial causation like alcohol consumption, smoking, physical inactivity, obesity, use of exogenous hormones, exposure to ionizing radiation and occupational chemical exposures. Head and neck cancer refers to a group of biologically similar cancers originating from the upper aero digestive tract including lip, oral cavity (mouth), nasal cavity, paranasal sinuses, pharynx and larynx, salivary glands and the thyroid gland.
In 2009 the estimated number of head and neck cancer is of 35,720 new cases. Every year 80,000 oral cancer cases were diagnosed in our country. In India it is estimated 9.4% patients with oral cavity cancer, 6.9% with oropharynx carcinoma, 5.8% with hypopharynx cancer and 4% with larynx cancer.

The standard therapies to treat head and neck cancer includes surgical treatment, radiation therapy, biological therapy. But radiation therapy is a health indicator to treat the head and neck cancer. The most common complication of radiation therapy is oral mucositis. It has been estimated 30-60% of cases develops oral mucositis as a complication of radiation therapy for head and neck cancer. (Cancer statistics, 2009).

Honey is one of the oldest medicines. The honey is one of the natures most amazing and enduring medicinal product. Recent studies shows honey a natural byproduct of flower nectar from upper aerodigestive tract of the honey bee is effective in managing radiation induced mucositis (Liza, 1999).

The bacteriostatic and bactericidal effects of honey has been well documented. Honey possesses an effective antituberculosis effect. It was demonstrated that the growth of mycobacteria was inhibited by adding 10% of honey to the media. Based on this results Avicenna, is a recommended honey in the treatment of Tuberculosis.

1.1. NEED FOR THE STUDY

By 2020 the global burden of cancer is expected to rise by 50% due to increasing age population and rising trends in cancer risk factors. In the developed countries, this explosion of cancer cases is beginning to happen due to confluence of
two trends. The first is the fact that cancer strikes people over the age of 50 years with
greater frequency than it does in youth (Feeley, 2008).

Radiation therapy plays an important role in the management of head and neck
cancer. The majority of new cases with invasive head and neck cancer will require
radiation therapy as a primary treatment, as an adjunct to surgery. The most common
acute complication of radiation therapy in the head and neck region is oral mucositis.
It is estimated that 30-60% of patients receiving radiation therapy for head and neck
cancer develops radiation induced mucositis (Petersen, 2005).

Normally cell of the mouth undergo rapid renewal over a 7-14 days cycle.
Radiation treatment interferes with cellular regeneration and reduce the ability of the
oral mucosa to regenerate. Direct somato toxicity is usually seen 5-7 days after
administration of radiation therapy. The early radiation reaction causes discomforts in
drinking, swallowing which results in nutritional problems (National Institute of
health conference, 1980).

The consensus development panel of the National Institutes of health has
stated that no drugs can prevent mucositis. Routine oral care programs, removal of
mucosal irritation factors, cleansing of mucosa with chlorhexidine gluconate, saline
rinses, sodium bicarbonate rinses, local antibiotics, lozenges, is not found to be
effective in the management of radiation induced mucositis.

The radiation induced mucositis alters the patients quality of life creating pain
and discomfort. This enforces the Western Consortium Cancer Nursing research
foundation to form Oral mucositis assessment scale for the systematic ongoing
assessment of the oral mucosa for the patients undergoing radiation therapy. (Scully, 1996).

Complementary therapies such as massage, acupressure, herbal remedies, and aroma therapy are raising in popularity among patients and nursing care professionals and are increasingly used in palliative and preventive care to improve the quality of life among patients (Hanyu, 2002).

Honey is an ancient remedy for the treatment of infected wound which has recently being rediscovered by the medical profession particularly where the conventional modern therapies are failing. There is also wide evidence suggests that honey actively promote healing. In laboratory studies honey has been shown to have an antimicrobial action against a broad spectrum of bacteria and fungi (Molan, 1992).

It has an excellent track record over 4000 years of usage as a wound dressing. Honey has potent antibacterial activity and is very effective in clearing wounds and protecting wounds from infection. It also has a debriding effect, an anti-inflammatory action and stimulatory effect of granulation and epithelialisation. (Allen, et al., 2000).

Honey contains 0.5% of proteins, mainly enzymes and aminoacids. Three main honey enzymes are diastase, invertase and glucose oxidase. The glucose oxidase produces hydrogen peroxide exert an antibacterial effect into the oral cavity (Somal, et al., 1994).
Honey inhibits the growth of microorganisms and fungi. The antibacterial effect of honey, mostly against gram negative bacteria is very well documented. The high sugar content of honey inhibits bacterial growth (Molan, 1999).

It possess anti-inflammatory effects by reducing prostaglandins synthesis. Daily ingestion of 70 gm honey reduces mean plasma concentration of thromboxane and the level of prostaglandins was decreased by 31% at 2 hours and 14% after 3 hours of honey ingestion (Nasuti, 2006).

Honey has been found to contain significant anti oxidant activity including glucose oxidase, phenolic acids, carotenoids derivatives and flavonoids. A significant correlation between the anti oxidant activity and the presence of phenolic acids. Anti oxidant activity of honey is linked to the observed anti cancer and anti atherosclerosis effects (Mamary, 2002).

A randomized single blind clinical trial was conducted among 40 patients with head and neck cancer requiring radiation therapy to oro-pharyngeal mucosa. 20 patients were assigned to study group and they receive honey while the control group received standard protocol regimens. In study group 20 ml honey was applied to 15 minutes before and after radiation therapy and 6 hours of post radiation therapy. In control group patients were instructed to rinse with 20 ml of saline after radiation therapy. Patients were evaluated weekly for progression of mucositis using Oral mucositis assessment scale. The mucositis scores for the two groups analysed using Friedman test and at the end of each week the study group has significant lower score than control group (Motallebnejad, 2008).
According to clinical study oral honey stimulates antibody production during primary and secondary immune responses against thymus-dependent and thymus-independent antigens. It has been reported that honey stimulates T-lymphocytes in cell culture to multiply, and activates neutrophils. In an study with humans receiving a diet supplemented with a daily honey consumption of 1.2 g/kg body weight has the following effects: Increase of serum iron by 20% and decrease of plasma ferritin by 11%, an 50 % increase of monocytes and slight increases of lymphocyte and eosinophil percentages, reduction in serum of immunoglobulin E (34%) aspartate transaminase (22%) and alanine transaminase (18%), lactic acid dehydrogenase (41%), fasting sugar (5%) and creatine kinase and finally an increase in blood of copper (33%) and slight elevations of zinc and magnesium, hemoglobin and packed cell volume (Waili, 2003).

