

**EFFECTIVENESS OF SODIUM BICARBONATE MOUTH WASH IN
REDUCING ORAL MUCOSITIS AMONG ORAL CANCER PATIENTS
RECEIVING RADIATION THERAPY IN C.S.I MISSION HOSPITAL
NEYYOOR**



**A DISSERTATION SUBMITTED TO THE TAMIL NADU
DR. M.G.R. MEDICAL UNIVERSITY, CHENNAI,
IN PARTIAL FULFILLMENT OF THE
REQUIREMENTS FOR DEGREE
OF MASTER OF SCIENCE
IN NURSING**

APRIL – 2016

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BY

301412202

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A Quasi experimental study to assess the effectiveness of sodium bicarbonate mouth wash in reducing oral mucositis among oral cancer patients undergoing radiation therapy in C.S.I mission hospital at neyyoor

RESEARCH GUIDE:

Prof. Mrs. J.M Jerlin Priya M.Sc (N)., Ph.D,
Principal,Professor,Dept of Medical Surgical Nursing,
Annammal College of Nursing, Kuzhithurai,
K.K District, Tamil Nadu.

CLINICAL GUIDE:

Mrs. Starina flower. M.Sc (N).,
Assistant Professor,Dept of Medical SurgicalNursing,
Annammal College of Nursing, Kuzhithurai,
K.K District,Tamil Nadu.

MEDICAL GUIDE:

Dr. Sudhaharaen.M,D.,DMRT.,
Head of Department of oncology,
C.S.I Mission Hospital,Neyyoor,
K.K District,Tamil Nadu.

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APRIL – 2016**



Certified that this is the bonafide work of

301412202

At the Annammal College of Nursing,

Kuzhithurai.

*Submitted in partial fulfillment of the requirements for
the degree of Master of Science in Nursing from the Tamilnadu*

Dr. M.G.R, Medical University, Chennai.

Examiners

1. _____

2. _____

Prof. Mrs. J.M.Jerlin Priya., M.Sc (N)., Ph.D,

Principal

APRIL-2016

DECLARATION

I hereby declare that the present dissertation titled as **“A Quasi experimental study to assess the effectiveness of sodium bicarbonate mouth wash in reducing oral mucositis among oral cancer patients undergoing radiation therapy in C.S.I mission hospital at neyyoor** is the outcome of the original research work undertaken and carried out by me under the guidance of **Prof. Mrs. J.M Jerlin Priya M.Sc(N), Ph.D, Principal cum professor** in the department of Medical Surgical Nursing Department, and **Mrs. Starina flower, M.Sc.,(N),** department of Medical Surgical Nursing . I also declare that the material of this has not found in any way, the basis for the award of any degree or diploma in the university or any other university.

301412202

M Sc (N) II year

ACKNOWLEDGEMENT

ACKNOWLEDGEMENT

I wish to acknowledge my heartfelt gratitude to **Lord Almighty** for all the wisdom, knowledge, guidance, strength, protection, shield and support. He has offered me throughout this endeavour and given me courage to overcome the difficulties and thus complete this study successfully.

It is my honour to thank our beloved chairman **Dr. Sheeba Jayala IMBBS., DGO.,** for providing entire facility and encouragement for conducting this study.

I express my sincere gratitude to **Dr. Jayalal MS., FICS., DLS(Germany), MBA., FIAGES.,** Hon. Secretary of Annammal College of Nursing for giving me the precious opportunity to be a part of this esteemed institution.

I consider myself to be privileged to express my honest and sincere gratitude to **Prof. Mrs. J.M Jerlin Priya, M. Sc., (N), Ph.D,** Principal cum Professor, Annammal College of Nursing, for her invaluable guidance, continuous support, promising criticisms, suggestion and concern during the entire course of this dissertation.

At this moment I convey my profound gratitude to **Mrs. Sujatha , M.Sc.,(N),** Vice Principal cum Class Coordinator, for her support which helped me in completion of this dissertation.

I extend my deepest gratitude to **Mrs. Starinaflower, M.Sc. (N),** Assistant professor in department of Medical Surgical Nursing for her constant source of inspiration, which was a key for the successful completion of this study.

I express my thanks to the **entire faculty of Annammal College of Nursing., Kuzhithurai,** for their co-operation and encouragement.

I am pleased to convey my profound thanks to **Dr.S.Rajesh Sathya** Medical Superintendent and **Dr.Sudhaharaen M.D,DMRT.,** Head of Department of Oncology from C.S.I Mission

Hospital Neyyoor, who permitted me to conduct this study and for their excellent guidance, expert suggestions, encouragement and support .

My sincere thanks and honour to **Mr. Anto John Britto, MSc, MED., MPhil, PG., DBM.,** Professor of Bio statistics for extending his helping hands in the course of analysis of the data collection and interpretation.

I am very much grateful to **Mrs. Mary Shajitha** librarian for helping me in referring journals and books

I thank all the **office staff** for their help in taking photocopies of study reviews.

I express my deep sense of gratitude and heartfelt thanks to the **experts** who had validated and edited my study and devoted their valuable hours in solving my doubts .

I would like to express my thanks to the **study participants** for their co-operation and participation, without whom this study would have been impossible.

I express my heart felt gratitude to my **family members** for their love, support and encouragement. A word of thanks to **my colleagues** for their help and support throughout the course of this study.

301412202

MSc. (N) II YEAR

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ABSTRACT

EFFECTIVENESS OF SODIUM BICARBONATE MOUTH WASH IN REDUCING ORAL MUCOSITIS AMONG ORAL CANCER PATIENTS WHO RECEIVING RADIATION THERAPY

INTRODUCTION

The World Health Organization defines health as "a state of complete physical, mental, and social well being and not merely the absence of disease or infirmity." The maintenance and promotion of health is achieved through different combination of physical, mental, and social well-being, together sometimes referred to as the "health triangle." Systematic activities to prevent or cure health problems and to promote good health in humans are delivered by health care providers. Cancer in medical term is called malignant neoplasm. The word neoplasm is derived from Greek word 'neon' means new and 'plasia' known as moulding.

Cancer may affect people of all ages, even fetuses, but the risk for most varieties increases with age. Usually the cancer has three treatment modalities such as chemotherapy, radiation therapy and surgery. Cancer chemotherapy is used to destroy rapidly proliferating cells. However, normal cells with high mitotic indexes are also affected by chemotherapy, particularly those in the oral and gastro intestinal mucosa and the hemopoietic system. Ultimately, this may lead to certain oral complications of cancer chemotherapy such as mucositis, infection, haemorrhage, xerostomia, neurologic and nutritional disorders. Radiation therapy is a type of palliative therapy. It uses a high energy ionizing radiation. Those rays will destroy the cell's ability to reproduce. Surgery is mainly done for the diagnosis, staging, and treatment. Surgery plays a good role in rehabilitation and palliation. In some of the cancer condition either one or two modes are provided. The treatment is mainly to decrease the cell multiplication and further complication. Addition to the advance technologies in these modalities of medical science has its own role towards good prognosis. Mucositis is the painful inflammation and ulceration of the mucous membranes lining the digestive tract.

The effect of a sodium bicarbonate mouthwash solution is thought to aid in the formation of granulation tissue and to promote healing. Sodium bicarbonate mouthwash solution is safe and

economical and has been used in cancer patients. Sodium bicarbonate mouthwash solution gargles cleanses the wound, reduces swelling, and can decrease pain

STATEMENT OF THE PROBLEM

A Quasi experimental study to assess the effectiveness of sodium bicarbonate mouth wash in reducing oral mucositis among oral cancer patients undergoing radiation therapy in C.S.I mission hospital at neyyoor.

OBJECTIVES OF THE STUDY ARE

- To assess the level of oral mucositis before and after administration of sodium bicarbonate mouth wash among oral cancer patients in experimental and control group.
- To compare the effectiveness of sodium bicarbonate solution with existing practices in reducing oral mucositis among oral cancer patients undergoing radiation therapy in experimental and control group.
- To determine the association between post interventional levels of oral mucositis among oral cancer patients undergoing radiation therapy with selected socio demographic variables and clinical variables.

HYPOTHESES

- H₁:** There will be a significant difference between the pre and post interventional level of oral mucositis among oral cancer patients in experimental group and control group.
- H₂:** There will be a significant difference between the post interventional level of oral mucositis among oral cancer patients in experimental and control group.
- H₃:** There will be a significant association between the post interventional level of oral mucositis among oral cancer patients with the selected demographic and clinical variables.

RESEARCH METHODOLOGY

The study was conducted in order to find out the effectiveness of sodium bicarbonate mouth wash in reducing oral mucositis among oral cancer patients who are receiving radiation therapy. In this study, 60 samples were selected by using purposive sampling technique. Socio demographic variables and clinical variables were collected. The pre-test was done by using WHO oral mucositis assessment scales. Sodium bicarbonate mouth wash was given for 3 times for a period of two weeks. The post test level of oral mucositis was evaluated by conducting a

post-test on 4th day, 7th day, 10th day, 13th day and 16th day for both the groups with oral mucositis scale. After the conduction of the pre-test and post-test, data analysis was done to find out the effectiveness of sodium bicarbonate mouth wash. The patients cooperated well during data collection.

DATA ANALYSIS

The t test was used to evaluate the effectiveness of sodium bicarbonate mouth wash in reducing oral mucositis among oral cancer patients. Chi-square test was used to find out the association between the post test level of oral mucositis with selected socio demographic variables and clinical variables among oral cancer patients.

RESULT AND SUMMARY

In experimental group, the mean post test score was 1.433 with standard deviation 1.145 where as in control group the mean post test was 1.166 with standard deviation of 0.933. The obtained t-test value was 2.52 and the p value was 0.02. Hence the research hypotheses H_1 was accepted and it was inferred that sodium bicarbonate mouth wash was effective in reducing oral mucositis. There was a significant association between post interventional level of oral mucositis and selected socio demographic variables and clinical variables in experimental group and control group

CONCLUSION

The study concluded that sodium bicarbonate mouth was effective in reducing oral mucositis among oral cancer patients who received radiation therapy.

CHAPTER I

INTRODUCTION

- *Background of the study*
- *Need for the study*
- *Statement of the problem*
- *Objectives of the study*
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- *Operational definitions*
- *Assumptions*
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- *Reliability*
- *Pilot study*
- *Data collection procedure*
- *Plan for data analysis*
- *Ethical consideration*

CHAPTER IV

DATA ANALYSIS AND INTERPRETATION

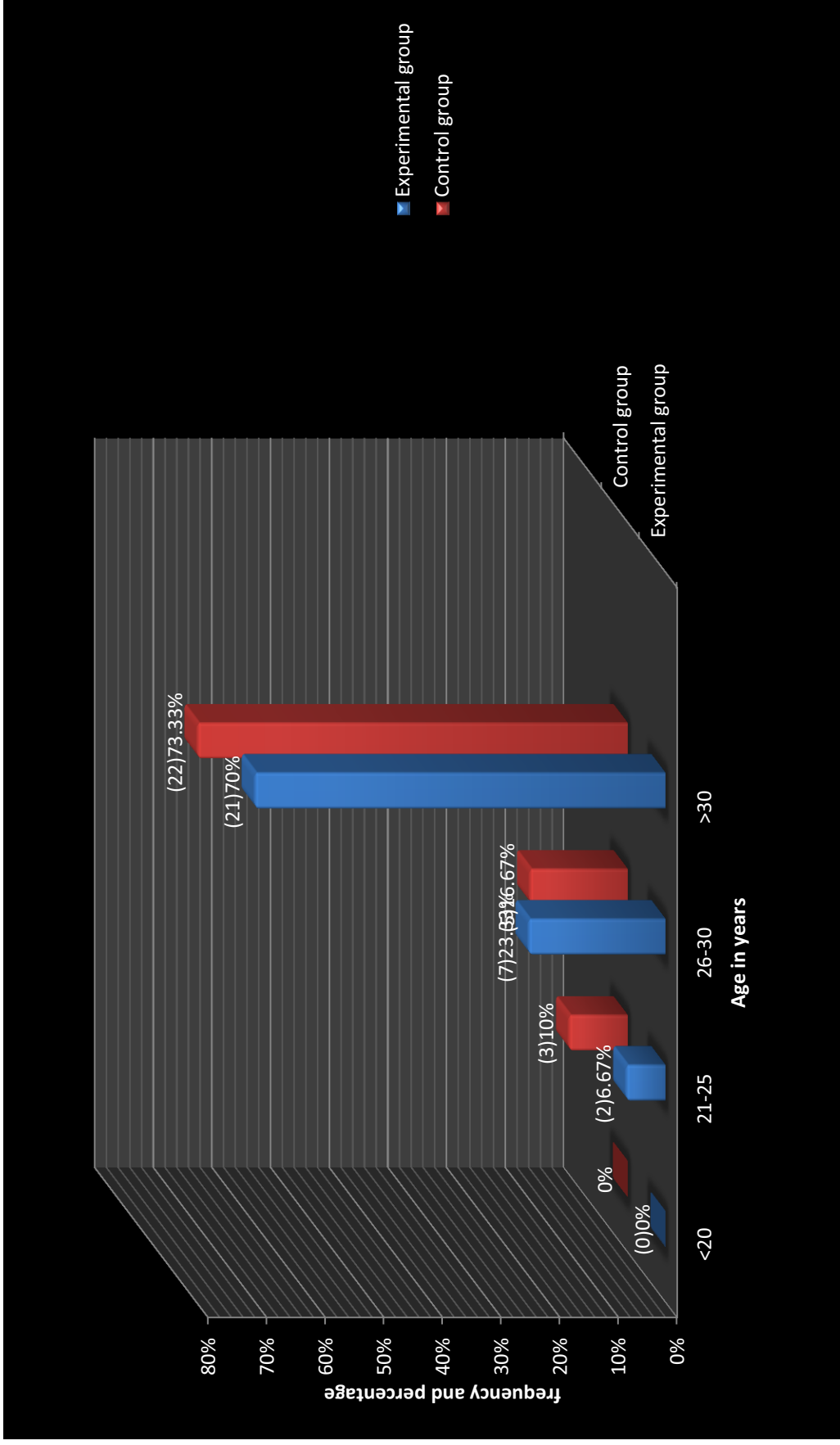


Fig:3 Frequency and Percentage distribution of oral cancer patients with regard to their age

