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RESEARCH ARTICLE

EFFICACY OF NORMAL SALINE VS CHLORHEXIDINE MOUTHWASH IN PREVENTION OF ORAL MUCOSITIS AMONG PATIENTS UNDERGOING RADIATION THERAPY

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Key words:

Radiation therapy: use of
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Normal saline: 0.9% sodium
chloride

Chlorhexidine: a chemical
compound consists of 2%
chlorhexidine gluconate.

Oral mucositis: inflammation of
oral mucosa.

ABSTRACT

Research findings of A study to assess the efficacy of normal saline and chlorhexidine mouth wash in prevention of oral mucositis among patients undergoing radiation therapy at radiation oncology ward, SVIMS, Tirupati was undertaken to reduce the complications of radiation therapy. The study findings reveals that in normal saline group the mean pre interventional oral mucositis intensity was 0.240 with SD of 0.650 and the post interventional mean was 1.293 with S.D of 1.743 and the paired 't' value obtained was 4.266 which is significant at $P < 0.01$ level. In chlorhexidine group the pre interventional mean obtained was 0.280 with S.D of 0.776 and the post interventional mean was 0.620 with S.D of 1.181 and paired t value obtained was 1.743 which is statistically not significant. When comparing the post interventional mean of normal saline group is 1.293 with S.D of 1.743 and the mean in chlorhexidine group is 0.620 with S.D of 1.181 and student 't' value obtained was 2.260 which is statistically significant at $P < 0.01$ level. These findings indicate that there was significant reduction in oral mucositis among patients receiving chlorhexidine mouth wash when compared with normal saline mouth wash.

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INTRODUCTION

Cancer is an abnormal growth of cell or an organ due to a specific stimulus. This growth is an uncoordinated, purposeless one, which continues to grow even after the cessation or withdrawal of the stimulus (Hagop M.Katarja, 2006). The basic modalities of cancer treatment are surgery, radiation therapy, chemotherapy, immunotherapy and hormone therapy (Charless M.Washington, Dennis Leaver, 2004).

Radiation therapy or radiotherapy is the medical use of ionizing radiation as part of cancer treatment to control malignant cells. Radiation therapy works by damaging the DNA of cells. The DNA damage is inherited through cell division, accumulating damage to the cancer cells, causing them to die or reproduce more slowly (Annm. Berger, John L.Shurter, 2007). The main acute side effects from radiation therapy are fatigue, skin irritation, damage to the epithelial surfaces (skin, oral mucosa, pharyngeal, bowel mucosa and ureter), edema, infertility. The

long term side effects include fibrosis, hair loss, xerostomia, and cognitive decline (Gurak Rath, Bindhu K Mohanti, 2007). The common complications of radiation include mucocutaneous changes and oral mucositis, loss of taste, salivary dysfunction, dental carries, candidiasis, osteonecrosis, osteoradionecrosis, and soft tissue necrosis. Mucositis is defined as the painful inflammation of the mucous membrane lining the digestive tract, usually as an adverse effect of chemotherapy and radiotherapy treatment for cancer. Oral and gastrointestinal mucositis can affect up to 100% of patients undergoing high dose chemotherapy and hematopoietic stem cell transplantation, 80% of patients with malignancies of head and neck receiving radiotherapy (Loka Bikrom Thapa, Nitapokhrel, 2007).

Risk factors contributing to oral mucositis are of two types, direct factors and indirect factors. Direct factors include: age, gender, preexisting dental hygiene, nutritional status, oral care during treatment, radiation: dose and schedule, chemotherapy: drug, dose, schedule, and xerostomia. Indirect factors include: myelosuppression, immunosuppression, reduced secretory IgA,

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infections: bacterial, viral and fungal. Normally, cells of the mouth undergo rapid renewal over a 7 – 14 day cycle. Both chemotherapy and radiotherapy interferes with cellular mitosis and reduces the regenerative ability of the oral mucosa. Direct stomatotoxicity usually is seen from 3 days of treatment onwards. In non myelosuppressed patients, oral lesions heal within 2 to 3 weeks (S.H.Levitt, 2008).