Considering the above facts the researcher implements the topical application of honey on oral mucosa as a non-pharmacological measure to reduce the complication of radiation therapy induced mucositis.

1.2. STATEMENT OF THE PROBLEM

EFFECT OF TOPICAL APPLICATION OF HONEY ON ORAL MUCOSA AMONG PATIENTS WITH HEAD AND NECK CANCER UNDERGOING RADIATION THERAPY AT SRI RAMAKRISHNA HOSPITAL, COIMBATORE.

1.3. OBJECTIVES

1.3.1. Topical application of honey on oral mucosa before and after exposure to Radiation therapy among patients with head and neck cancer.
1.3.2. Identify the effect of honey on radiation induced mucositis among Patients with head and neck cancer.

1.4. OPERATIONAL DEFINITION

1.4.1. Effect

It is a state of reduction of oral mucositis after topical application of honey.

1.4.2. Topical application

Application of medication on body surfaces such as the skin or mucous membranes.

1.4.3. Honey

Honey is a natural product obtained from upper aero digestive tract of honey Bee.

1.4.4. Oral mucosa

It is a protective covering layer of an oral cavity.

1.4.5. Radiation Therapy

An electric machine generating ionizing radiation to control the abnormal Proliferation of cancer cells

1.5. CONCEPTUAL FRAME WORK

Widen Bach’s helping art clinical nursing theory (1964) was chosen as conceptual framework for this study. It consists of three components such as identification, ministration and validation.
(i) **Identification**

Patients with head and neck cancer of all stages undergoing radiation therapy were selected based on the demographic variables including age, Gender, Personal habits, Co-morbid illness, Diagnosis, Radiation cycle, Bio-physiological parameters (temperature, pulse, respiration, blood pressure), and general examination of oral cavity.

(ii) **Ministration**

The researcher randomizes the samples into experimental group and control group. The experimental group receives intervention and control group receives only the routine care. The experimental group receives topical application of honey on oral mucosa in the following sequence, 15 ml of honey applied 15 minutes prior to radiation therapy, 15 minutes after radiation therapy and 6 hours of post radiation therapy for the duration of 5 days. The experimental group receives routine nursing care and an ongoing assessment was done for both experimental and control group.

(iii) **Validation**

In post test, the researcher assesses the effect of honey on oral mucosa of experimental group using world health organization oral toxicity assessment scale.
FIG. 1.1.
CONCEPTUAL FRAMEWORK ON MODIFIED WIDEN BACH’S HELPING ART OF CLINICAL NURSING THEORY (1964)

Identification

(i) Age
(ii) Gender
(iii) Personal habits
(iv) Co-morbid illness
(v) Diagnosis
(vi) Radiation cycle
(vii) Bio-physiological parameters (temperature, pulse, respiration, blood pressure)
(viii) General examination of oral cavity

Ministration

Experimental group

(i) Make patient in a comfortable position.
(ii) Ongoing assessment of oral cavity
(iii) Topical honey application (15 ml) on oral mucosa
   a. 15 minutes before radiation therapy
   b. 15 minutes after radiation therapy
   c. Six hours of post radiation therapy

Control group

(i) Ongoing assessment of oral cavity.
(ii) No administration of topical honey application on oral mucosa

Validation

Assess the progression of oral mucositis by WHO oral toxicity assessment

Experimental group
No development and progression of mucositis

Control group
Development and progression of mucositis

Identifying a need for help

(Source: Wesley, 1964)
1.6. PROJECTED OUTCOME

Topical application of honey on oral mucosa among patients with head and neck cancer undergoing radiation therapy will help to manage and prevent the radiation induced oral mucositis.
REVIEW OF LITERATURE

Literature review is an essential component for the researcher to understand the research problem and its major aspect. It helps the researcher to apply different approaches to solve the problem. The components described in this chapter are literatures related to cancer, honey application, studies on honey application and the management of radiation induced mucositis.

2.1. LITERATURES RELATED TO CANCER

Cancer is a disease that begins in the cells of the body. In normal situations, the cell grows and divide as the body needs them. This orderly process is disturbed when new cells form that the body were not needed and cells die (Smeltzer, 2009).

Cancer affects all communities world wide, approximately 10 million people are diagnosed with cancer and more than 6 million die of the disease every year. About 22.4 million persons were living with cancer in the year 2000. The most common cancers world wide is lung cancer (12.3%), breast cancer (10.4%) and colorectal cancer (9.4%). Males are predominantly affected by lung, stomach, esophageal, liver, stomach, esophageal, liver and bladder cancers (Park, 2009).

The burden of cancer is distributed equally between developed and developing countries, the total cancer burden is highest in effluent societies mainly due to high incidence of tumor associated with smoking and western life style ie., cancer of the lung, colorectum, breast, and prostrate. In developing countries, upto 25% of tumors are associated with chronic infections (eg) hepatitis B (liver cancer), human papilloma viruses (cervical cancer), and Helicobacter pylori (stomach cancer). In some western
countries, cancer mortality rates have recently started to decline, due to reduction in smoking, early detection of cancer by effective screening and advancements in cancer therapy (Park, 2009).

In India, the national cancer registry programme of the Indian Council for Medical Research (ICMR) provides data on incidence, it is estimated that there are approximately 2-2.5 million cases of cancer in India at any given point of time, with each year. The cancer registries in India cover a population of 34 million, i.e., 18.4 million males and 15.6 million females. Among males, high incidence rates were reported for tobacco-related cancers. The number of cancer cases among males is estimated as 3.9 lakhs and among females as 4.5 lakhs. The more frequent cancer in males in India are mouth/oropharynx, oesophagus, stomach, and lower respiratory tract (trachea/bronchus/lungs). For women cancer of cervix, breast, mouth/oropharynx and esophagus are the most frequent (Park, 2009)

2.2. LITERATURES RELATED TO RADIATION INDUCED MUCOSITIS

The term mucositis is coined to describe the adverse effects of radiation and chemotherapy treatments. Mucositis is the common adverse reactions encountered in radiation therapy for head and neck cancers. It is estimated that there is 30-60% incidence of developing mucositis among patients receiving radiation therapy for head and neck cancer. The exact pathophysiology of development of mucositis is not known.

Annually 400,000 cases of treatment induced damage to the oral cavity. Severe oral toxicities also compromise the delivery of optimal cancer therapy protocols. A variety of patient related factors are responsible for the increased
potential for developing mucositis. It is stated that up to 75% of the general population has chronic periodontal diseases, and acute bacterial superinfections may follow chemo and radiation therapy.