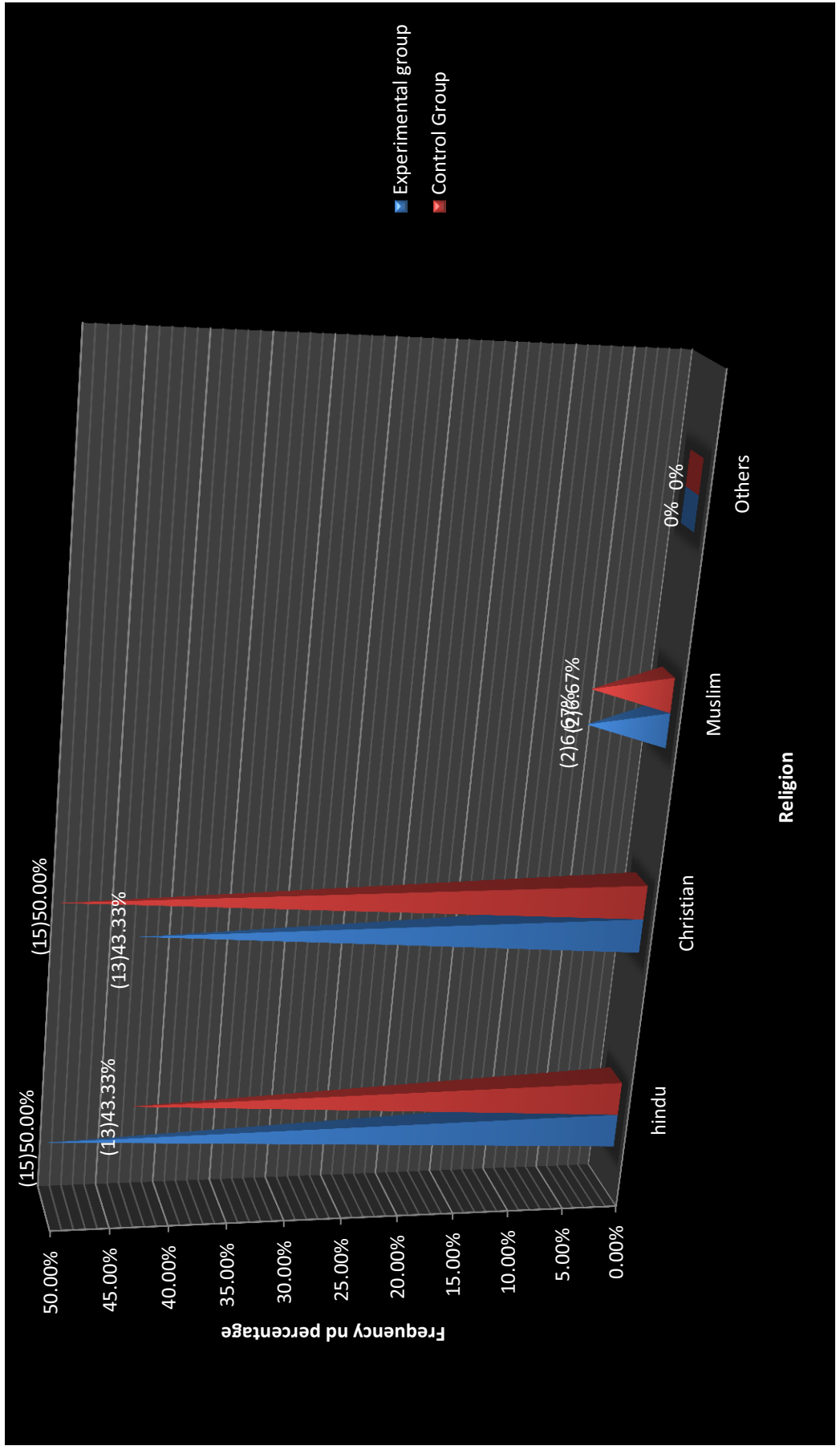


Fig:4 Frequency and Percentage distribution of oral cancer patients with regard to their Religion

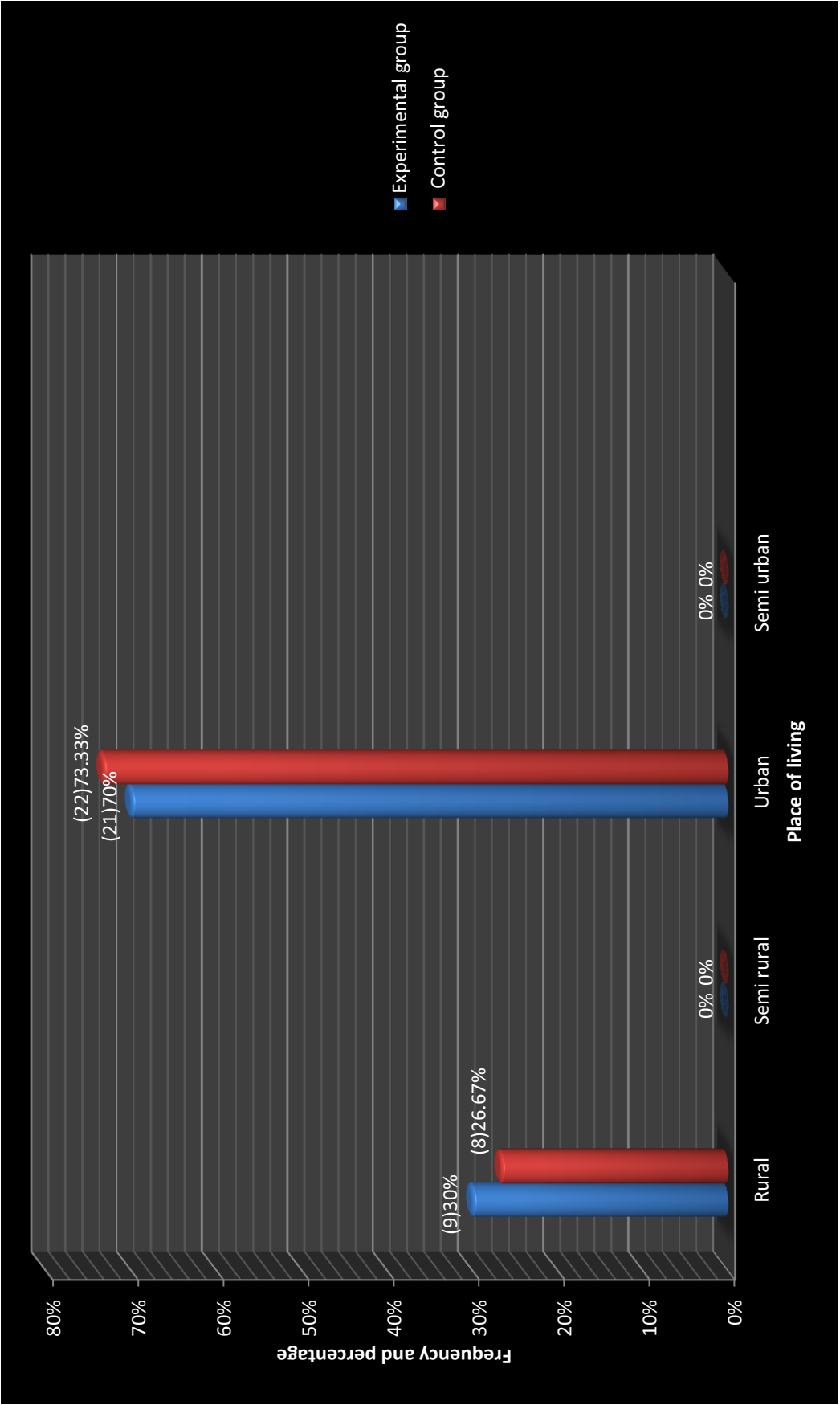


Fig:5 Frequency and Percentage distribution of oral cancer patients with regard to their place of living

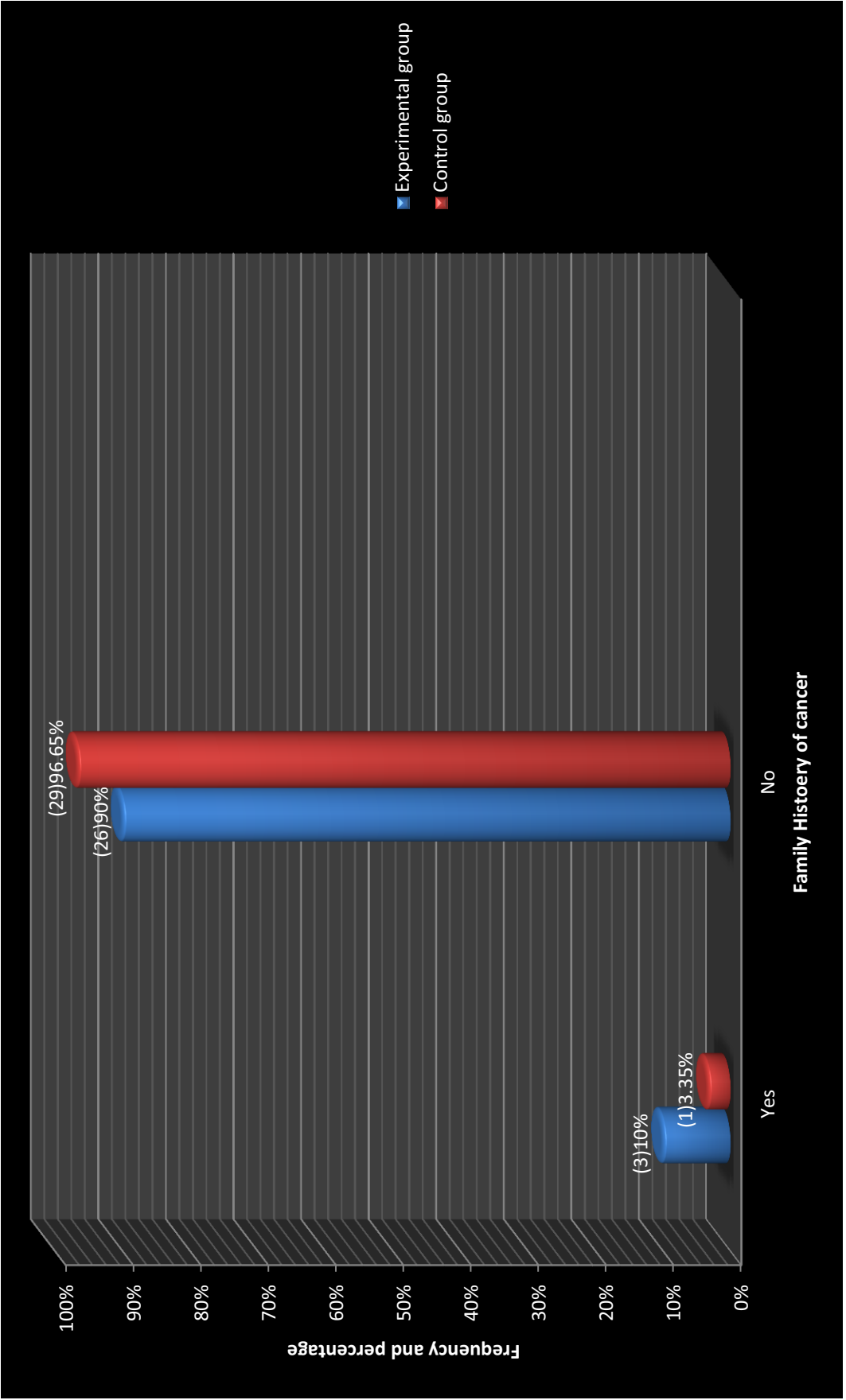


Fig:6 Frequency and Percentage distribution of oral cancer patients with regard to their Family history of cancer