The most common sites affected include the labial, buccal, and soft palate mucosa, as well as the floor of the mouth and ventral surface of the tongue. Clinically, oral mucositis presents with multiple complex symptoms: the condition begins with asymptomatic redness, erythema and progresses as solitary, white, elevated desquamate patches that are slightly painful to contact pressure, to large, contiguous, pseudo membranous, acutely painful lesions with associated dysphasia and decreased oral intake (S.H.Levitt, 2008). Cancer is a second largest non communicable disease and it has a sizable contribution in the total number of deaths. The World Cancer Report documents that cancer rates are set to increase at an alarming rate globally. Cancer rates could increase by 50% to 15 million new cases in the year 2020. For most cancer treatments, about 5 – 15% of patients get oral mucositis. Radiotherapy to the head and neck or to the pelvis or abdomen is associated with grade 3 and grade 4 oral or gastrointestinal mucositis, respectively, often exceeding 50% of patients (Bernard W.Stewart, Paul Klilwes, 2003).

Incidence of cancer patients at SVIMS Hospital

Year	Number of admissions
2005	667
2006	648
2007	575
2008	1166
2009	2392

Patients with cancer undergoing radiation therapy have experienced severe oral mucositis with in short period of time. Oral mucositis results in altered health perception, pain, anorexia, dysphasia and halitosis. Naidu M.U, Ramana G.V, et al, estimated that there is 40% incidence of oral mucositis in patients treated with standard chemotherapy. Patient receiving radiation, in particular to head and neck cancer, have a 30% to 60% chance. Chemotherapy and or radiation therapy will interfere with the normal turnover of epithelial cells leading to mucosal injury, subsequently it can also occur due to indirect invasion of gram negative bacteria and fungal species because most of the cancer drugs will cause changes in blood counts(8).

Sonis ST, oral mucositis is a common and debilitating painful side effect in many forms of chemotherapy and radiation therapy. The erythematous, atrophic, and ulcerative lesions that develop are a consequence of epithelial damage and death mediated through a complex series of molecular and cellular events. The consequences of mucositis are far – reaching and include chemotherapy dose reductions, breaks in radiation treatment, cessation of cancer therapy, reliance on parenteral nutrition, hospitalization and morbidity. The underlying molecular and cellular pathobiology of oral mucositis is characterized in five phases: initiation, the primary damage response, signaling and amplification, ulceration and healing.

The role of reactive oxygen species, transduction and transcription pathways, signaling and functional mediators, and bacteria on the development and resolution of mucositis are described as a dynamic process in which epithelial stem cells are the targets. Insights into the mechanism of oral mucositis are generating new approaches for effective target treatment(9).

Motallebnejad M. Akram S, et al, conducted a randomized single blind clinical trial study to assess the effect of pure natural honey on radiation induced oral mucositis. Among 40 patients 20 were assigned to the study group received honey, and control group patients were instructed to rinse with 20ml of normal saline before and after radiation. Patients were evaluated weekly for progression of oral mucositis using the oral mucositis assessment scale. Data were analyzed using the independent t-test, Mann-Whitney, and Friedman tests. The result shows a significant reduction in oral mucositis among honey received patients compared with normal saline (10).

Langos I, Herrera D, et al, conducted a parallel, double blind, prospective, randomized clinical trial to assess the effects of antiseptic, non-alcohol based mouth rinses containing chlorhexidine and acetylpyridinium chloride in preventing the oral complications associated with radiation therapy in head and neck cancer patients. A total of 70 patients were screened and 36 were included in the study and results suggest that the use of tested mouth rinse (chlorhexidine) may lead to some improvement in clinical parameters in patients irradiated for head and neck cancer (11).

Epstein JB, Vickars L, et al, conducted a randomized study among 86 adults patients with leukemia treated with chemotherapy or bone marrow transplantation which was aimed to assess the potential role of chlorhexidine, nystatin, and normal saline solution rinses to reduce the findings of oral mucositis, gingivitis, and oral infection. The results of this study did not show a reduction in oral mucositis with the use of these rinses. However, potential bacterial and fungal pathogens were identified less frequently in the patients using chlorhexidine(12).