**MECHANISMS OF MUCOSITIS DEVELOPMENT**

*Direct Mucositis*

The epithelial cells of the oral mucosa undergo rapid turnover, usually every 7 to 14 days which makes susceptible to the effects of cytotoxic therapy. Radiation therapy interferes with the maturity and cellular growth of epithelial cells, causing changes to normal turnover and cell death.

*Indirect Mucositis*

Oral mucositis can also be caused by the indirect invasion of Gram-negative bacteria and fungal species. Patients are at increased risk for oral infections when they are neutropenic. The onset of mucositis develops with in 10-21 days.

**PHASES OF MUCOSITIS DEVELOPMENT**

*Phase I: Initial inflammatory / vascular phase*

During this phase, exposed cells (epithelial, endothelial, and connective cells) in the buccal mucosa release free radicals, modified proteins, and proinflammatory cytokines, including interleukin – 1B, prostaglandins, and tumor necrosis factor. These inflammatory mediators cause further damage either directly or indirectly by increasing vascular permeability, there by enhancing cytotoxic drug uptake into the oral mucosa.
**Phase II: Epithelial phase**

In this phase, radiation retards cell division in the oral mucosal epithelium, leading to reduced epithelial turnover and renewal, resulting in epithelial breakdown. This results in erythema from increased vascularity and epithelial atrophy 4-5 days after the initiation of radiation therapy. At this stage, microtrauma from day-to-day activities such as speech, swallowing, and mastication leads to ulceration.

**Phase III: Ulcerative/ bacteriological phase**

Epithelial break down ultimately results in the ulcerative phase which occurs with in 1 week of therapy.

**Phase IV: Healing phase**

The duration of this phase usually lasts from 12 to 16 days and depends on factors such as epithelial proliferation rate, absence of factors interfering with wound healing like infection and mechanical irritation.

**2.3. LITERATURES RELATED TO HONEY APPLICATION**

Subrahamanyam (1991) included 104 cases of superficial burn injury to assess the efficiency of honey as a dressing in comparison with silver sulfadiazine gauze dressing. In 52 patients treated with honey and the 91 percent of wounds were rendered sterile within 7 days. In 52 patients treated with silver sulfadiazine, 7% showed control of infection within 7 days. Healthy granulation tissue was observed earlier in patients treated with honey (mean 7.4 versus 13.4 days). In control group only 10% of wounds healed within 15 days. It shows honey as an ideal dressing in the treatment of burns.
Ladas, Haritos., Raptis (1995) conducted a clinical trial at Greece. This hypothesis was investigated in 20 healthy volunteers (13 males, 7 females) with a mean (+/- SD) age of 35.9 +/- 12.1 y. Each subject drank the following aqueous solutions in random order: 20 g lactulose, 100 g honey, 50 g honey, and 35 g each of a glucose and fructose mixture. Within 10 h after the ingestion of 100 g honey, 50 g honey, and the glucose-fructose mixture, six, three and none of the volunteers, respectively, reported loose stools (chi 2 = 7.1, df = 2, P < 0.03). The results of this study suggest that honey have a laxative effect.

Bell (1996) conducted 2 studies at Neonatal intensive care unit, All children Hospital, Saint Petersburg using honey for treating wounds (in skin damage in children, total of 50 samples were selected and 25 samples allotted to experimental group and 25 to control group and at the end of 10 days of honey application it has been evaluated that the use of honey for treatment of wound infections in neonates is very effective and other reported honey for treatments of diaper dermatitis.

Subrahmanyam (1998) randomly allocate 25 patients in two groups, compare the effectiveness of honey with silver sulfadiazine dressing on superficial burn wound healing of the wounds treated with honey 84 percent showed satisfactory epithelialization by the 7th day and 100% of patients by the 21st day. In wounds treated with silver sulfadiazine, epithelialization occurred by 7th day in 72% of patients and in 84% of patients by 21 days. Thus in honey dressed wounds, early subsidence of acute inflammatory changes, better control of infection and quicker wound healing.
Vardi (1998) described 9 neonates who had undergone major operations and presented with chronic open wounds that failed to heal with conventional treatment after 14 days. Conventional treatment failure was defined after 14 days of systemic antibiotics, the wound was still open, with oozing pus. The honey based dressing usage resulted in improved wound healing in all neonates after 5 days of treatment and all wounds closed within 21 days.

Moore, Campbell, Seers, Quay, Moore (2000) investigates topical application of honey in superficial burns and wounds through a systematic review randomized controlled trials. One study in infected postoperative wounds compared honey with antiseptics plus systemic antibiotics. The number needed to treat with honey for good wound healing compared with antiseptic was 2.9 (95% confidence interval 1.7 to 9.7). Five studies in patients with partial thickness or superficial burns involved less than 40% of body surface area, the number treated for seven days with honey produce 2.6 compared with other treatment. It shows honey is useful.

Molan (2001) proves honey dressing provides a moist healing environment, rapidly clears infection, deodorizers and reduces inflammation, edema and exudation. Also the results shows the healing rate of wound is increased by the stimulation of angiogenesis, granulation and epithelization.

Fox (2002) conducted a case studies at University of Wikato, Hamilton, Newzealand and identified various clinical observations on medicinal effect of honey which states honey is effective in rapid clearance of infection, inflammation, swelling
and pain. It reduces odour by inducing shedding of necrotic tissue. Honey hastens the granulation and epithelization and minimize the scarring.

Lusby, Coombes, Wilkinson (2002) states that physicochemical properties i.e., osmotic effects and pH of honey aid in antibacterial effects. Honey also possess anti-inflammatory activity and stimulate immune responses within a wound. This multiple studies conducted by Lusby reviews that honey must incorporated into the management of a large number of wound types.

Topham (2002) reported scales healing when honey is used in some cavity wounds. He suggested 3 potential mechanisms like saccharides at the wound surface encourage hyaluronic acid production which simultaneously suppresses the fiber forming collagens, enables wound healing proteoglycans and the sugar attachers to the collagen may change its structure.

Misirlioglu, Eroglu, Karacaoglan, Akan, Akoz & Yidirim (2003) compared honey impregnated gauze with 3 other dressings (hydrocolloid, paraffin gauze and saline soaked gauze) on split- thickness, skin graft donor sites. Eighty eight patients grafts were treated half with the honey based dressing and half with one of the other 3 dressings. The honey treated group shows foster epithelization time and lower pain compared to other dressings.