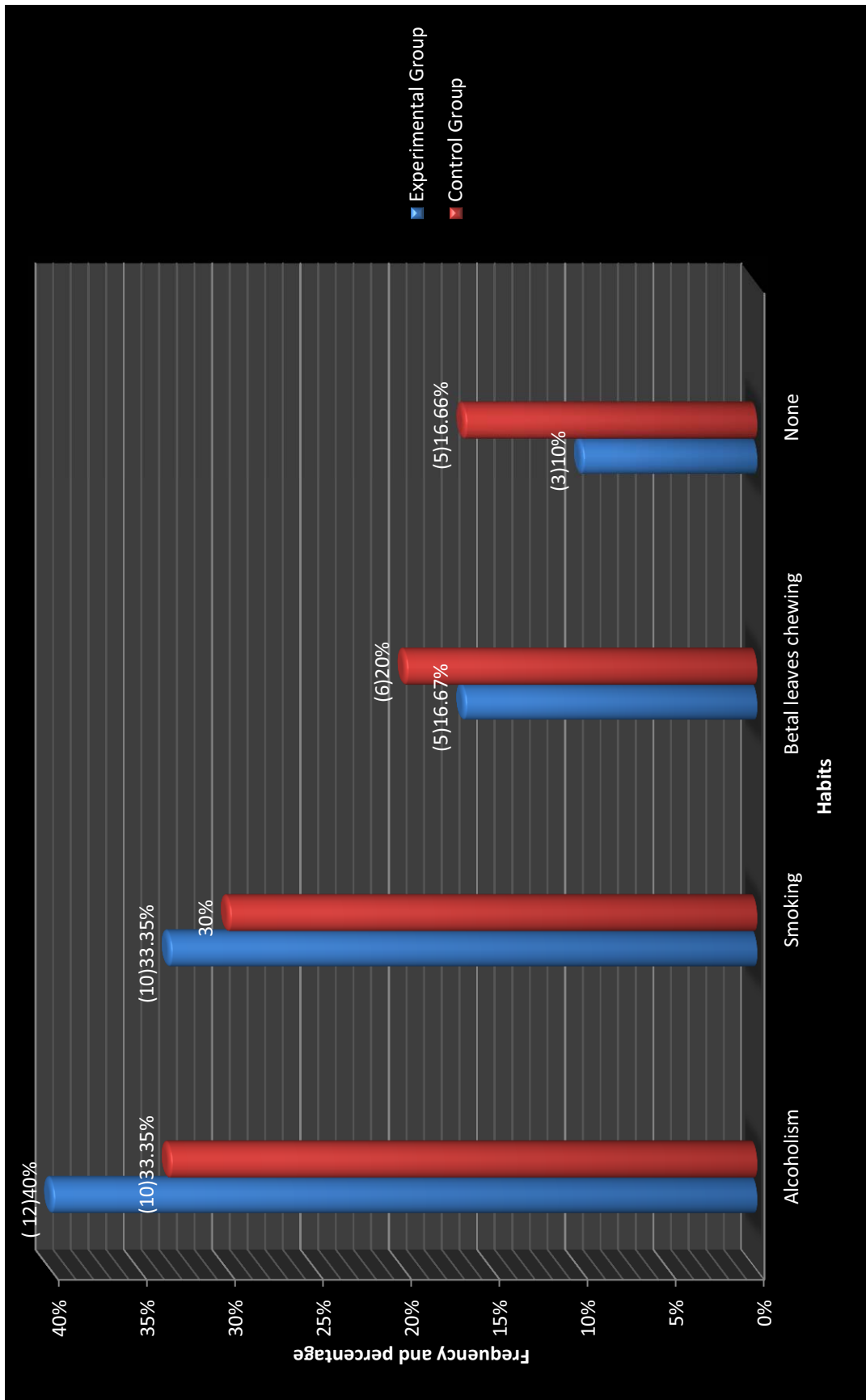


Fig :7 Frequency and Percentage distribution of oral cancer patients with regard to their habits

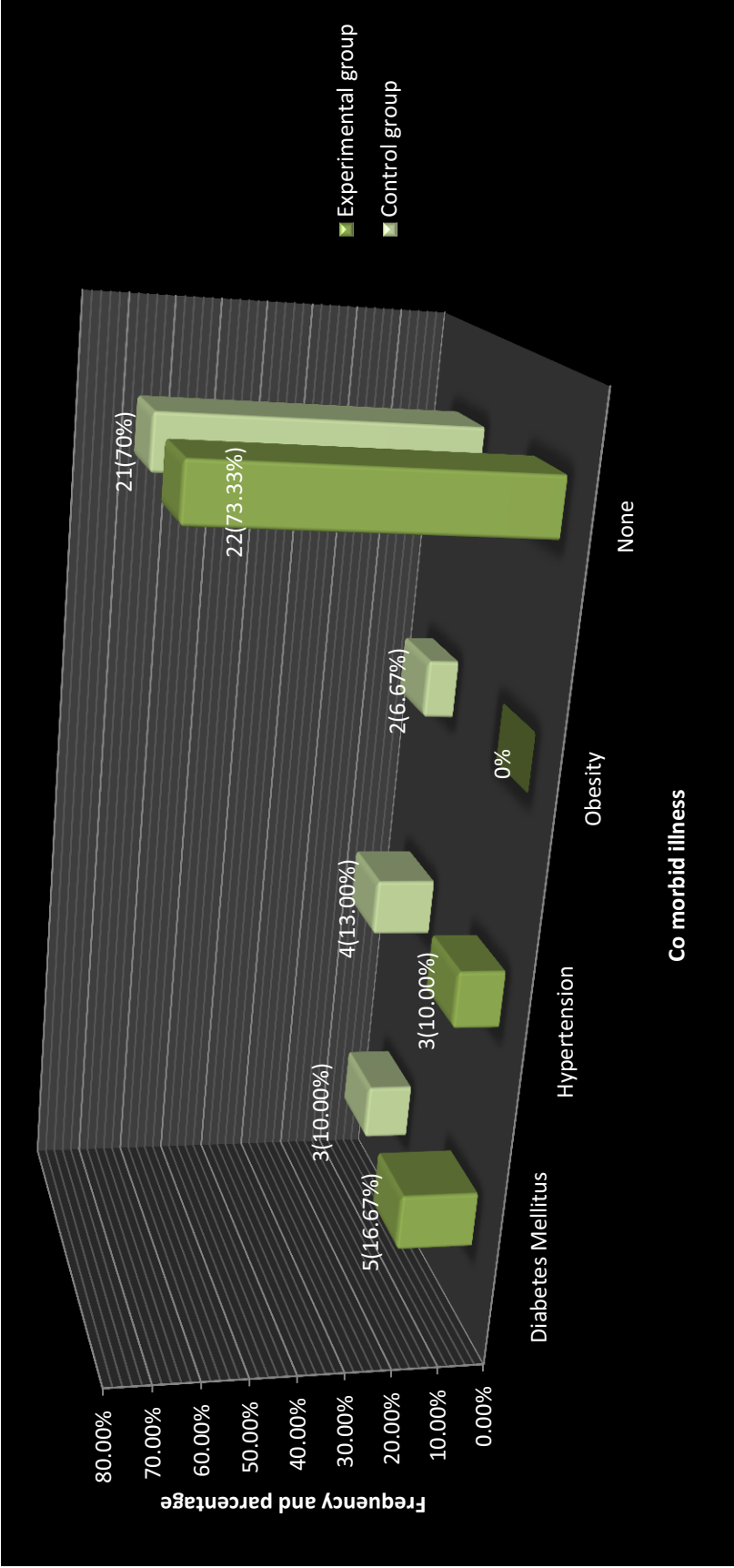


Fig:8 Frequency and Percentage distribution of oral cancer patients according to their co morbid illness

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ANNEXURES

ANNEXURE I

LETTER SEEKING PERMISSION TO CONDUCT THE STUDY

 **Annammal College of Nursing**
(Approved by Govt. of Tamilnadu, TN Nurses & Midwives Council,
Indian Nursing Council and Affiliated to The Tamilnadu Dr. MGR Medical University)
Annammal Hospital Campus, KUZHITHURAI - 629 163
K.K. Dist, Tamil Nadu. Ph : 04651 - 260614, Fax : 04651 - 260605
www.annammalnursing college.com Email : annammalcollege2007@yahoo.co.in

Our Motto : "Heal us to Heal others"

Dr. Sheeba Jayal MBBS, DGO
Chairperson

Date :

From

Prof.Mrs.J.M.JerlinPriya, M.Sc(N), Ph.D.,
Principal,
Annammal College of Nursing,
Kuzhithurai.

To

Dr. S. Rajesh sathya,
Kanyakumari medical Mission C.S.D,
International cancer centre,
Neyyoor.
Respected Sir,

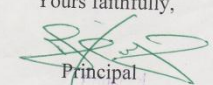
Permit to
S. J. Jayal
11/2/16


Sub: Seeking permission to conduct the research study.

Ms.Jescin Deepa, II year M.Sc(N) student of Annammal College of Nursing, Kuzhithurai, is approaching you to conduct a research on "A Quasi experimental study to assess the effectiveness of sodium bicarbonate mouth wash is reducing Oral Mucositis among Oral Cancer patients undergoing Radiation Therapy in C.S.I mission hospital Neyyoor at Kanyakumari District". Which she has to complete as a partial fulfillment of university requirement for the award of Master of science in nursing degree.

In this regards I humbly request you to give permission to conduct the study in your hospital.

Thanking you

Yours faithfully,

Principal
Annammal College of Nursing
Kuzhithurai, K.K. Dist., - 629 163



"What we are is gift of god and What we become is gift to god"

ANNEXURE II

ETHICAL COMMITTEE LETTER

ANNEXURE II

ETHICAL CLEARANCE CERTIFICATE

Valid from : 2015

Valid to : 2016

Name of the Investigator: Miss.Jesin Deepa. N.

The Ethical committee meeting held on 07-03-2015 had reviewed the project titled "A Quasi experimental study to assess the effectiveness of sodium bicarbonate mouth wash in reducing oral mucositis among oral cancer patients undergoing radiation therapy in C.S.I mission hospital at neyyoor.." The proposal was submitted before the ethical committee for the acceptance and found to be acceptable on ethical grounds. The ethical committee held responsibility and accountability for the investigator for any other administrative approvals that may pertain to this research. This has to be carried out according to conditions outlined in the original protocol submitted for ethical review.

This certificate of approval is valid for the time period provided, there is no change in the methodology protocol or consent process and documents.

Any significant change should be reported to guide for its considerations in advance for its implementation.

Signature of Ethical Committee members:

1. **Dr. Sheeba Jayalal M.B.B.S.,D.G.O.,**
Chief Medical Officer



2. **Dr. Jayalal M.S.,F.I.C.S.,(Germany),M.B.A.,F.I.A.G.E.S**
Chief Surgeon



3. **Dr. ShanthiAppavu M.Sc(N),,PhD**
Nursing Research Advisor


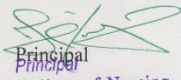



4. **Mrs. Jerlinpriya M.Sc (N),,PhD**
Research Guide



ANNEXURES III

LETTER SEEKING EXPERTS OPINION FOR THE VALIDITY OF THE TOOL

	<p><i>Annammal College of Nursing</i> (Approved by Govt. of Tamilnadu, TN Nurses & Midwives Council, Indian Nursing Council and Affiliated to The Tamilnadu Dr. MGR Medical University) Annammal Hospital Campus, KUZHITHURAI - 629 163 K.K. Dist, Tamil Nadu. Ph : 04651 - 260614, Fax : 04651 - 260605 www.annammalnursing college.com Email : annammalcollege2007@yahoo.co.in</p>
	<p>Dr. Sheeba Jayal MBBS, DGO Chairperson</p> <p>Date :</p>
<p><i>Our Motto : "Heed us to Heed others"</i></p>	<p>From Prof.Mrs.J.M.Jerlin Priya, M.Sc(N)., Ph.D., Principal, Annammal College of Nursing, Kuzhithurai.</p> <p>To</p>
	<p>Respected Sir,</p> <p>Sub: M.Sc Nursing Programme - Dissertation –Validation of the tool request –reg.</p> <p>Ms. Jescin Deepa N, II year M.Sc (N) student of Annammal College of Nursing, Kuzhithurai is approaching you to obtain validation of his study tool pertaining to his dissertation in partial fulfillment of the requirements for the degree of Master of Science in Nursing. The selected topic is</p> <p>“A Quasi experimental study to assess the effectiveness of Sodium Bicarbonate mouth wash in reducing Oral Mucositis among Oral Cancer patients undergoing Radiation Therapy in C.S.I Mission Hospital, Neyyoor at Kanyakumari District”.</p> <p>In this regards I humbly request you to kindly extent possible technical guidance and support for successful completion of dissertation.</p> <p>I enclosed here with checklist for your evaluation.</p> <p>Thanking you</p> <p>Yours faithfully</p> <p> Principal Annammal College of Nursing Kuzhithurai, K.K. Dist.,- 629 163</p> <p></p>
<p><i>“What we are is gift of god and What we become is gift to god”</i></p>	

ANNEXURE IV

EVALUATION CRITERIA CHECKLIST FOR VALIDATING THE TOOL

Instructions

The expert is requested to go through the following criteria for evaluation. Three columns are given for responses and a column for remarks. Kindly place tick mark in the appropriate column and give remarks.