Conceptual Framework

The present study was based on the concept that administering normal saline mouth wash and chlorhexidine mouth wash from the initial period of radiation therapy will enable effective oral mucositis prevention. The investigator adopted the Wiedenbach’s Helping Art of Clinical Nursing Theory proposed by Ernestine Wiedenbach’s in 1964 as a base for developing the conceptual framework. This is an prescriptive theory which directs action towards an explicit goal.

The conceptualization of nursing practice according to this theory has three components, such as: **Identification** of the patient’s need for help, **Ministration** of the help needed and **Validation** that the action taken was helpful to patient. **Identification** constitutes the determination of the need for help is by the process of sample selection on the basis of the inclusion criteria followed by the pre interventional oral mucositis assessment among patients in the normal saline and

chlorhexidine mouth wash group. **Ministration** refers to the provision of required help to fulfill the identified need which includes the provision of normal saline mouth wash to first group and chlorhexidine mouth wash to second group of patients undergoing radiation therapy. **Validation** helps to evaluate that the ministered actions were indeed helpful. This is accomplished by post interventional oral mucositis assessment among patients in normal saline and chlorhexidine mouth wash groups.

METERIAL&METHODS

The research approach used was “Quasi experimental” and research design was “pretest and posttest” experimental design. The setting of the study was Radiation Oncology Ward, Sir Venkateswara Institute of Medical Science, Tirupati. The sampling technique used was non-probability purposive sampling. The population includes patients with the age 18 to 65 years, undergoing radiation therapy, who are falling under inclusion criteria. Sample Size constitutes 100 patients, 50 subjects in normal saline group, 50 subjects in chlorhexidine group.

Schematic representation of research design

Group	Before (O ₁)	Intervention (X)	After (O ₂)
R ₁	Assessment of oral mucosa and mucositis related pain on 1 st day of radiation therapy	Administration of normal saline mouth wash 30 ml, 3 minutes, 3 times a day for 7 days	Assessment of oral mucosa and mucositis related pain on 7 th day.
R ₂	Assessment of oral mucosa and mucositis related pain on 1 st day of radiation therapy	Administration of chlorhexidine mouth wash 15 ml, 30 sec, 3 times a day for 7 days	Assessment of oral mucosa and mucositis related pain on 7 th day.

R₁ = Random assignment of subjects to experimental group-I

R₂ = Random assignment of subjects to experimental group II

X= Intervention: Administration of normal saline and chlorhexidine mouthwash.

O₁=Assessment of oral mucosa and mucositis related pain before the initiation of intervention.

O₂= Assessment of oral mucosa and mucositis related pain after the completion of 7th day intervention.

Variables of the study

Independent variables are normal saline and chlorhexidine mouth wash

Dependent variables are oral mucositis and mucositis related pain.

Extraneous variable which could influence the prevention of oral mucositis are demographic variables, habits, familial history and knowledge.

Criteria for sample selection

Inclusion criteria

- Patients undergoing radiation therapy with the age 18 to 65 years and includes both genders.
- Patients willing to participate in the study.

Exclusion criteria

- Patients with the age less than 18 and more than 65 years.
- Patients with existing mouth ulcers or oral cancer.
- Patients with hearing impairment.

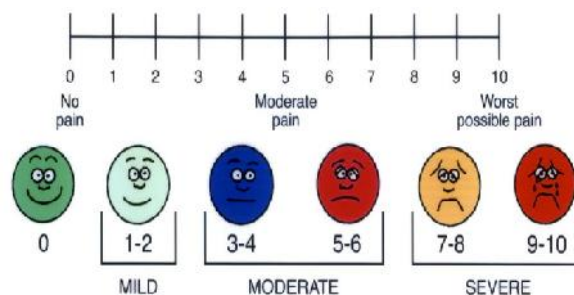
Development and description of tool: The tool consists of 3 sections, Section I: personal and social profile, section II: habits, family history and knowledge on radiation induced oral mucositis, section III: oral mucositis assessment tool.

The Western Consortium for Cancer Nursing Research staging system was used to assess oral mucositis. The scale focuses on three components such as lesions, color and bleeding.