Namias (2003) explored the use of honey in necrotizing soft tissue infections, post surgical wound infections, wounds other than post surgical infections. The purpose of the paper is to stimulate thought among surgeons to consider the use of honey when more conventional therapies failed.
Ahmed, Hoektra, Hage, Kari (2003) examined the use of honey dressings with 21 patients with chronic wounds, 23 with complicated surgical wounds, and 16 with acute traumatic wounds. Treatment lasted for 1 to 28 weeks, all wounds had failed previous treatments. In this 57 of 59 patients (96.6%) achieved healing of their wounds. During honey treatment there is decreased edema, wound exudate, decreased odour and advanced epithelialization.

Hon (2005) conducted case study design with samples of 50 with dystrophic epidemolysis bullosa. The inclusive criteria states that the interventional group must possess chronic wounds, and they were treated with honey impregnated dressing. The results shows healing of wound take place in 15 weeks and wound closed completely.

Okeniyi, Olubanjo, Ogunlesi, Oyelami (2005) examined healing of 43 incised pyomyositis abscess wounds with honey in 32 Nigerian children. The most common cause of infection was S. aureus, which was attributed to hot and humid tropical climate, poor hygiene and malnutrition. All children received antibiotics, but the hospital length of stay was shorter and wounds healed faster in the honey treated group.

Ingle, Levin, Pollinder (2006) compare the effectiveness of honey and intrasite gel dressings on wound healing. A prospective, randomized, double blind controlled trail was carried out among goldmine workers. The results shows the mean healing times of shallow wounds treated with honey shows P=0.75, 355 confidence interval on wound healing, 27%-101% patients treated with honey experienced less itching and pain. The average cost of treatment per patient with honey was 0.49 and Rs. 12.03 with intrasite Gel. It shows honey is a safe, satisfying and effective healing agent.
Mcintosh, Thompson (2006) conducted double blind randomized trial with participants (n=100) and randomly assigned n=52 to honey based dressing and n=48 receives paraffin impregnated tulle gauze. Mean healing times were 40.38 days (SD 18.1) for honey group and 52.02 days (SD 25.42) for a paraffin tulle gras.

Moolengaar, et al., (2006) initiated a prospective randomized controlled study in Caucasian women who receive radiotherapy to the breast or the thoracic wall and developed grade 3 radiation induced dermatitis. In 21 women 24 skin reactions were evaluated. 12 were treated with a honey dressing and 12 with paraffin dressings. Subjects treated with honey dressing had a trend toward less pain, itching and irritation.

Mphande, Kilowe, Phalira, Jones, Harrison (2007) investigate the efficacy of honey and sugar dressings on wound healing. In this randomized controlled trial 40 patients were enrolled, 18 received sugar dressings and 22 with honey dressings. In honey group 55% of patients had positive wound cultures at the start of treatment and 23% at one week, compare with 52% and 39% respectively in the sugar group. The rate of healing in first two weeks of treatment was 3.8cm2/ wk for honey group and 2.2cm2/wk for sugar group. The results shows honey appears to be more effective than sugar in reducing bacterial contamination and promoting wound healing in treating superficial wounds or burns.

Khan, Abadin & Rauf (2007) did extensive literature search and found interesting facts about nutritional and medical value of honey. Honey is not only used as nutrition but also used in wound healing and as an alternative treatment for clinical conditions ranging from gastro intestinal tract (GIT) problems to ophthalmic
conditions. It has also been sued as wound barrier against tumour implantation in laproscopic oncological surgery. Based on these facts use of honey is highly recommended in the surgical wards.

Gunes, Eser (2007) conducted a randomized clinical trial comparing honey dressing versus ethoxy-diaminoacridine dressing (n=11) on pressure (n=15) ulcer healing). Wounds were traced and evaluated with pressure ulcer scale. The honey group had 4 times healing rate than of control group.

Gethin, Cowman (2008) conducted a randomized clinical trail at Royal College of Surgeons in Ireland, to compare the efficacy of honey and hydrogen dressing in sloughy venous leg ulcers. It was prospective open label multicentre randomized controlled trail with blinded microbiological outcome analysis. Wound swabs were taken at the initial stage and after 4 weeks of the treatments. Total of 108 patients with 35 males, 73 females aged 24-89 years (mean 68) enrolled into the study. The experimental group receives honey based dressing and the control group receives hydrogel based dressing and at the end of 4 weeks 33% treated with honey shows 70% chronic venous ulcers desloughed and elimination of methicillin resistant staphylococcus aureus comparing with the group under hydrogel dressing.

According to a clinical trail conducted by Eddy, Gideonsen &Mack (2008). At University of Wisconsin School of medicine and public health, identify the low cost effectiveness of honey based dressing for treating diabetic ulcers. The experimental group receives honey based gauze dressings on the diabetic wound for a duration of 6 months. At the end of second week granulation tissues appeared 4 at a period of 6 to
12 months the ulcers resolved completely. It shows honey based dressing has excellent track on wound healing.

Medhi (2008) did an extensive study to evaluate the efficacy of honey application in the treatment of wound healing. Literature research was carried out from 1966 to July 2008. The 5 observational studies with 160 patients and 963 cases in 10 controlled trials where 511 patients were treated with honey. Most of the patients reported 99% of complete wound healing within 2-9 weeks in observational and 56% in controlled trails.

Wijesinghe, Weatherall, Perrin, Beasley (2009) conducted a systematic review and metaanalysis of randomized controlled trials to compare the effectiveness of honey and silver sulfadiazine impregnated dressing in the management of burns. Eight studies with 624 subjects were included in the meta-analysis. In most studies unprocessed honey, an usage shows wound healing at 15 days comparing to other dressings.

2.4. LITERATURES RELATED TO TOPICAL APPLICATION OF HONEY IN THE MANAGEMENT OF RADIATION INDUCED MUCOSITIS

Biswall, Zakaria, Ahmad (2000) conducted randomized clinical trial to identify the effect of topical application of honey on oral mucosa for the patients with head and neck cancer undergoing radiation therapy. Using radiation therapy oncology group grading scale the oral mucosa is assessed and the experimental group received 20 ml of honey 15 minutes and 6 hours after radiation. The control group received no intervention. Patients receives honey application shows a significant reduction of
mucositis form grade III to grade II. The patients in control group progresses from grade III to grade IV. It shows honey is significant in reduction of mucositis.

Springer Berlin, Heidelberg (2003) conducted a randomized controlled trial by selecting 40 patients diagnosed with head and neck cancer requiring radiation to the orpharyngeal mucosa were divided into two groups. In the experimental group patients were advised to take 20 ml of pure honey 15 min before, 15 min after and 6 hour post radiation therapy. The results show the significant reduction in symptomatic grade ¾ mucositis among honey treated patients compared to control.