Interpretation of column

Column I : Meets the criteria.

Column II : Partially meets the criteria.

Column III :Does not meet the criteria.

S.NO	CRITERIA	1	2	3	REMARKS
1	Content <ul style="list-style-type: none">• Adequacy• Relevance• Organized				
2	Language <ul style="list-style-type: none">• Simplicity• Clarity• Relevant				
3	Scoring <ul style="list-style-type: none">• Easy To Score• Clarity				
4	Practicability <ul style="list-style-type: none">• Procedure• Utility• Feasibility				

Signature:

Name :

Designation :

Signature of the expert

ANNEXURE V

LIST OF EXPERTS.

1. Dr.Sudhakaran MD.,DMRT.,

Oncologist,,
C.S.I Mission Hospial,
Neyyoor,
Kanyakumari District.

2. Dr. (Mrs.) S.S SharmilaJansi Rani ,M.Sc(N), Phd.,

Professor,
Christian college of Nursing,
Neyyoor,
Kanyakumari District.

3. Mrs. Sherlin, M.Sc,(N).,

Asst.Professor,
C.S.I college of Nursing,
Karakonam,
Trivandrum District.

4. Mr. Joseph Merlin, M.Sc,(N).,

Asst..Professor,
Saraswathy college of Nursing,
Parassala,
Trivandrum District.

5. Mrs. Merlin Suji ,M.Sc,(N),

Reader,
CSI College of Nursing,
Marthandam,
Kanyakumari District..

6. Mrs. Sheeba, M.Sc,(N),

Reader,
Christian college of Nursing,
Neyyoor,
Kanyakumari District.

6. Mrs. Vinitha Bai, M.Sc,(N),

Asst. Professor,
CSI College of Nursing,
Marthandam,
Kanyakumari District.

7. Mrs. Nesalin Suji, M.Sc,(N),,

Lecturer,
College of Nursing,
Marthandam,
Kanyakumari District..

8. Mr. Anto John Britto, M.Sc., M.Ed., M.Phill., P.G., BBM.,

Bio Statistician
Scott Christian college,
Nagercoil.

ANNEXURE VI
RESEARCH PARTICIPANT CONSENT FORM

Dear participant,

I am Jescin deepa. N II yr M.Sc Nursing student of Annammal College of Nursing, Kuzhithurai. As a part of my study, a research on ‘Effectiveness of sodium bicarbonate mouth wash in reducing oral mucositis among oral cancer patients who are undergoing radiation therapy The findings of the study will be helpful in reducing the oral mucositis in oral cancer patients . I here by seek your consent and co-operation to participate in the study. Please be frank and honest in your responses. The information collected will be kept confidential and anonymity will be maintained.

Signature of the researcher

I hereby consent to participate and undergo the study.

Place:

Date:

Signature of the participant

ANNEXURES VII
CERTIFICATE FOR ENGLISH EDITING

CERTIFICATE OF ENGLISH EDITING

TO WHOMEVER IT MAY CONCERN

This is to certify that the dissertation, "A Quasi experimental study to assess the effectiveness of sodium bicarbonate mouth wash in reducing oral mucositis among oral cancer patients undergoing radiation therapy in C.S.I mission hospital, neyyoor at Kanyakumari district" by Miss. Jescin deepa.N, 2nd year MSc(N) student of Annammal College of Nursing was edited for English language appropriateness by



Signature: 
HEADMASTER
ANNAMMAL COLLEGE OF NURSING
KUZHITHURAI

Signature

ANNEXURES VIII
CERTIFICATE FOR TAMIL EDITING

CERTIFICATE OF TAMIL EDITING

TO WHOMEVER IT MAY CONCERN

This is to certify that the dissertation, "A Quasi experimental study to assess the effectiveness of sodium bicarbonate mouth wash in reducing oral mucositis among oral cancer patients undergoing radiation therapy in C.S.I mission hospital, neyyoor at Kanyakumari district" by Miss. Jescin deepa.N , 2nd year MSc(N) student of Annammal College of Nursing was edited for Tamil language appropriateness by



[Handwritten Signature]
24/7/16
HEADMASTER
KUZHITHURAI GIRLS MIDDLE SCHOOL
KUZHITHURAI

Signature

TOOL I

SAMPLE NO:

DEMOGRAPHIC VARIABLES

Instruction: kindly place a tick mark against the option which you feel as appropriate.

1. Age of the patient

- a) 20-30yrs
- b) 31-40yrs
- c) 41-50yrs
- d) More than 50 yrs

2. Sex

- a) Male
- b) Female

3. Educational status

- a) Illiterate
- b) Primary school certificate
- c) Middle school certificate
- d) High school certificate
- e) Intermediate or Post high school diploma
- f) Graduate or Post graduate
- g) Professional or honors
- h) Graduates and others

4. Occupational status

- a) Professional
- b) Semi professional

- c) Shop owners
- d) Skilled workers
- e) Semi skilled workers
- f) Unskilled workers
- g) Unemployed

5. Religion

- a) Hindu
- b) Christian
- c) Muslim
- d) Others

6. Place of living

- a) Urban
- b) Semi urban
- c) Rural
- d) semi rural

7. Family monthly income

- a. ≥ 36017
- b. 18000-36016
- c. 13495-17999
- d. 8989-13494
- e. 5387-8988
- f. 1803-5386
- g. ≤ 1802

TOOL-II

CLINICAL VARIABLE PROFORMA

Instruction: kindly place a tick mark against the option which you feel as appropriate.

1. Family history of cancer

- a) Yes
- b) No

2. Previous exposure of knowledge regarding oral mucositis

- a) Yes
- b) No

3. Treatment modalities

- a) Radiation therapy
- b) Chemo therapy
- c) Both

4. Co morbid illness

- a) Diabetes Mellitus
- b) Hypertension
- c) Obesity
- d) None

5. Habits

- a) Alcoholism
- b) Smoking
- c) Betal leaves chewing

6. Dietary pattern

- a) Vegetarian

b) Non-vegetarian

7. Duration of illness

a) <1 year

b) 1-5 years

c) 5 years and above

8. Previous experience of surgery

a) Yes

b) No

gFjp I

Nehahspapd; nghJ tptuk;

gapw;rpf;F Njh;T nra;j eghpd; vz;zpf;if :

Fwpg;G: fPNo nfhLf;fg;gl;Ls;s Nfs;tpfSf;F rhpahd tpilia Njh;e;njLj;J mjw;Fhpa
fl;lj;jpy; rhp [√] vd FwpapLf.

1) taJtuk;G

1. 20taJKjy; 30 taJtiu

2. 31taJKjy; 40 taJtiu

3. 41taJKjy; 50 taJtiu

4. 51 tajpw;FNkYs;Nshh;

2) ,dk;

1. Mz;

2. ngz;

3) fy;tpj;jFjp

1. gbg;gwptpy;yhjth;

2. njhlf;fepiyf;fy;tp

3. ,ilepiyf;fy;tp

4. cah; epiyf;fy;tp

5. Nky; epiyf;fy;tp

6. gl;ljhpm; yJKJfiygl;ljhhp

7. njhopy;Kiwf;fy;tp
8. gpw fy;tp
- 4) njhopy; tptuk;
1. gapw;rpngw;wnjhopyhsh;
2. ,ilgl;lgapw;rpngw;wnjhopyhsh;
3. filchpikahsh;
4. jpwikahdnjhopyhsh;
5. ,ilgl;ljpwikahdnjhopyhsh;
6. gapw;rpngwhjnjhopyhsh;
7. Ntiyapy;yhjth;
- 5) kjk;
1. ,e;J
2. fpwp];jth;
3. K];yPk;
4. gpw kjk;
- 6) thOkplk;
1. efh;g;;Gwk;
2. ,ilg;gl;lefh;g;;Gwk;
3. fpuhkg;Gwk;
4. ,ilg;gl;lfpuhkg;Gwk;
- 7) khjtUkhdk;
1. &gha; 36017 kw;Wk;; mjw;FNky;
2. &gha; 18000 Kjy; &gha; 36016 tiu
-

3. &gha; 13495 Kjy; &gha; 17999 tiu

4. &gha; 8989 Kjy; &gha; 13494 tiu

5. &gha; 5387 Kjy; &gha; 8988 tiu

6. &gha; 1803 Kjy; &gha; 5386 tiu

7. &gha; 1802; kw;Wk;;mjw;FfPo;

gFjpII

kUj;Jtrk;ke;jkhdfhuzpfs;

Fwpg;G: fPNo nfhLf;fg;gl;Ls;s Nfs;tpfSf;F rhpahd tpilia Njh;e;njLj;J mjw;Fhpa
fl;lj;jpy; rhp [√] vd FwpapLf.

1. cq;fs; FLk;gj;jpy; ahUf;fhtJGw;WNeHa; te;jJz;lh?

1) Mk;

2) ,y;iy

2. cq;fSf;Ftha;topkpAf;Nfhrpb]; gw;wpaKe;ijamwpTntspg;ghLcz;lh?

1) Mk;

2) ,y;iy

3. mjw;fhd rpfpl;irKiwfs;

1) fjph;tPr;Rrpfpl;ir

2) fPNkhnjugp

3) vJTk;,y;iy

4. ,jDld; rhh;e;jgpwNeha;fs;

1) rh;f;fiuNeha;

2) ,uj;jmOj;jNeha;

3) cly; gUkd;

4) vJTk; ,y;iy

5. gof;ftof;fq;fs;

1) kJ mUe;Jjy;

2) Gifgpbj;jy;

3) Gifapiyrhg;gpLjy;

4) vJTk; ,y;iy

6. czTKiw

1) irtczTKiw

2) mirtczTKiw

7. vt;tsTfhykhfcq;fSf;FGw;WNeHa; cs;sJ?

1) 1 Mz;Lf;FFiwthf

2) 1 Mz;LKjy; 5 Mz;Lfshf

3) 5 Mz;LfSf;FNky;

8. ,jw;FKd;GmWitrpfpl;irgw;wpamDgtk; cz;lh?

1) Mk;

2) ,y;iy

TOOL-III

WHO ORAL MUCOSITIS ASSESSMENT SCALE

Grading of oral mucositis	Day-1	Day-4	Day-7	Day-10	Day-13	Day-16
Grade 0 None						
Grade 1 Soreness erythema no ulceration						
Grade 2 Erythema ulcers patient can swallow solid diet						
Grade 3 Ulcers,excessive erythema,patients can swallow solid diet						
Grade 4 Mucositis to the extent that alimination is not possible						

SCORING AND INTERPRETATION

- Mild - 1
- Moderate - 2
- Severe - 3
- Extreme level -4

CHAPTER -I

INTRODUCTION

“The most important thing in illness is never to lose heart”

~Nikolai Lenin

The World Health Organization defines health as "a state of complete physical, mental, and social well being and not merely the absence of disease or infirmity." The maintenance and promotion of health is achieved through different combination of physical, mental, and social well-being, together sometimes referred to as the "health triangle". Systematic activities to prevent or cure health problems and to promote good health in humans are delivered by health care providers. Cancer in medical term is called malignant neoplasm. The word neoplasm is derived from Greek word 'neon' means new and 'plasia' known as moulding.

Cancer may affect people of all ages, even fetuses, but the risk for most varieties increases with age. Usually the cancer has three treatment modalities including chemotherapy, radiation therapy and surgery. Cancer chemotherapy is used to destroy rapidly proliferating cells. However, normal cells with high mitotic indexes are also affected by chemotherapy, particularly those in the oral and gastro intestinal mucosa and the hemopoietic system. Ultimately, this may lead to certain oral complications of cancer chemotherapy such as mucositis, infection, haemorrhage, xerostomia, and neurologic and nutritional disorders. Radiation therapy is a type of palliative therapy. It uses a high energy ionizing radiation. Those rays will destroy the cell's ability to reproduce. Surgery is mainly done for the diagnosis, staging, and treatment. Surgery plays a good role in rehabilitation and palliation. In some of the cancer condition either one or two modes are provided.