Wccnr staging system			
Score	Lesions	Colour	Bleeding
0	None	Pink > 50%	None
1	1 – 4	Slightly red	None
2	>4	Moderately red >50%	With eating or with mouth care
3	Coalescing lesions on 50% or more of the mouth surface	Very red > 50%	Spontaneous – fresh bleeding apparent or dried blood on pillow

Directions for use of this staging system is by using gloves, a penlight, and a tongue blade and inspect all the surfaces of mouth including gingivae, tongue, lips and the floor of the mouth, and the buccal surfaces.

Harris Olson’s oral mucositis related pain assessment tool was modified to assess the oral mucositis related pain. Wong Baker Facial Grimace scale was used to assess the pain intensity



Wong Baker Facial Grimace Scale

Scoring key: Add the scores for lesion, color and bleeding. Categorization of the scores are as follows:

- No oral mucositis = 0
- Mild oral mucositis = 1-3
- Moderate oral mucositis = 4-6
- Severe oral mucositis = 7-9

The tool was validated by experts and the original questionnaire was translated into Telugu and back translated with the help of bilingual experts. The reliability of the tool was confirmed by test-retest method and the value obtained was r =0.96. Pilot study was conducted on ten samples. Analysis was done by using descriptive and inferential statistics. Analysis of the Pilot study revealed that the ‘t’ value of 3.343 significant at P<0.01 level.

METHOD OF DATA COLLECTION

As a part of data collection procedure the investigator utilized the equipments like pen torch, disposable tongue depressors, examination gloves and the solutions like normal saline 0.9% and chlorhexidine mouth wash. The investigator introduced herself to the patients, explained about the purpose of the study and steps of procedure to be followed while rinsing the mouth with normal saline and chlorhexidine mouthwash, collected the initial data and base line profile and assessed the oral mucosa and oral mucositis related pain by using Western Consortium for Cancer Nursing Research (WCCNR) scale, Harris Olson's oral mucositis related pain assessment tool and Wong baker facial grimace scale.

To the first group of patients normal saline mouth wash 30 ml, 3 minutes, 3 times a day for 7 days was given and for second group of patients chlorhexidine mouth wash 15 ml, 30sec, 3 times a day for 7days was administered. At the end of 7th day posttest was conducted to assess oral mucositis and oral mucositis related pain in both the groups.

Statistical Analysis

Data was analyzed by using descriptive and inferential statistics.

- Frequency, percentage were used to assess demographic variables, initial assessment of oral mucositis and mucositis related pain in normal saline and chlorhexidine group, Percentage, mean distribution and standard deviation were used for oral mucositis and mucositis related pain in normal saline and chlorhexidine group.
- **Paired 't' test** was used for comparing pre and post mouth wash effect on prevention of oral mucositis among patients in normal saline and chlorhexidine group, **Student 't' test** was used for comparing the effect of normal saline and chlorhexidine mouth wash in prevention of oral mucositis, **Chi-square test** was used to associate the effect of normal saline and chlorhexidine mouth wash in prevention of oral mucositis with selected demographic variables.

Ethical consideration

The study was approved by scientific research ethics committee, faculty of Nursing, SVIMS University. Participants were given explanation about the purpose of the study and they were also informed that they could withdraw from the study at any time before the completion of the study. Participants who agreed to complete this study were asked to sign a consent form. Confidentiality of participants was assured and the data were accessed only by the investigator involved in the study.

RESULTS

11(22%) in 51_55yrs were in normal saline group and 7(14%) were in chlorhexidine group. Among 56 to 60 years age group 11(22%) were in normal saline group and 18(36%) were in

chlorhexidine group. 41 (82%) were males in normal saline group and 34(68%) were in chlorhexidine group. 9(18%) were females in normal saline group and 16(32%) were in chlorhexidine group, 29(58%) in normal saline group and 24(48%) in chlorhexidine group were diagnosed with cervical cancers rest followed by breast cancers. Regarding religion, majority were Hindus 49 (98%) in normal saline group and 45(90%) in chlorhexidine group, 32(64%) were illiterate in normal saline group and 26(52%) in chlorhexidine group, 11(22%) have primary education in normal saline group and 16(32%) in chlorhexidine group.