Rashad, Gezawr, Gezawy, Azzar (2009) conducted a study among 40 patients diagnosed with head and neck cancer. Controlled patients were randomized either treatment group receiving concomitant chemotherapy and radiation therapy. Study group receives topical application of pure honey and control group without honey. Patients were evaluated clinically every week to assess the development of radiation induced mucositis. In the treatment group no patients developed grade four mucositis and only three patients (15%) developed grade 3 mucositis. In control group 13 patients (65%) grade 3 or 4 mucositis (p<0.05). This study shows honey as prophylactic in reducing mucositis resulting from radio chemotherapy in patients with head and neck cancer.

Motallebnejad, Akram, Moghadamnia, Moulana, Omidi (2003) conducted randomized single blind (examiner blind) clinical trial of 40 patients with head and neck cancer requiring radiation to the oral pharyngeal mucosa and they were randomly assigned to study and control groups. In the study group patients were instructed to take 20ml of honey 15 minutes before radiation therapy, then again at
intervals of 15 minutes and six hours after radiation. In the control group patients were instructed to rinse with 20 ml of saline before and after radiation. Patients were evaluated weekly for progress and mucositis using oral mucositis assessing scale (OMAS). The results shows a significant reduction in mucositis among honey received patients compared with controls (p=0.000).
METHODOLOGY

The present study was designed to explore the effectiveness of honey on oral mucosa among patients with head and neck cancer undergoing radiation therapy. The methodology of the present study includes research design, setting, population, criteria for sample selection, variables of the study, material for data collection, validity of the tool, hypothesis and techniques of data analysis and interpretation.

3.1. RESEARCH DESIGN

Post test with control group was adopted in this study.

FIG.3.2
RESEARCH DESIGN

Population
Sample identified
Random assignment

Experimental Group (N=10)
Topical honey application
Progress of mucositis
Prevention and reduction of oral mucositis
Effect of honey application

Control Group (N=10)
No Topical honey application
Progress of mucositis
Progression and development of oral mucositis
3.2. SETTING

The study was conducted in Sri Ramakrishna Hospital, Oncology unit. The Department of Oncology and Research unit consists of 150 beds. The Head and Neck cancer patients were treated as inpatient and out patient basis. Nearly 50 patients with head and neck cancer were treated with radiation therapy per month.

3.3. POPULATION

3.3.1. Population

The population for the present study was patients with different stages of head and neck cancer posted for radiation therapy.

3.4. CRITERIA FOR SAMPLE SELECTION

3.4.1. Inclusion criteria

(i) Patients diagnosed as Head and neck cancer

(ii) Patients posted for radiation therapy

(iii) Patients of age group above 18 years

3.4.2. Exclusion criteria

(i) Patients with Diabetes mellitus

(ii) Patient with Tracheostomy tube

(iii) Critically ill patients

(iv) Patients with grade IV mucositis

3.5. SAMPLING

A convenient sampling of 20 participants with different stages of head and neck cancer, both male and female were drawn as sample for the present study.
3.6. VARIABLES OF THE STUDY

Variables

- Independent variable → Topical application of honey on oral mucosa
- Dependent variable → Radiation induced mucositis

3.7. MATERIALS

1. Assessment of bio-physiological parameters
2. Oral toxicity assessment scale (World Health Organisation, 1979)

3.7.1. Assessment of bio-physiological parameters

The bio-physiological parameter helps to provide opportunity for early identification of deviations from normal. The appropriate standardised instruments and procedures for assessing the bio-physiological parameters were followed by every professional in the clinical setting. Hence the researcher adopted the same method in checking the bio-physiological parameters such as respiratory rate, pulse rate, systolic blood pressure and diastolic blood pressure.

3.7.2. Oral Toxicity Assessment Scale

Oral toxicity assessment scale was recommended by World Health Organisation to measure anatomical, symptomatic and functional components of oral mucositis.

<table>
<thead>
<tr>
<th>GRADE</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Soreness + Erythema</td>
<td>Erythema ulcers, and patient can swallow solid food</td>
<td>Ulcers with extensive erythema and patient cannot swallow solid food</td>
<td>Mucositis to the extent that alimentation is not possible</td>
<td></td>
</tr>
</tbody>
</table>
Administration

1. Assessment of oral cavity and bio-physiological parameters before topical application of honey on oral mucosa
2. Make patient in a comfortable position
3. Apply 15 ml of pure honey on oral mucosa using sterile cotton tip applicator in the following sequence:
   - 15 minutes before radiation therapy
   - 15 minutes after radiation therapy
   - 6 hours of radiation therapy
4. Ongoing assessment of oral cavity and the bio-physiological parameters was done for the duration of 5 days among the control group and study group

3.8. VALIDITY OF THE TOOL

The WHO Oral toxicity assessment scale (1979) has internal consistency and the reliability obtained for this tool is 0.90 and yielded high correlation (Sung, 2007).

3.9. HYPOTHESES

Following alternative hypothesis were formulated

H₁: There is a significant difference between the oral mucositis score of experimental and control group after topical application of honey on oral mucosa.

3.10. PILOT STUDY

Pilot study was conducted to find out the feasibility and practicability of the study. The study was conducted in Sri Ramakrishna Institute of Oncology and Research at Coimbatore for a period of ten days. A convenient samples of 14 head and neck cancer patients were selected, seven to experimental group and seven to
control group were randomly assigned. Bio-physiological parameters and World health organisation oral toxicity assessment scale was used to assess the oral mucosa before and after honey application radiation therapy. The result revealed that there is significant prevention and reduction of mucositis in experimental group.

3.11. MAIN STUDY

The main study was conducted to meet the objectives of the present study. A convenience sampling of 20 patients was selected. The baseline data were obtained from records of the patients. The oral cavity assessment was graded using WHO oral toxicity assessment scale and bio-physiological parameters were assessed in both experimental and control group prior to intervention. After the intervention, WHO oral toxicity scale was administered to assess the progression of oral mucositis and bio-physiological parameters in experimental group where as in control group along with daily routine care oral cavity and bio-physiological parameters were assessed without intervention. At the end of 5th day the experimental group does not progressed in development of oral mucositis and control group progressed and developed oral mucositis.