The treatment is mainly to decrease the cell multiplication and further complication. Addition of advance technologies in these modalities of medical science has its own role towards good prognosis. Mucositis is the painful inflammation and ulceration of the mucous membranes lining the digestive tract. Oral mucositis refers to the particular inflammation and ulceration that occurs in the mouth and throat. The discomfort can range from mild to severe. Mild discomfort is a change in the way the mouth feels. It is easily treated and quickly healed. Moderate discomfort is considered to be redness and open sores in the mouth. Severe mucositis involves many sores in the mouth, bleeding, and severe pain. None of these discomfort levels are pleasant.

Each can cause other problems including difficulty in swallowing, talking, eating, and infection.

Baking soda (oral rinse) has become almost a cheapest and readily applicable method in reducing the development or decreasing the severity of oral mucositis caused due to cancer treatment. Sodium bicarbonate is basically a chemical compound, which is also often known as baking soda, breadsoda, cooking soda and bicarbonate of soda also nick named sodium bicarbonate as sodium bicarb, bicarb soda. Sometimes it is also simply known as bi-carb. The Latin name for sodium bicarbonate is Saleratus, which means, 'aerated salt'. Sodium bicarbonate is a natural buffer that maintains a healthy pH in mouth to promote a clean and fresh oral environment.

A mouthwash can be prepared by dissolving one teaspoon full of sodium bicarbonate in a glass of water. It is recommended for patients suffering from mucositis or erosion, due to its ability to increase salivary pH and suppress the growth of acid uric micro-organisms. Sodium bicarbonate can improve taste and it neutralizes acids and thus prevents erosion. It is bland and will not irritate the oral mucosa in patients with mucositis.

The effect of a sodium bicarbonate mouthwash solution is thought to aid in the formation of granulation tissue and to promote healing. Sodium bicarbonate mouthwash solution is safe and economical and has been used in cancer patients. Sodium bicarbonate mouthwash solution gargles cleanses the wound, reduces swelling, and can decrease pain. Sodium bicarbonate has also been used as a cleansing agent because of its ability to dissolve mucus and loosen the debris. The combination of salt and sodium bicarbonate raises oral pH and prevents overgrowth of bacteria. Sodium bicarbonate mouthwash solution is found to be as effective as other Mouth washes in management of mucositis.

BACKGROUND OF THE STUDY

Global Scenario

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. 76% cases are diagnosed with cancer in those over the age of 55 yrs. American cancer society reported that 1,399,790 persons were diagnosed with cancer in 2012. 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 10 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, breast cancer accounts for nearly 60 percent of all cancers. Several studies reported that oral cancer is proportionately on the increase in a metropolitan area of India.

Oral cancers are common in several regions of the world where tobacco use and alcohol consumption is high. The age standardized incidence rate of oral cancer (around 1990) in males exceeds 30/100,000 in regions of France, Hong Kong, the Indian sub-continent, Central and Eastern Europe, Spain, Italy, Brazil, and among US blacks. High rates (> 10/100,000) in females are found in the Indian sub-continent, Hong Kong and Philippines. The highest incidence rate reported in males are 63.58 and in females are 15.97 (India, Chennai). The variation in incidence of cancers by subsite of oral cancer is mostly related to the relative distribution of major risk factors such as tobacco or betel chewing, cigarette or bidi smoking, and alcohol consumption.

Indian Scenario

Incidence of oral mucositis among cancer patients for radiation therapy among head and neck cancer patients of India was 44.8 and 23.7 for males and females respectively compared to 11.2 per 100,000 in USA. Cancers of oral cavity are high in Kerala (southern India) and pharyngeal cancer in Mumbai (western India). Incidence of mouth cancer in Mumbai is 5.7 per 10,000. The incidence is dependent upon the cancer treatment regimen.

Regional Scenario

In Tamilnadu there would be about 1.5 lakhs cancer cases and 35,000 new cancer cases are added to this pool each year.

The current oral cancer radiation therapy protocols have a mucositis incidence of 85-100%. For fractionated radiation, the incidence is 100%, for chemo radiation 89% and for conventional radiation 97%. The incidence of mucositis can approach 90-100% in patients receiving aggressive myelo-ablative chemotherapy.

Sodium bicarbonate mouthwash gargles cleanses the wound, reduces swelling, and can decrease pain. Sodium bicarbonate has also been used as a cleansing agent

because of its ability to dissolve mucus and loosen the debris. The combination of salt and sodium bicarbonate raises oral pH and prevents overgrowth of aciduric bacteria.

Current studies says that the most effective measure to treat radiation therapy induced mucositis among patients with oral cancer is frequent oral rinsing with a bland water such as saline, sodium bicarbonate rinse in order to reduce the amount of microbial flora.

NEED FOR THE STUDY

Cancer is already emerged as a major non communicable health problem globally. Cancer is not a single disease with a single cause. It is group of distinct diseases with different causes, manifestation, treatment and prognosis. It is characterized by a number of associated symptoms that impair the quality of life of patients.

Mucositis is inflammation of the mucosa in the mouth. It occurs as a common side effect of radiation treatment. It inhibits the ability of the mucosal layer to repair micro lesions, leading to ulceration exacerbated by infection. It is extremely important to keep patients free from the oral foci of infection and pain to minimize local infection and bacteremia and to enable them to maintain a nutritious diet.

Oral mucositis is a frequent adverse effect of radiation therapy. Conditioning regimens for hematopoietic stem cell grafting often causes severe oral mucositis, preventing patients from drinking and eating normally. Complication can be attenuated by timely oral care such as extraction of damaged teeth, treatment of tooth decay, and care of trauma due to dentures.

Effective approaches for the prevention or treatment of oral mucositis have not been standardized, and vary considerably among institutions. Prophylactic measures begin with an increased emphasis on improved oral status.

Ganesh .R, John,(2011) conducted a cross sectional study in a cancer hospital at Chennai. The study population were subjects with oral cancer who are reported for treatment. A pretested interviewer administered questionnaire to assess the socioeconomic status of oral cancer patients. Pareek's scale of classification was used for rural population and Kuppaswamy's classification was used in urban population to assess the socioeconomic status. Total of 266 oral cancer patients aged 21-60 years and above comprised the study population. Most of the study subjects belonged to the lower socio economic classes, about 48.5% of rural subjects had agriculture as a source of occupation and 28.6% of urban subjects were unskilled labourers. In both

rural and urban subjects, majority, 94.9% and 71.9% had family income less than Rs 5000. The percentage of illiterates was high in both rural and urban class (i.e.) 55.8% and 21.9% respectively. The difference in the prevalence of oral cancer among different levels of literacy and occupation was found to be significant statistically.

Sathyasri, (2012) 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) or a control. Mucositis was assessed among 76 patients. Patients in the Povidone-Iodine or salt/soda group had significantly lower mucositis scores when compared to the control group from the first week of radiotherapy. Their scores were also significantly lower when compared to the chlorhexidine groups from the fourth and fifth week respectively, after radiotherapy. This study demonstrates that use of alcohol-free Povidone-Iodine or salt/soda mouthwash can reduce the severity and delay in the onset of oral mucositis caused by anti-neoplastic radiotherapy.

Aggressive cancer therapy places patients at greater risk for oral complications and treatment-related consequences.

Radiation-induced oral mucositis affects the quality of life of the patients and the family concerned. The present day management of oral mucositis is mostly palliative and or supportive care. The current management should focus more on palliative measures, such as pain management, nutritional support, and maintenance, of good oral hygiene.

Suzanne L. Dibble, (2013) conducted a study to identify the effectiveness of 3 mouthwashes to treat chemotherapy-induced mucositis. The mouthwashes include salt, soda, chlorhexidine, and “magic” mouthwash (lidocaine, Benadryl, and Maalox). A randomized, double-blind clinical trial was implemented among 23 outpatient and office settings. Nurses used the Oral Assessment Guide for initial assessment. Among 142 out of 200 patients, there was a cessation of the signs and symptoms of mucositis within 12 days. No significant differences in time for the cessation of the signs and symptoms were observed among the 3 groups. Comparatively it was found that the sodium bicarbonate mouth wash is least costly than any other solutions used as mouth wash.

Sodium bicarbonate mouth wash was used as a cleansing agent because of its ability to dissolve mucus and loosen the debris. Sodium bicarbonate mouth wash raises the oral pH and prevents overgrowth of aciduric bacteria and it is readily available.

Nurses have a critical role in all aspects of managing mucositis, including assessing it, teaching oral care, administering pharmacologic interventions, and helping patients cope with symptom distress. Mucositis can have a negative impact on the overall treatment experience, especially when severe pain or infection occurs. Many interventions for managing mucositis exist; however, some are based on tradition or expert opinion and have not been studied in large, randomized, controlled trials.

Many reviews provided empirical evidence related to interventions for oral mucositis. Oral care and rinses, pharmacologic interventions, and other techniques are evaluated.

The researcher, during the clinical posting observed that many developed oral mucositis induced by radiation therapy. It can be reduced by the use of sodium bicarbonate mouth wash. Discussion with the experts also helped the investigator to believe that, this study is needed and will be useful for patients. Hence the particular topic was selected for research.

STATEMENT OF THE PROBLEM

A Quasi experimental study to assess the effectiveness of sodium bicarbonate mouth wash in reducing oral mucositis among oral cancer patients undergoing radiation therapy in C.S.I mission hospital at Neyyoor.

OBJECTIVES

- To assess the level of oral mucositis before and after administration of sodium bicarbonate mouth wash among oral cancer patients in experimental and control group.
- To compare the effectiveness of sodium bicarbonate solution with existing practices in reducing oral mucositis among oral cancer patients undergoing radiation therapy in experimental and control group.
- To determine the association between post interventional levels of oral mucositis among oral cancer patients undergoing radiation therapy with selected socio demographic variables and clinical variables.

HYPOTHESES

H₁: There will be a significant difference between the pre and post interventional level of oral mucositis among oral cancer patients in experimental group and controlgroup .

H₂: There will be a significant difference between the post interventional level of oralmucositis among oral cancer patients in experimental and control group.

H₃: There will be a significant association between the post interventional level of oralmucositis among oral cancer patients with the selected demographic and clinical variables.

OPERATIONAL DEFINITION

Assess

In this study, it refers to the process of measuring the presence of oral mucositis among the oral cancer patient by using WHO oral assessment scale.

Effectiveness

Effectiveness refers to the extent to which sodium bicarbonate mouth wash has produced desirable effects on reducing oral mucositisin GRADE-IVas measured by WHO oral assessment scale.

Sodium bicarbonate mouth wash

In this study, it refers to mouth wash of sodium bicarbonate solution. One tea spoonful of sodium bicarbonate in 250 ml of water 3 times a day for one week.

Oral mucositis

In this study, it refers to the presence of redness, swelling, pain and ulceration related to inflammation of oral mucosa in the oral cavity as measured by WHO oral mucositis assessment scale.

ASSUMPTIONS

The study assumed that

- oralmucositis is treatable.
- sodium bicarbonate mouthwash is effective in reducing oral mucositis.It raises oral pH and prevents overgrowth of aciburic bacteria.

DELIMITATIONS

The study was delimited to

- the sample size of 60 oral cancer patients.
- two weeks of interventions

- patients undergoing treatment in C.S.I Mission Hospital at Neyyoor.
- data collection period for one month.

PROJECTED OUTCOME

- The study helps to find out the level of oral mucositis among oral cancer patients undergoing radiation therapy.
- The study helps to find out the association between post interventional level of oral mucositis among oral cancer patients undergoing radiation therapy with selected demographic and clinical variables.
- The study helps to find out the effectiveness of administration of Sodium bicarbonate mouth wash in reducing oral mucositis among oral cancer patients undergoing radiation therapy in both experimental and control group.

CONCEPTUAL FRAMEWORK

A conceptual framework is a group of concepts and a set of propositions that spells out the relationship between them. Conceptual framework plays several interrelated roles in the progress of science. The overall purpose is to make scientific findings meaningful and generalizable.

The conceptual framework selected for the study was based on **“Wiedenbach’s prescriptive theory”** “which was described as a system of concept invented for a purpose. Prescriptive theory may also be described as one that conceptualizes both the desired situations and the perception by which it is to be brought about as an outcome.

The study is based on the concept that administration of sodium bicarbonate mouth wash helps to reduce the oral mucositis. The investigator has adopted the Wiedenbach’s helping art of clinical nursing theory (1964) as a base of developing the conceptual framework. This is a prescriptive theory, which directs action towards an expected goal.