Agriculture were the occupation 24(48%) in normal saline group and 16(32%) in chlorhexidine group, 11(22%) were home makers in normal saline group and 10(20%) in chlorhexidine group, 11(22%) were coolie in normal saline group and 16(32%) in chlorhexidine group. 42(84%) were married in normal saline group and 45(90%) were in chlorhexidine group, 7(14%) were widow or widowers in normal saline group and 5(10%) were in chlorhexidine group. oral gargling habit 3(6%) were seen in normal saline 3(6%) and 2(4%) were seen in chlorhexidine group, majority 50(100%) in normal saline and 49(98%) in chlorhexidine group do not have family history of cancer.

With regard to awareness on radiation induced oral mucositis, none of the patient in both the groups possesses knowledge. The mean pre interventional oral mucositis intensity in normal saline group was 0.240 with S.D of 0.650 and the post interventional mean was 1.293 with S.D of 1.743 and the paired 't' value obtained was 4.266 which is significant at P<001. The mean preinterventional oral mucositis mean in chlorhexidine group is 0.280 with S.D of 0.776 and the post interventional mean was 0.620 with a S.D of 1.181 and the paired 't' value obtained was 1.743 which was not significant.

Table-3 Pre and post interventional scores of normal saline and chlorhexidine mouth wash group in prevention of oral mucositis. N=100

	Normal Saline Mouth Wash Group (n=50)		Paired 't' value	Chlorhexidine mouth wash Group (n=50)		Paired 't' value
	Mean	S.D		Mean	S.D	
Pre mouth wash	0.240	0.650	4.266**	0.280	0.776	1.743NS
Post mouth wash	1.293	1.743		0.620	1.181	

**= P<0.01

When comparing the normal saline and chlorhexidine mouth wash, the post interventional mean in normal saline group was 1.293 with S.D of 1.743 and the mean in chlorhexidine group was 0.620 with S.D of 1.181 and the student 't' value obtained was 2.260 statistically significant at P<0.05

Table-4 Comparing the effect of normal saline and chlorhexidine mouth wash in prevention of oral mucositis.

	Normal saline group (n=50)		Chlorhexidine group (n=50)		Student 't' test value
	Mean	S.D	Mean	S.D	
Pretest	0.240	0.650	0.280	0.776	0.280 NS
Post test	1.293	1.743	0.620	1.181	2.260*

Note: *= P<0.05

These findings indicate that there was significant reduction in oral mucositis among patients receiving chlorhexidine mouth wash when compared with normal saline mouth wash.

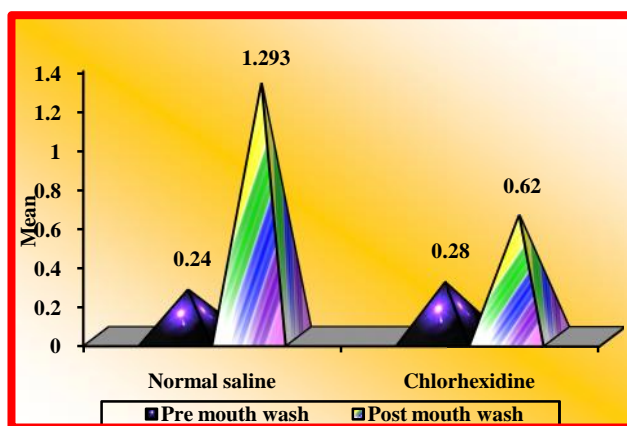


Fig- 2 Comparison of mean of pre and post interventional stomatitis intensity among patients receiving normal saline and chlorhexidine mouth wash

The association of demographic variables with the effect of normal saline and chlorhexidine mouth wash in prevention of oral mucositis was determined by chi-square test, which reveals that the demographic variable like age ($p < 0.05$), betel leaves chewing ($p < 0.05$), frequency of oral gargling ($p < 0.01$), frequency of consuming tea or coffee ($p < 0.05$), smoking ($p < 0.01$), family history of cancer and relationship with the patient shows significant association ($p < 0.01$).