3.12. TECHNIQUES OF DATA ANALYSIS AND DATA INTERPRETATION

Appropriate statistical techniques such as descriptive statistics and inferential statistics was applied to analyse the data.
DATA ANALYSIS AND INTERPRETATION

This chapter represents the method of analysis and interpretation of the data. The study was conducted to find out the effect of topical application of honey on oral mucosa among cancer patients undergoing radiation therapy. Data was collected from 20 samples. The findings were tabulated, analysed and interpreted in this chapter. The data was computed using descriptive and inferential statistics.

SECTION – I

4.1.BASELINE DATA PRESENTATION

The demographic proforma of cancer patients were collected in terms of age and gender. These data was presented in the form of table and groups.
TABLE 4.1.
DISTRIBUTION OF AGE
(N = 20)

<table>
<thead>
<tr>
<th>Age in years</th>
<th>Experimental group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of Patients</td>
<td>Percentage (%)</td>
</tr>
<tr>
<td>31 – 40</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>41 – 50</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>51 – 60</td>
<td>4</td>
<td>40</td>
</tr>
<tr>
<td>61 – 70</td>
<td>2</td>
<td>20</td>
</tr>
<tr>
<td>71 – 80</td>
<td>2</td>
<td>20</td>
</tr>
<tr>
<td>81 – 90</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>91 – 100</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

The above mentioned table reveals that in experimental group around 40% of them were between 51-60 years of age. In control group around 60% of them ranges from 41-80 years of age.
The above mentioned table reveals that both in experimental group and control group 60% were male and 62% were female respectively.
TABLE 4.3.
DISTRIBUTION OF RESPONDENTS BY COMORBID ILLNESS

(N = 20)

<table>
<thead>
<tr>
<th>Comorbid illness</th>
<th>Experimental group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of Patients</td>
<td>Percentage (%)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1</td>
<td>10</td>
</tr>
</tbody>
</table>

The above mentioned table reveals 10% of control group were diabetic and 30% of control group were hypertensive.
TABLE 4.4.  
DISTRIBUTION OF RESPONDENTS BY PERSONAL HISTORY 
(N= 20)

<table>
<thead>
<tr>
<th>Group</th>
<th>Smoking</th>
<th></th>
<th>Alcoholic</th>
<th></th>
<th>Tobacco chewing</th>
<th></th>
<th>Betal leaf chewing</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of patients</td>
<td>Percentage (%)</td>
<td>No. of patients</td>
<td>Percentage (%)</td>
<td>No. of patients</td>
<td>Percentage (%)</td>
<td>No. of patients</td>
<td>Percentage (%)</td>
</tr>
<tr>
<td>Control group</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>10</td>
<td>1</td>
<td>10</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Experimental group</td>
<td>1</td>
<td>10</td>
<td>3</td>
<td>30</td>
<td>3</td>
<td>30</td>
<td>3</td>
<td>30</td>
</tr>
</tbody>
</table>

The above table shows 30% of control and experimental group were smokers, 20% of them in control and experimental group were tobacco chewers.

FIG. 4.4.  
DISTRIBUTION OF RESPONDENTS BY PERSONAL HISTORY
SECTION – II

4.2. ANALYSIS OF MUCOSITIS SCORE OF EXPERIMENTAL AND CONTROL GROUPS

‘t’ test for unpaired samples were used to analyse the mean difference in oral mucositis scores of experimental and control group.

TABLE 4.5.
ANALYSIS OF MUCOSITIS SCORE OF EXPERIMENTAL AND CONTROL GROUPS

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean</th>
<th>Mean%</th>
<th>SD</th>
<th>‘t’ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental</td>
<td>4.7</td>
<td>4.7</td>
<td>8.187</td>
<td>2.157**</td>
</tr>
<tr>
<td>Control</td>
<td>12.6</td>
<td>12.6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

** Significant at 0.05

The above table shows the difference between mean, mean%, standard deviation and ‘t’ value of experimental and control groups before and after honey application. The ‘t’ value was found to be greater than the calculated value. Hence the hypotheses “ there is a significant difference between the experimental and control group after topical application of honey is accepted.
RESULTS AND DISCUSSION

The study was conducted in Oncology unit of Sri Ramakrishna Hospital, Coimbatore with the aim of identifying the effect of honey application on oral mucosa among patients with head and neck cancer under going radiation therapy. Topical honey application on oral mucosa was administered to the experimental group. Grading of oral mucosa and bio-physiological parameters were assessed before and after honey application in the experimental and control group. The grading of oral mucosa was assessed using World Health Organisation oral toxicity assessment scale. The results of both groups were compared, interpreted and discussed in this chapter.

5.1. FINDINGS RELATED TO BASELINE DATA

5.1.1. Age

Table 4.1 shows that among 20 patients, 5% (1) belongs to the age group of 31 – 40 years, 15% (3) of the patients were between the age group 41 – 50, 30% of the patients belong to the age group of 51 – 60 years, 15% (3) of the patients belongs to the age group of 61 – 70 years, 20% (4) belongs to the age group of 71 – 80 years, 10% (2) of the patients belongs to the age group of 81 – 90 years, and the rest of the patients, 5% (1) were between the age group of 91 – 100 years. The maximum participants to the age group of 51.60 years and the minimum participants belongs to the age group of 31-40 years.

5.1.2. Gender

Table 4.2 shows that among 20 patients, 60% (12) of the patients were male and remaining 40% (8) were females. The majority of participants were males.
5.1.3. Comorbid Illness

Table 4.3 shows that among 20 patients, 5% (1) had diabetes mellitus and 20% (4) had hypertension.

5.1.4. Personal Habits

Table 4.4 shows that among 20 patients, 5% (1) were smokers, 20% (4) were alcoholic, 20% (4) were tobacco chewers, 20% (4) had the habit of betal leaf chewing.

5.2. ANALYSIS OF MUCOSITIS SCORE OF EXPERIMENTAL AND CONTROL GROUP

With regard to the mucositis score 20 patients were randomly assigned to experimental and control group. Oral mucositis grading was done before and after administering of honey application using world health organization oral toxicity assessment scale. Unpaired ‘t’ test was used to prove the significance of the therapy. Table 4.5 analyses the mean difference in mucositis scores of experimental and control group.

The mean percentage of experimental group was 4.7% after honey application and the mean percentage of control group was 12.6%. The standard deviation obtained is 8.187. The ‘t’ value was found to be 2.157. These findings shows that ‘t’ value is found to be greater than the table value. Hence the hypotheses that there is a significant effect of topical honey application is accepted and these findings are consistent with the studies conducted by Biswall (2000).

The present study findings shows that there is a significant decrease in the progression of mucositis after the honey application. The comparision of the results of
the present study to the Biswall shows the effect of honey on mucositis is due to antibacterial properties.