The conceptual model of nursing practice according to this theory consists of 3 steps as follows

Step 1: Identifying the need for help

Step 2: Ministering to the need

Step 3: Validating the met need

STEP 1: IDENTIFYING THE NEED FOR HELP

The first step is to identify the need to plan further actions to meet them. The need identified among the sample is to reduce the oral mucositis. The process began with sample selection on the basis of the inclusion criteria followed by the pre-testing the level of oral mucositis by WHO oral mucositis assessment scale.

STEP 2: MINISTERING TO THE NEED

The second step refers to the provision of required help to fulfil the identified need. It has two components

- Prescription: It means fulfilment of central purpose in order to reduce oral mucositis
- Realities: It includes agent, recipient, goal, means and framework.

The various aspects which constitute realities are as follows

Agent The investigator is the agent who prepared and administered the sodium bicarbonate mouthwash.

Recipient The oral cancer patients were the recipients.

Goal In this study, it refers to the reduction of oral mucositis.

Means and activities A pre-test was carried out to assess the level of oral mucositis, followed by which a sodium bicarbonate mouth wash is administered 3 times a day and is monitored by WHO oral mucositis assessment scale.

STEP 3: VALIDATING THE MET NEED

The last step is to validate the met need. In this study the validation of the need was done by conducting a post-test on 4th day, 7th day, 10th day, 13th day and 16th, day. Findings revealed that the mean post-test score was significantly higher than their mean pre-test score, showing the effectiveness of sodium bicarbonate solution in reducing oral mucositis.

SUMMARY

This chapter has dealt with the objectives, the operational definitions, variables, assumptions and hypotheses which are predictive statements of the relationship between the independent and dependent variables, and delimitations of the study. The conceptual framework of the present study was based on the Wiedenbach's prescriptive theory.

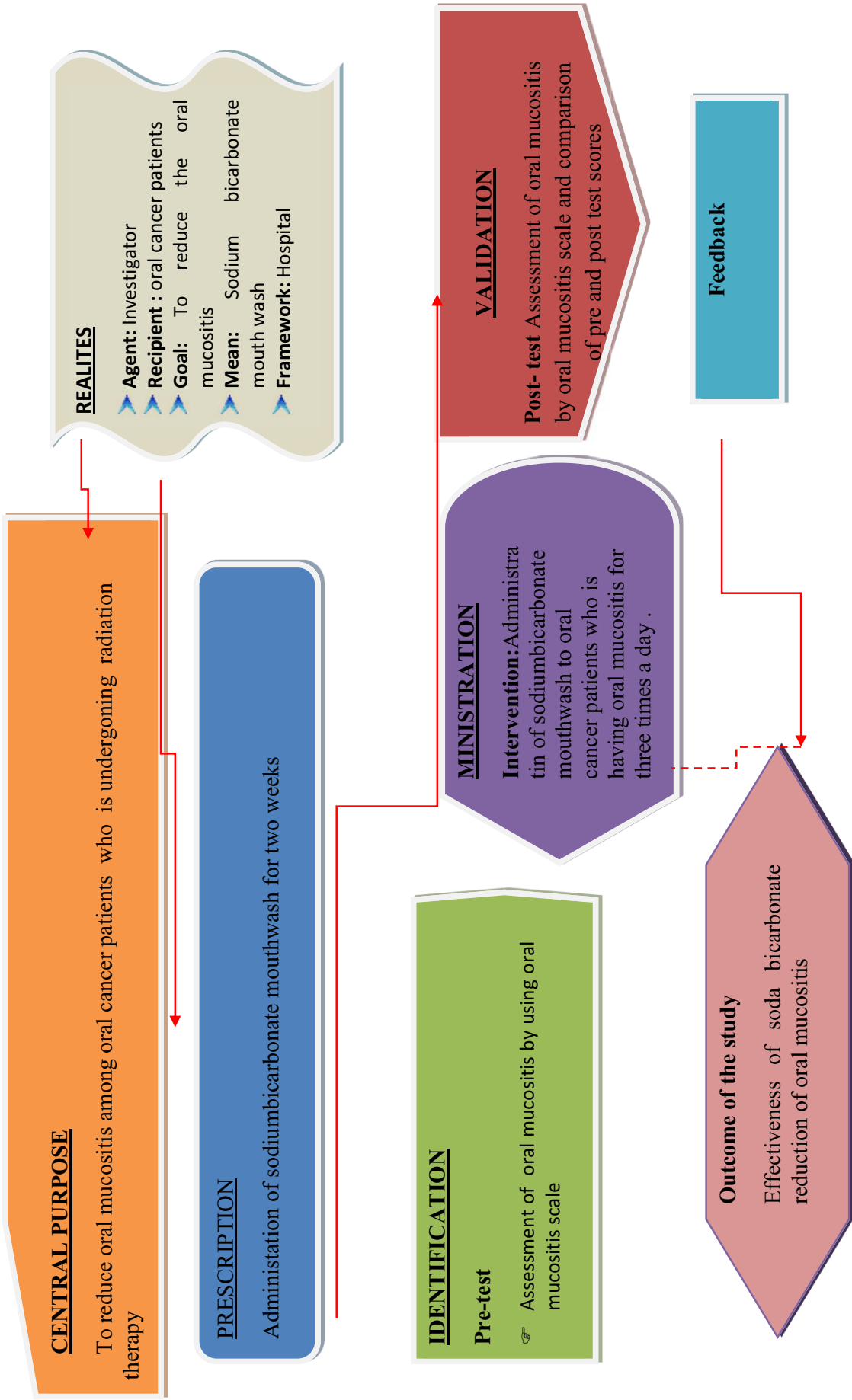


Fig: 1 CONCEPTUAL FRAME WORK BASED ON WIEDENBACH'S PRESCRIPTIVE THEROY (1964)

CHAPTER –II

REVIEW OF LITERATURE

Review of literature is a key step in research process. It refers to an extensive, exhaustive and systematic examination of publications relevant to the research project. Nursing research may be considered as a continuing process in which knowledge gained from earlier studies is an integral part of research in general.

(Basavanthappa B.T,1998)

Literature review refers to the activities involved in searching for information on a topic and developing a comprehensive picture of the state as knowledge on that topic.

(Polit and Hungler, 1993)

Therefore the investigator studied and reviewed the related literature to broaden the understandings about the topic and to gain insight about the selected problem under study.

The literature has been reviewed under the following headings

- I. Empirical studies related to prevalence of cancer.**
- II. Empirical studies related to radiation therapy induced oral mucositis.**
- III. Empirical studies related to sodium bicarbonate mouthwash for patients with oral mucositis.**

I. EMPIRICAL STUDIES RELATED TO PREVALENCE OF CANCER

Ajitmishra, (2014) conducted a descriptive cross sectional study to determine the prevalence of Oral Cancer among patients who have attended the outpatient department, at Maitri Dental College and Research centre Anjora, Durg for a period of 24 months from 2011 to 2012. Further various modes of tobacco and alcohol consuming habits were assessed along with the site of occurrence of oral cancer. About 32349 subjects belonging to district of Durg in Chhattisgarh (India) were screened. Tobacco and alcohol consumption was the common habit among the study population. Out of these about 42 cases showed Oral Cancer. The prevalence of Oral Cancer was 0.12. The findings in the present study reveal a high prevalence of Oral Cancer and a rampant misuse of variety of addictive substances in the community.

JananiSelvaraj, et al,(2014) conducted a cross sectional study to explore the cancer incidences in the western regions of Tamil Nadu. A sum of 14392 cancer cases was recorded from the hospital. It shows that Coimbatore district recorded the highest number of incidences among all districts. Among all age-groups, the adults aged 50-74 carry the highest burden of cancer. Through this study, it is observed that Coimbatore district is under major threat and needs further investigation of risk factors for implementing optimized treatment and prevention strategies for reducing the adverse effects of cancer

Daniel saman,(2012) conducted a case-control study among Italian and Swiss men who were at increased risk of oral cancer (OR = 228) and pharyngeal cancer (OR = 100). The highest level of drinking (≥ 77 drinks/week) and smoking (≥ 25 cigarettes/day) plays a significant role in development of cancer. The authors of this study found that there would be synergistic effects of smoking and alcohol consumption on OPC. The increase in oral cancer would be greater than the increase in pharyngeal cancer. This was shown to be the case in this study because the authors explain that the ratios of ORs between oral cancer and pharyngeal cancer was about 2-times greater for oral cancer than for pharyngeal cancer for each combined level of smoking and drinking

Sandhya G.I, (2012) conducted a community based cross-sectional survey among 1076 randomly selected male fishermen aged 25 years and above in three randomly selected coastal villages of Trivandrum district. Chi-square test and standard deviation and percentage values were used as the statistical tool. The p value less than 0.05 is considered as significant. The Result showed that the prevalence of panmasala use was 28.3%. panmasala use is highest among the men of age group between 45-50 years. The mean age of onset of panmasala use was 17.7 (standard deviation 9.7). Only 40.4% of the study population had awareness about the fact that pan chewing can cause oral cancer. 87.2% subjects agreed that panmasala which they consume regularly contain tobacco. The factors which favour panmasala use were $p < 0.05$ low education, aging and lack of awareness. The study highlights the need of an extensive oral cancer screening and awareness programmes against panmasala use in the coastal areas for early detection and prevention of tobacco induced oral potentially malignant disorders and oral cancer.

Ravi mehrotra,(2011) conducted a retrospective study for 11 years from the year 2000 to 2011. Data was collected year-wise using the tumor registry data. All

biopsies submitted for histopathology to the Pathology department were reviewed and analyzed for demographic data, site and diagnosis. The Kolmogorov-Smirnov Two-Sample Test was utilized to determine whether two distributions are the same. A total of 40559 biopsies were examined in the department, of which, lesions of the head and neck region, excluding the oral cavity, constituted 694 biopsies (409 males and 285 females). One hundred and forty-four malignant lesions were reported, 114 being males and 30 females. A comparison of the age-specific prevalence rates of cancer during the study period showed that the prevalence was highest in patients belonging to 50-59 years age group and among them the squamous cell carcinoma Grade II was the most prevalent type.

Ganesh .R, John,(2011) conducted a cross sectional study in a cancer hospital at Chennai. The study population were subjects with oral cancer who are reported for treatment. A pretested questionnaire was used to assess the socioeconomic status of oral cancer patients. Pareek's scale of classification was used for rural population and Kuppaswamy's classification was used in urban population to assess the socioeconomic status. Total of 266 oral cancer patients aged 21-60 years and above comprised the study population. Most of the study subjects belonged to the lower socio economic classes. About 48.5% of rural subjects had agriculture as a source of occupation and 28.6% of urban subjects were unskilled labours. In both rural and urban subjects, majority, 94.9% and 71.9% had family income below Rs 5000. The percentage of illiterates was high in both rural and urban class (i.e.) 55.8% and 21.9% respectively. The differences in the prevalence of oral cancer among different levels of literacy and occupation were found to be significant statistically.

Deepak Ganjewala,(2009) conducted a study on epidemiology of cancer in parts of Madhya Pradesh and Uttar Pradesh. The results showed that most commonly affected people were in age group of 25-50 and 50-75 years. Around ~ 41 and 51% patients were in age group of 25-50 and 50-75 years, respectively. Of which 41% patients were in age group of 25-50 years, 37% were female whereas 30 were in age group in 50-75 years,51% were males. In MP, CIR (%) rate of cervical cancer was almost double than other type of cancers .Tobacco and diet particularly non-vegetarian were identified as major risk factors. 87% patients were non-vegetarians and 41% were tobacco chewers. Thus, the study suggests that females between the age group 25-50 years are at high risks of cervix and other female cancers. Unlikely,

males in between the age group 50-75 years are most susceptible. Also study has proven that tobacco and diet as a crucial risk factors for cancers in MP and UP.

II. EMPIRICAL STUDIES RELATED TO RADIATION INDUCED ORAL MUCOSITIS

RenataLazari, (2011) conducted an interventional study, In this study result shows immediate pain relief was achieved in 66.6% of the patients after the first application. Based on the functional scale, mucositis grade III (not capable to eat solids) was reduced in 42.85% of the cases. According to the scale based on the clinical features, mucositis grade IV (ulcerative lesions) was reduced in 75% of the patients that presented this grade of mucositis at the beginning of laser therapy as a conclusion Low-energy laser was well-tolerated and showed beneficial effects on the management of oral mucositis, improving the quality of life during the oncologic treatment.

Murphy B A ,(2009) conducted a non-intervention study was he found that (76%) patients reported severe mouth and throatsoreness pain and functional impairment because of mouthand throat soreness increased during the course of therapydespite the use of opioid analgesics in 64 (85%) of thepatients. As a conclusion this study demonstrates thatmucositis related pain and functional impairment isassociated with increased use of costly health resources. Aneffective treatment to reduce the pain and functionalimpairment of oral mucositis is needed in this population.