DISCUSSION

The first objective of the study was to assess the efficacy of normal saline Vs chlorhexidine mouth wash in prevention of oral mucositis. The effectiveness of normal saline and chlorhexidine mouth wash was assessed by comparing the pre and post interventional oral mucositis grading. The pre test mean normal saline mouth wash was 0.240 ± 0.650 & post mouth wash was 1.293 ± 1.743 and the 't' value obtained was 4.266 which is significant at $P < 0.01$, the pre mouth wash in chlorhexidine group was 0.280 ± 0.776 and the mean value of post mouth wash in chlorhexidine group was 0.620 ± 1.181 and the paired 't' value obtained was 1.743 which is statistically not significant. This signifies that in spite of normal saline mouth wash there is increase in incidence of oral mucositis and there was no increase in incidence of oral mucositis among patients receiving chlorhexidine mouth wash. It was concluded that normal saline mouth wash has got poor effect in prevention of oral mucositis, Prophylactic use of chlorhexidine mouth wash is effective in prevention of oral mucositis. A randomised single blind clinical trial was conducted to assess the effect of pure natural honey on radiation induced oral mucositis shows a significant reduction of oral mucositis among honey patients compared to normal saline group (10) Based on the review the null hypothesis Ho1 has been rejected.

The Second objective of the study was to compare the effect of normal saline and chlorhexidine mouth wash in prevention of oral mucositis. The study findings reveals that the post interventional mean in normal saline group was 1.293 ± 1.743 and the mean in chlorhexidine group was 0.620 ± 1.181 and the student t-test value obtained was 2.260 statistically significant

at $P < 0.05$ level. The result signifies that the administration of chlorhexidine mouth wash significantly prevented the occurrence of oral mucositis, when compared with normal saline mouth wash. This supports that prophylactic use of chlorhexidine mouth wash in prevention of oral mucositis. A parallel double blind prospective randomized clinical trial was conducted to assess the effect of antiseptic, nonalcoholic based mouth rinses containing chlorhexidine & acetylpyridinium chloride in preventions of oral complications associated with radiotherapy suggests that use of tested mouth rinses (chlorhexidine) may lead to some clinical improvement in clinical parameter (11). Based on the review the null hypothesis Ho2 has been rejected.

The Third objective of the study was to determine the association between selected demographic variables and the effect of normal saline and chlorhexidine mouth wash in prevention of oral mucositis. The study finding revealed that the demographic variables like gender, diagnosis, religion, education, occupation, income, marital status, residence, diet, hydration, brushing, and product used for brushing, awareness on oral mucositis has no significant association with effect of normal saline and chlorhexidine mouth wash. But the demographic variable like age ($p < 0.05$), betel leaves chewing ($p < 0.05$), frequency of oral gargling ($p < 0.01$), frequency of consuming tea or coffee ($p < 0.05$), smoking cigarettes/day, family history of cancer and relationship with the patient shows significant association ($p < 0.01$). Naidu M.U, Ramana G.V, et al⁸ explained that, oral mucositis may limit the patient's ability to tolerate chemotherapy or radiation therapy, and nutritional status is compromised. It may drastically affect cancer treatment as well as the patient's quality of life. The incidence and severity of oral mucositis will vary from patient to patient and the risk factors such as age, nutritional status, type of malignancy, and oral care during treatment will play important roles in the development of oral mucositis. Many treatment options are available to prevent and treat this condition, but none of them can completely prevent or treat oral mucositis. Based on the review the null hypothesis Ho3 has been rejected.

CONCLUSION

Chlorhexidine mouth wash is effective than normal saline mouth wash in prevention of oral mucositis among patients undergoing radiation therapy. So chlorhexidine mouth wash can be used as a prophylactic measure in prevention of oral mucositis in all the patients receiving radiation therapy. Though the cancer at advanced stage is not curable, the complications resulting from cancer chemo radiotherapy can be managed by prophylactic measures such as promoting hygienic practices, maintenance of good dietary habits, promoting fluid intake and by inculcating healthy life style practices. One of the common distressing problems that are oral mucositis can be better prevented and controlled by using prophylactic chlorhexidine mouth wash.

Recommendations

- A longitudinal study can be conducted to see the prolonged effect of chlorhexidine mouth wash.

- STP can be conducted on management of radiation therapy induced oral mucositis.
- A descriptive study can be conducted to assess the quality of life among patients receiving radiation therapy.

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