Within the limits of study conducted by Motallebnejad and the present study seems the effect of honey is not only based on antibacterial effects or geographic location and source of pollens but due to the combination of all useful properties in the natural honey. Same study was conducted by Rashad et al (2009) which shows topical honey application found to be a prophylactic in reducing radiation induced mucositis. Similar study conducted by Springer Berlin et al concluded that there is a significant reduction in grade ¾ mucositis among honey treated groups.
SUMMARY AND CONCLUSION

This chapter summarizes the major findings, limitations, implications in the field of nursing education, nursing practice, nursing research and recommendations.

This study is to identify the effect of topical honey application on oral mucosa among head and neck cancer patients. The study design was quasi experimental (post test with control group design). The data was collected for a period of thirty days at Sri Ramakrishna Institute of Oncology and Research, Coimbatore. The study was conducted on 20 patients, 10 each were randomly assigned to experimental and control group. Topical honey application was administered to the experimental group and routine interventions was given to the control group. Grading of mucositis was assessed by WHO Oral toxicity assessment scale.

6.1 MAJOR FINDINGS OF THE STUDY

1. The demographic data reveals that maximum number of participants (ie) 30% of the patients were in the age group of 51-60 years.
2. The majority of samples were males.
3. Among 20 patients 10 % had diabetes mellitus and 20% had hypertension.
4. The progression of mucositis was found to be greater in control group
5. After the application of honey on oral mucosa, the mucositis was prevented and controlled cancer patients
6. Symptomatic expression of pain reduction in experimental group
7. The significant differences were identified by comparing experimental and control group.
6.2. LIMITATIONS OF THE STUDY

1. The study was conducted on less number of subjects
2. The study was limited only to patients with grades 0, 1, 2, 3 mucositis
3. The patients undergoing chemotherapy were not included

6.3. NURSING IMPLICATIONS

6.3.1. Nursing Education

The people with head and neck cancer, receives radiation therapy. The acute complications of radiation therapy includes oral mucositis. To manage these symptoms effectively, many patients are turning towards alternative therapies like herbal remedies, special diets. Among these therapies, topical application of honey is one of the fastest growing complementary therapy.

In the field of nursing education, topical application of honey is concerned with holistic care of patients. Honey application in practice will help nurses to improve the patient at any stage in the disease process. Thus, it is appropriate to incorporate alternative therapies like topical application of honey into nursing curriculum.

6.3.2. Nursing Practice

The nurse working in the oncology unit should be intensive trained in implementing complementary therapy to bring out positive physical and psychological responses as an adjunctively to other pharmacological treatment to promote comfort and well being among the cancer patients.
6.3.3. Nursing Research

The nursing research need to focus more on the evidence based and holistic practice by understanding the various techniques that can bring about significant positive and psychological outcomes for patients with cancer.

The nursing research intended to offer up-to-date suggestions in implementing the herbal remedy like topical honey application as one of the nursing intervention in relieving patients from pain and to improve the quality of life.

6.4. RECOMMENDATIONS

1. Oncology nurses can include the topical honey application in routine oral care protocol before and after radiation therapy.

2. An extensive experimental study can be conducted for larger number of samples in the health care settings.

3. Further research can be conducted with the help of other oral mucositis assessment scale.

4. The effect of topical application of honey can be conducted among patients receiving chemotherapy.

5. A comparative study can be conducted to identify the effect of honey versus soda bicarbonate on oral mucosa among head and neck cancer patients undergoing radiation therapy.

6. Further research can be carried out to find out the effect of honey application on wound healing.
CONCLUSION

Cancer is one of the world leading causes of death. Radiation therapy is an essential initial line of management for patients with head and neck cancer. Oral mucositis an earlier complication alters the patients quality of life and also it inhibits the treatment process. Honey is a product with rich nutritional qualities that could be a pleasant, simple and economic modality for the management of radiation induced mucositis.
References


ANNEXURE – I

To test the hypothesis unpaired ‘t’ test was applied to find out the significant difference after honey application in experimental group.

\[
t = \frac{X_1 - X_2}{S} \sqrt{\frac{n_1 n_2}{n_1 + n_2}}
\]

\[
S^2 = \frac{\sum(x_1 - \overline{X}_1)^2 + \sum(x_2 - \overline{X}_2)^2}{n_1 + n_2 - 2}
\]

Where, \( \overline{X}_1 \) = mean of the first sample

\( \overline{X}_2 \) = mean of the second sample

\( n_1 \) = number of observation in the first sample

\( n_2 \) = number of observation in the second sample

\( S \) = Combined standard deviation
Sri Ramakrishna Hospital
Medical Service : M/s. S.N.R. SONS CHARITABLE TRUST
Phone : 4500000 Grams : "RAMHOSP" Fax : 2240521

SRH/DEAN/F 19/2009 -10
9th December 2009

NOTE

Ms.M.Regupriya I M.Sc., Nursing student, College of Nursing, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore is permitted to utilize the hospital facilities for her project work on “EFFECT OF TOPICAL APPLICATION OF HONEY ON RADIATION INDUCED MUCOSITIS AMONG PATIENTS WITH HEAD AND NECK CANCER AT SELECTED HOSPITALS, COIMBATORE”. All are requested to extend support for her study.

CC. TO:
1. The Managing Trustee through The Chief Executive
2. The Resident Medical Officer
3. Dr.P.Guhan, MD.,DMRT.,DNB.,DM., Director,
   Sri Ramakrishna Institute of Oncology & Research
4. The Nursing Superintendent
5. The Principal, College of Nursing, SRIPMS
6. The Individual through the Principal
APPENDIX –II

LETTER REQUESTING TO VALIDATE THE RESEARCH TOOL AND CONTENT

From
M. Regupriya,
M.Sc Nursing II year,
College of Nursing,
Sri Ramakrishna Institute of Paramedical Sciences,
Coimbatore -44.

Through
The Principal,
College of Nursing,
Sri Ramakrishna Institute of Paramedical Sciences,
Coimbatore -44.

To
DR. P. GUHAN MD,DM RT,DMB,DM
CONSULTANT MEDICAL ONCOLOGIST
SRI RAMAKRISHNA INSTITUTE OF ONCOLOGICAL RESEARCH

Sub: Requisition for tool Validation –reg.

Respected Sir,

I have selected a project work topic entitled, EFFECT OF TOPICAL APPLICATION OF HONEY ON RADIATION INDUCED MUCOSITIS AMONG PATIENTS WITH HEAD AND NECK CANCER AT SRI RAMAKRISHNA HOSPITAL, COIMBATORE” for the requirement of M.Sc.Nsg Degree, the following tools are tend to be used. Hence, I request you to kindly give valuable suggestion and necessary modification in the same.