Goyal M,(2006) conducted an observational study among the patients receiving radiation for oral cancer.He found that the grades of mucositis were marginally higher in the evening irradiated group (38%) than in the morning irradiated group (26%). In conclusion the observed incidence of grade III / IV mucositis in morning vs. evening irradiated patients may be because of the existence of circadian rhythm in the cell cycle of normal mucosa.

ShanthiAppavu,(2007) conducted a descriptive study about oral complications related to cancer treatment. Out of 118 patients 9 had developed complications. The overall prevalence rate was found to be higher in oncology ward (13.6%) as compared to medical ward (4.2%). In this study mouth was found to be the common complicated area during the treatment. The findings revealed that the majority of staff (67.5%) reported they give more importance to oral mucositis. More than one third of the nurses had also reported that they inspect for local infection (37.5%), Xerostomia

(37.55), functional disabilities (15.0%), taste alteration (20.0%) and abnormal dental development (10.0%). As a conclusion there is a great need to educate not only nurses but relatives and the patients to adopt certain preventive strategies to reduce the prevalence of oral complications related to cancer treatment.

III. EMPIRICAL STUDIES RELATED TO SODIUM BICARBONATE MOUTH WASH

Shitha,(2012)conducted a research study on the current treatments for radiation therapy-(RT- induced mucositis in patients with oral cancer). In this study she found out that the most effective measure to treat RT-induced mucositis in patients with oral cancer is frequent oral rinsing with a bland mouthwash, such as saline or a sodium bicarbonate which will help to reduce the amount of oral microbial flora. Dental care, consistent oral assessments, and the initiation of a standardized oral hygiene protocol before the initiation of cancer treatment are also the most effective approaches for oral mucositis.

Sathyasri, (2012) 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) or a control. Mucositis was assessed Among the 76 patients who completed the study, patients in the Povidone-Iodine or salt/soda group had significantly lower mucositis scores when compared to the control group from the first week of radiotherapy. Their scores were also significantly lower when compared to the chlorhexidine groups from the fourth and fifth week respectively, after radiotherapy. This study demonstrates that use of alcohol-free Povidone-Iodine or salt/soda mouthwash can reduce the severity and delay the onset of oral mucositis due to anti-neoplastic radiotherapy

Stotts NA, (2009) done a comparative study to determine the efficacy of a mouthwash in relieving mucositis induced discomfort in patients receiving chemotherapy, (lidocaine, diphenhydramine and sodium bicarbonate innormal saline mouthwash) when they developed mucositis of any severity. The complications were assessed on the CALGB (Cancer and Leukaemia Group B) scale. The response to the mouthwash was reported on a self assessment scale. Patients' response data were analyzed with reference to: (1) relief throughout the duration of mucositis and (2)

relief during the worst stage (for each episode) of mucositis. The average duration of mucositis was 7.9 days (range 3–23 days), and the mean duration of the worst stage of mucositis was 4.81 days (range 2–13 days). The mean mucositis severity score was 1.9 (range 1–4), and the average self-assessment (response) score was 0.81 (range 0–2). The mean mucositis score during the worst stage of mucositis was 2.25 (range 1–4), and the average self-assessment (response) score during the worst stage of mucositis was 0.91 (range 0–2.7). These results suggest that this three-drug mouthwash provides effective symptomatic relief in patients.

SUMMARY

This chapter had dealt with the review of literature related to prevalence of cancer; radiation therapy induced oral mucositis and effectiveness of sodium bicarbonate mouthwash for patients with oral mucositis. In brief the literature review has provided an understanding and broadened the investigator's outlook necessary for designing the conceptual framework, research design and construction of the tool of the study.

CHAPTER III

RESEARCH METHODOLOGY

Research methodology involves the systematic procedures by which the researcher starts from the initial identification of the problem to its final conclusion. It involves steps, procedures and strategies for gathering and analyzing data during the research investigation.

Denise F. Polit (2011)

This chapter deals with the methodology adapted to this study. It includes Research approach, Research design, Variables, Settings, Population, Sample, Sample size, and Criteria for sample selection, Sampling technique, Description of tool, Content validity, reliability, Pilot study, Method of data collection, plan for data analysis and Protection of human rights and data collection schedule.

RESEARCH APPROACH:

The research approach tells the researcher what data to collect and how to analyze it. It also suggests possible conclusion to be drawn from the data, in view of the nature of the problem under study and to accomplish the objectives of the study.

Denise F. Polit (2011)

Quantitative research approach was used as an appropriate research approach for the present study to evaluate the effectiveness of sodium bicarbonate solution in reducing oral mucositis among oral cancer patients who are receiving radiation therapy in C.S.I Mission Hospital, at Neyyoor.

RESEARCH DESIGN

Research design provides the clue that holds the research project together. A Design is used to structure the research to show how all the major parts of the research project works together to try to address the initial research question.

Denise F. Polit (2011)

The research design adopted for the present study is Quasi-experimental non equivalent control group pre test- post test design. The design is represented below.

EXPERIMENTAL GROUP	0₁	X	0₂
CONTROL GROUP	0₂	-	0₄

0₁and0₃ - Pre-test assessment of oral mucositis

0₂ and 0₄ - Post-test assessment of oral mucositis

X - Sodium bicarbonate mouth wash

VARIABLES

Variables are defined as “An attribute that varies, that it, takes on different values.”

Denise F. Polit (2011)

Dependent variable

In this study,the dependent variable is the reduction of oral mucositis among oral cancer patients with oral mucositis.

Independent variable

Independent variable is defined as “The variable that is believed to cause or influence the dependent variable.

In this study, independent variable is sodium bicarbonate mouth wash.

Extraneous variables

A variable that confronts the relationship between the independent and dependent variable and that needs to be controlled either statistically or in the research design

In this study, it refers to age, sex, occupation,dietary pattern, place of living ,maintenance of oral hygiene, duration of radiation therapy

SETTING

Setting refers to the physical location and condition in which data collection takes place.

Denis F. Polit (2011)

The present study was conducted in C.S.I Mission Hospital, Neyyoor in kanyakumari district.The in-patient who is receiving radiation therapy was selected for the study.It is 420 bedded hospitals.There was an average of 8 patients for inpatients radiation therapy per day with the statistics of 240 patients per month.

POPULATION

A population is defined as “the entire set of individuals or objects having some common characteristics”.

Denise.F. Polit (2011)

In this study, population consists of stage II to stage IV of oral cancer patient who are undergoing radiation therapy in selected hospitals at kanyakumari district.

Target population

Target population is the group of population that the researcher aim to study and to whom the study findings will be generalized.

Denise.F. Polit (2011)

In this study, the target population comprises of stage II to stage IV oral cancer patients with oral mucositis who are undergoing radiation therapy.

Accessible population

The accessible population is the list of population that the researcher finds in study.

Denise.F. Polit (2011)

In this study, accessible population was stage II to stage IV oral cancer patients with oral mucositis in C.S.I hospitals at Kanyakumari District.

SAMPLE

Sample is defined as “a subset of a population comprising those selected to participate in the study”.

Denise.F. Polit

The samples consists of stage II to stage IV oral cancer patients who have undergone radiation therapy in C.S.I hospitals at Kanyakumari district

SAMPLE SIZE

Sample size is defined as, “the number of people who participate in the study”.

Denise.F. Polit

Sample size consists of the total sample size of 60 oral cancer patients. Among them 30 was in experimental group and 30 were in control group.

SAMPLING TECHNIQUE

Sampling technique is defined as “the process of selecting a portion of the population to represent the entire population”.

Denise.F. Polit (2011)

Sampling procedure adopted was purposive sampling technique.

SAMPLING CRITERIA

Sampling Criteria involves selecting cases that meet some predetermined criterion of importance. The criteria for sample selection are mainly depicted under two headings, which includes the inclusion criteria and exclusion criteria.

Inclusion criteria

The study includes oral cancer patients who

- are willing to participate.
- are in stage II to IV
- are available at the time of data collection
- can understand Tamil, Malayalam.
- are having oral mucositis.
- are above the age 20 and above.

Exclusion criteria

The study excludes oral cancer patients who

- have undergone chemotherapy
- are in stage I
- belongs to stage I cancer
- is having other types of cancer
- are not willing to participate.

SELECTION AND STUDY TOOL

Tool development is a complex and time consuming process. It consists of defining the construct to be measured, formulating the items, assessing the items for content validity, developing instructions for respondents, pre-testing, estimating the reliability and conducting pilot-study.

(Polit and Hungler,1993)

The tool was prepared on the basis of objectives of the study. The following methods were used for the development of the tool by the investigator. Reviewed the literature from books, journals, other publications and web-sites

The tool component includes three parts.

PART I

It comprised of socio demographic proformaincluding age of the patients, sex, education status, occupational status, religion, place of living and family income.

PART II

It comprised of clinical variable proforma including family history of cancer, previous knowledge, treatment modalities, co morbid illness, habits, dietary pattern, duration of illness and previous surgery.

PART III

WHO Oral mucositis scale which includes Grade I to Grade IV

TESTING OF TOOL VALIDITY

The content validity refers to the adequacy of the sampling of the domain being studied. Content validity of the tool was obtained after consulting with research guide and getting opinion from eight experts in the field of medical surgical nursing. One of the experts was a doctor, and other biostatistician. The validations have suggested some specific modifications in the clinical variable proforma. The modification and suggestions of experts were incorporated in the final preparation of the tool for assessing oral mucositis.

RELIABILITY OF STUDY INSTRUMENTS

Reliability refers to the accuracy and consistency of measuring the tool. The reliability of the tool was elicited by using Inter-rater reliability technique; Karl Pearson's 'r' was computed for finding out the reliability of study tool. For assessment scale the 'r' was found to be 0.9 which showed positive correlation, and checklist was found to be 0.9 which showed positive correlation, indicates that the tools are highly reliable.

PILOT STUDY

Pilot study is defined as, "a small- scale version or trial run, done in preparation of a major study."

Denise F. Polit (2011)

Pilot study was conducted in C.S.I mission hospital, Neyyoor. Initial permission was sought from the institution and formal permission was sought from the chief medical officer for conducting the pilot study. Pilot study was conducted in the month of September for a period of one week. The purpose was explained to the samples and confidentiality was assured. Consent was obtained from the participants.' The investigator selected 6 samples, 3 samples were allocated for experimental group and 3 were in control group using purposive sampling technique, who fulfilled the inclusion criteria. Investigator administered only sodium bicarbonate mouth wash for experimental group. Post test was conducted using socio-demographic proforma, clinical variable proforma and WHO oral mucositis assessment scale.

DATA COLLECTION PROCEDURE

Data collection is the gathering of information needed to address the problem. Before starting the study formal permission was obtained from the dissertation committee of Annammal College of nursing at Kanyakumari district. The data collection period is for 4 weeks in the month of December. At first a rapport was established with the patients and the purpose of the study was explained to them. Verbal and written consent was taken from the patients. Patients with oral mucositis among oral cancer patients who are undergoing radiation therapy were selected as study participants. The 60 samples were selected by using purposive sampling technique. Sociodemographic variables, clinical variables were collected. The pre-test was done by using WHO oral mucositis assessment Scale. Sodium bicarbonate mouth wash was given for 3 times for a period of two weeks. The post-test level of oral mucositis was evaluated by conducting a posttest on 4th day, 7th day, 10th day, 13th day, 16th day for both the groups with oral mucositis scale.

S.No	No of Samples	C.S.I Mission Hospital Neyyoor	
		Pre test	Post test
1	4	4/12/15	10/12/15
2	4	5/12/15	11/12/15
3	4	7/12/15	12/12/15
4	4	8/12/15	13/12/15
5	4	9/12/15	14/12/15
6	2	10/12/15	15/12/15
7	4	11/12/15	16/12/15
8	3	13/12/15	17/12/15
9	4	14/12/15	18/12/15
10	4	15/12/15	20/12/15
11	4	16/12/15	22/12/15
12	4	17/12/15	23/12/15
13	4	18/12/15	24/12/15
14	3	19/12/15	26/12/15
15	4	21/12/15	27/12/15
16	2	22/12/15	28/12/15
17	2	23/12/15	29/12/15

PLAN FOR DATA ANALYSIS

Data collected was analysed using both descriptive and inferential statistics such as mean, standard deviation, chi square, paired 't' test and unpaired 't' test.

Descriptive statistics

- Frequency and percentage distribution was used to assess the socio demographic and clinical variables of oral cancer patients with oral mucositis undergoing radiation therapy.
- Frequency and percentage distribution was used to assess the level of oral mucositis.
- Mean and standard deviation was used to assess the effectiveness of sodium bicarbonate mouth wash in reducing oral mucositis.