Thanking you,

Yours faithfully,

M. Regupriya

[Signature]
From
M. Regupriya,
M.Sc Nursing II year,
College of Nursing,
Sri Ramakrishna Institute of Paramedical Sciences,
Coimbatore - 641 004.

Through
The Principal,
College of Nursing,
Sri Ramakrishna Institute of Paramedical Sciences,
Coimbatore -44.

To
M.S. Raji-K
PROFESSOR
VICE PRINCIPAL
KGI COLLEGE OF NURSING
Sub: Requisition for tool Validation—reg.

Respected Sir,

I have selected a project work topic entitled, **EFFECT OF TOPICAL APPLICATION OF HONEY ON RADIATION INDUCED MUCOSITIS AMONG PATIENTS WITH HEAD AND NECK CANCER AT SRI RAMAKRISHNA HOSPITAL, COIMBATORE** for the requirement of M.Sc.Nsg Degree, the following tools are tend to be used. Hence, I request you to kindly give valuable suggestion and necessary modification in the same.

Thanking you,

Yours faithfully,

M. Regupriya
FORMAT FOR CONTENT VALIDITY

Name of the expert: Prof. Radhika

Address:
Vice Principal
K.G. College of Nursing
Art College Road
Coimbatore - 18

Total content for the tool: Adequate/Inadequate

Kindly validate each tool and tick wherever applicable.

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>No. of tool selection</th>
<th>Strongly agree</th>
<th>Agree</th>
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<th>Remarks</th>
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Date: 20/5/10

Signature of the Expert: [Signature]
FORMAT FOR CONTENT VALIDITY

Name of the expert : PROF. BALASUBRAMANIAM K

Address : DEPARTMENT OF MEDICAL SURGICAL NURSING
            KMCH COLLEGE OF NURSING
            COIMBATORE

Total content for the tool : Adequate / Inadequate

Kindly validate each tool and tick wherever applicable.

<table>
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Date:

Signature of the Expert
FORMAT FOR CONTENT VALIDITY

Name of the expert : Mrs. R. MAHILSH

Address : ASSOCIATE PROFESSOR
            GKNM INSTITUTE OF NURSING
            COIMBATORE

Total content for the tool : Adequate/ Inadequate

Kindly validate each tool and tick wherever applicable.

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</table>

Date: 03.06.10

Signature of the Expert
From: Thiru.V.Chandrasekaran, M.Sc.,
Public Analyst (i/c),
Food Analysis Laboratory,
219, Race Course Road,
Coimbatore - 18.

To: Selvi.M.Regupriya,
M.Sc., (Nursing), II Year,
College of Nursing,
Sri Ramakrishna Institute of
Paramedical Sciences,
Coimbatore - 641 044.


Dear Sir,

Sub: Public Health Food Analysis Laboratory
Coimbatore - Received a sample of Honey
Food for analysis - Report sent - Neg.


As per the reference cited, the sample of Honey for
analysis and the sample has been analysed the result of analysis
obtained and are detailed as hereunder:

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Details of Test Done</th>
<th>Result</th>
</tr>
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<tbody>
<tr>
<td>01.</td>
<td>Nature</td>
<td>Honey</td>
</tr>
<tr>
<td>02.</td>
<td>Moisture</td>
<td>9.1%</td>
</tr>
<tr>
<td>03.</td>
<td>Total Ash</td>
<td>0.21%</td>
</tr>
<tr>
<td>04.</td>
<td>Total Acidity (Formic acid)</td>
<td>0.1%</td>
</tr>
<tr>
<td>05.</td>
<td>% of Sucrose</td>
<td>3.2%</td>
</tr>
<tr>
<td>06.</td>
<td>Fructose – Glucose ratio</td>
<td>1.4%</td>
</tr>
</tbody>
</table>

Remark:
07. Total Reducing Sugars : 74.1%
08. Test for Saccharin : Negative
09. Fuchsin Aniline Chloride Test : Negative
10. Aniline Acetate Test : Negative
11. Fehling’s Test : Negative
12. Added colouring Matter : Negative

OPINION: This sample conform to standards of PFA Rules 1955.

Public Analyst
Food Analysis Laboratory
SECTION - A

DEMOGRAPHIC PROFILE

Sample Number : 
Age : 
Sex : 
Diagnosis : 
Date of admission : 
Radiation treatment : 
Co-morbid illness : Hypertension/Bronchial Asthma/ Diabetes Mellitus
Personal habits : Smoking /Alcoholic/Tobacco chewing
Diet : 
Address : 
SECTION – B

TOOL USED FOR ASSESSMENT OF MUCOSITIS

In routine clinical practice as well as in the area of research, proper assessment of oral mucosa is of a paramount importance. Standardized criteria that are routinely used for clinical and research purpose is:

WORLD HEALTH ORGANIZATION GRADING OF MUCOSITIS

World health organization oral toxicity scale was developed on 1979, Geneva. This scoring system is widely used in routine practice and clinical trails. The WHO oral toxicity scale measures anatomical, symptomatic functional components of oral mucosa.

<table>
<thead>
<tr>
<th>Grade</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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</thead>
<tbody>
<tr>
<td>WHO</td>
<td>None</td>
<td>Soreness</td>
<td>Erythema ulcers, and patient cannot swallow solid food</td>
<td>Ulcers with extensive erythema and patient cannot swallow solid food</td>
<td>Mucositis to the extent that alimentation is not possible.</td>
</tr>
</tbody>
</table>
PROTOCOL FOR TOPICAL APPLICATION OF HONEY

OBJECTIVES

1. To reduce the progress of radiation induced mucositis
2. To relieve discomfort

I. ARTICLES NEEDED FOR HONEY APPLICATION

A clean tray containing

1. Bowl with honey
2. Cotton tipped applicators
3. Ounce glass
4. Gloves
5. Mask
6. Kidney tray

II. PROCEDURE

A) Preparatory phase

1. Explain the procedure to the patient
2. Wash hands and gather equipments
3. Make patient in comfortable position
4. Provide chlorhexidine mouth wash

B) Performance phase

1. Apply 10-15 ml of pure honey on the oral mucus membrane 15 minutes before radiation therapy.
2. Apply 10-15 ml of pure honey 15 minutes after radiation therapy and 6 hours of post radiation therapy.

C) End phase

After procedure replace the articles

1. Make the patient comfortable
2. Replace the articles
3. Record the procedure