Inferential statistics

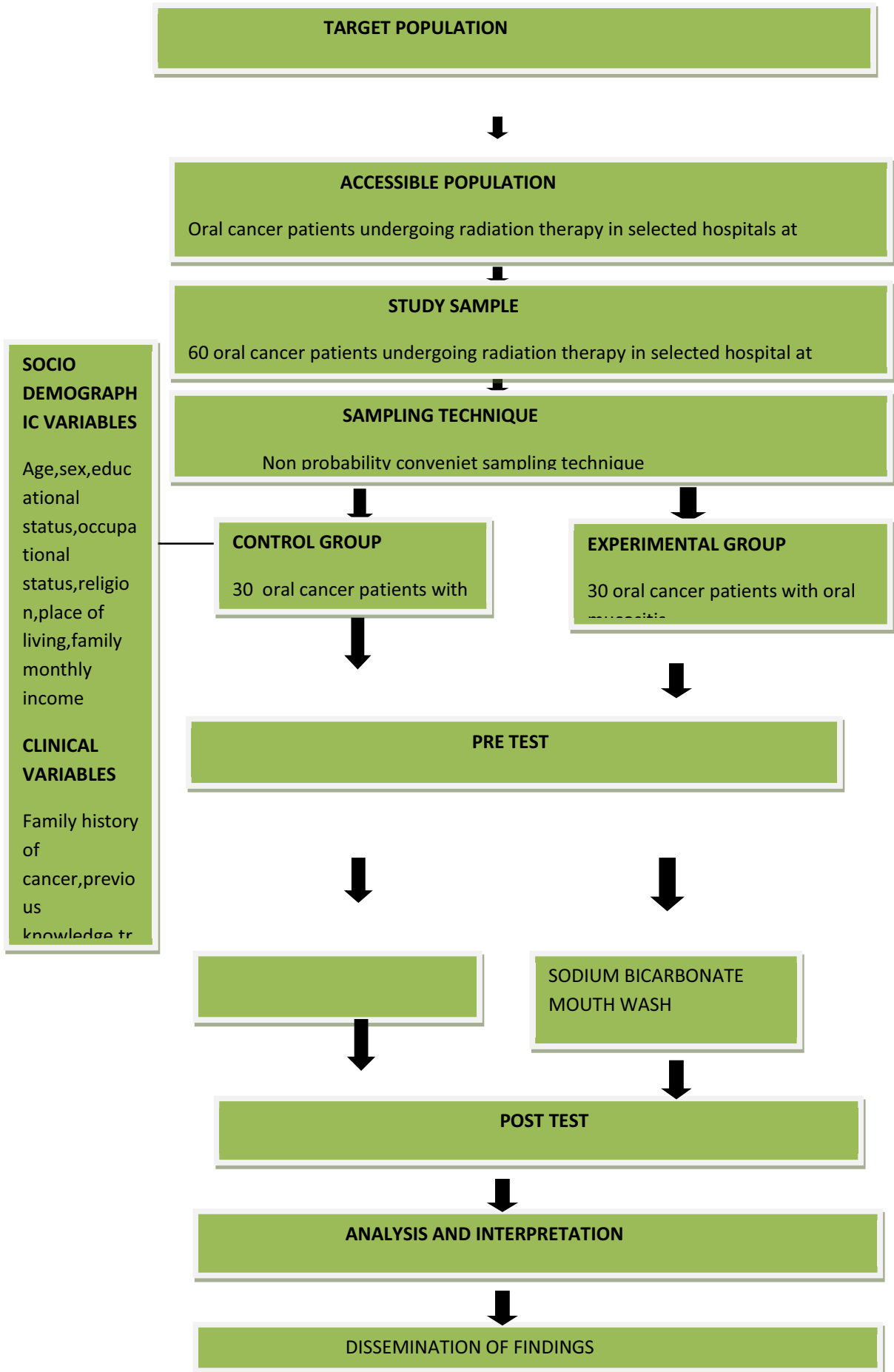
- Un paired 't' test was used to compare the post test level of oral mucositis between experimental and control group.
- Paired 't' test was used to evaluate the effectiveness of sodium bicarbonate in experimental group.
- Chi – square test was used to find out the association between the post test level of oral mucositis with the selected socio demographic and clinical variables in experimental and control group.

ETHICAL CONSIDERATION

- Pilot study and main study were conducted after the approval of research committee of Annammal College of nursing, Kuzhithurai.
- Permission is obtained from the ethical committee of selected hospitals in Kanyakumari district.
- Written consent is obtained from each patient before starting the data collection.
- Assurance is given to each patient regarding the confidentiality of the data collected

SUMMARY

This chapter has dealt with the selection about the research approach, research design, variables, setting of the study, population, selection criteria, development of tool, validity, reliability, pilot study, data collection, plan for data analysis and ethical considerations.



CHAPTER IV

DATA ANALYSIS AND INTERPRETATION

The analysis is defined as the method of organizing data in such a way that the research question can be answered.

(Polit and Beck, 2004)

Interpretation is the process of the result and of examining the simplification of findings with in a boarder context.

(Polit and Beck, 2004)

Analysis and interpretation of data of this study was done using descriptive and inferential statistics.

OBJECTIVES OF THE STUDY

The objectives of the study are

- To assess the level of oral mucositis before and after administration of sodium bicarbonate mouth wash among oral cancer patients in experimental and control group.
- To compare the effectiveness of sodium bicarbonate solution with existing practices in reducing oral mucositis among oral cancer patients undergoing radiation therapy in experimental and control group.
- To determine the association between post interventional level of oral mucositis among oral cancer patients undergoing radiation therapy with selected socio demographic variables and clinical variables

ORGANIZATION OF DATA

Data collected were edited, tabulated, analyzed, interpreted and findings obtained were presented in the form of tables and diagrams represented on the following

Section-I

- Data pertaining to frequency and percentage distribution of socio-demographic variables among oral cancer patients in experimental group and control group

Section-II

- Data pertaining to frequency and percentage distribution of pre test and post test level of oral mucositis among oral cancer patients receiving sodium bicarbonate mouth wash in experimental group.
- Data pertaining to frequency and percentage distribution of pre test and post test level of oral mucositis among oral cancer patients in control group.
- Data pertaining to comparison of post test level of oral mucositis among oral cancer patients in experimental and control group.
- Data pertaining to effectiveness of sodium bicarbonate mouth wash is reducing oral mucositis by comparing the post test level of oral mucositis in experimental and control group.

Section-III

- Data pertaining to association of post test level of oral mucositis with socio demographic variables in experimental group.
- Data pertaining to association of post test level of oral mucositis with clinical variables in experimental group.
- Data pertaining to association of post test level of oral mucositis with socio demographic variables in control group.
- Data pertaining to association of post test level of oral mucositis with clinical variables in control group.

SECTION – I

Table 1: Data pertaining to frequency and percentage distribution of socio demographic variables among oral cancer patients in experimental group and control group

N = 60

S. No	Socio demographic variables	Experimental group		Control group		χ^2	P value
		f	%	f	%		
1.	Age (in Years)						
	a)<20	0	0.00	0	0.00	0.557	df-2 0.756
	b)21-25	2	6.67	3	10.00		
	c)26-30	7	23.33	5	16.67		
	d)>30	21	70.00	22	73.33		
2.	Sex						
	a)Male	20	6.67	22	73.33	0.317	df-2 0.573
	b)Female	10	33.35	8	26.66		
3.	Education						
	a)Illiterate	2	6.67	0	0	1.678	df-6 0.251
	b)Primary School certificate	7	23.33	8	20.00		
	c)Middle school certificate	9	30	5	16.66		
	d)High school certificate	8	26.67	7	20.00		
	e)Intermediate or post high	4	13.33	8	23.33		
	f)School diploma	0	0	2	6.67		
	g)Graduate or Post Graduate	0	0	0	0		
	h)Professional or Honours	0	0	0	0		
	i)Others	0	0	0	0		
4.	Occupation						
	a)Profession	0	0.00	0	0.00		

	b)Semi Profession	0	0.00	0	0.00		
	c)Shop owners	5	16.66	7	20.00		df – 4
	d)Skilled worker	6	20	5	16.66	1.294	0.862
	e)Semi skilled worker	4	13.33	5	16.66		
	f)Unskilled worker	7	23.33	8	23.33		
	g)Unemployed	8	26.67	5	16.66		
5	Religion						
	a)Hindu	15	50.00	13	43.33		df-2
	b)Christian	13	43.33	15	50.00	0.28	0.866
	c)Muslim	2	6.67	2	6.67		
	d)Others	0	0.00	0	0.00		
6.	Family Monthly Income						
	a)>25000	0	0.00	0	0.00		
	b)20000 – 24999	0	0.00	0	0.00		df – 4
	c)15000 – 19999	13	43.33	12	40.00	0.422	0.935
	d)10000 – 14999	10	33.35	12	40.00		
	e)5000 – 9999	4	13.33	4	13.33		
	f)<5000	3	10	2	6.67		
7.	Place of Living						
	a)Rural	9	30.00	8	26.67	0.082	df – 1
	b)Semi Rural	0	0	0	0		0.774
	c)Urban	21	70.00	22	73.33		
	d)Semi Urban	0	0	0	0		

Table 1 represents the frequency and percentage distribution of oral cancer patients with selected socio demographic variables such as Age, Sex, Education, Occupation, Religion, Family monthly Income and Place of residence.

With regard to age, majority of 21 (70%) falls under age group of less than 30 years in both experimental group and control group. 7(23.33%) were in the age group of 26-30years in experimental group and 5(16.67%) were in control group,2(6.67%) were in the age group of 21-25 in experimental group and only 3(10%) were in

control group and none of them are in the age group of less than less than 20 in experimental group and control group.

Regarding educational status in experimental group, 9 (30%) acquired middle school education, 8(26.67%) had high school education, 7 (23.33%) completed primary school educations, 4(13.33%) undergone post high school diploma course and none of them were graduate or professional. In control group, 8(20.00%) completed primary school education, 8 (20.00%) completed post high school diploma education, 7(20.00%) completed high school education, 5(16.66%) completed middle school education and 2 (6.67%) were graduates and none of them were professionals in control group

With regard to occupational status, 8(26.67%) patients in experimental group were unemployed, 7(23.33%) were unskilled workers , 6(20%) were skilled workers and 5(16.66%) were shop owners and none of them were in profession and semi professional. In control group 8(23.33%) were unskilled worker, 7(20.00%) were shop owners, 5(16.66%) were skilled workers;semi skilled workers and un employed .none of them were in professional and semi professional.

With regard to religious status in experimental group majority of 15(50%) were Hindus, 13(43.33%) were Christians only 2(6.67%)were in muslims and none of them were from other religion where as in control group, Christian religion hold the leading proportion of 15(50%), next Hindu with 13(43.33%). Muslims were found limited in number of 2(6.67%) respectively

Regarding Family monthly income, in Experimental group , 13(43.33%) were earning salary between Rs 15000-19999 per month 10(33.355) were earning salary of Rs 10,000-14999 per month 4(13.33%) persons are earning between Rs 5000-9999 per month , Also a least of 3(10%) are earning less than 5000 per month in both Experimental group. and control group were 12 (40%) were earning 15,000-1999 and 10,000-14999, 4 (13.33%) were earning 5000-9999 and only 2(6.67%) were earning below 5,000 and none of them were earning money above Rs 20,000 in experimental and control group .

Regarding place of living , majority of study participants in Experimental group and control group were from urban background of 21(70.00%) and 22(73.33%) respectively 9(30.00%) from rural area in experimental group 8(26.67%) in control group none of them were in semi rural or semi urban background

Table 2: Data Pertaining to frequency and percentage distribution of clinical variables among oral cancer patients in experimental and control group

N = 60

S. No	Clinical Variables	Experimental group		Control group		χ^2	P value
		f	%	f	%		
1.	Family History of cancer						
	a)Yes	3	10	1	3.35	1.07	0.300
	b)No	27	90	29	96.67	1	df = 1
2.	Previous exposure of knowledge regarding oral mucositis						
	a)Yes	6	20	4	13.34	0.48	0.488
	b)No	24	80	26	86.66		df = 1
3.	Treatment modalities						
	a)Radiation Therapy	27	100	28	100	0.21	0.640
	b)Chemotherapy	0	0	0	0	8	df = 1
	c)Both	3	0	2	0		
4	Habits						
	a)Alcoholism	12	40	10	33.35		0.84
	b)Smoking	10	33.35	9	30	0.82	df=3
	c)Betel leaves chewing	5	16.67	6	20	5	
	d)None	3	10	5	16.66		
5	Dietary Pattern						
	a)Vegetarian	1	3.33	0	0	1.01	0.313
	b)Non vegetarian	29	96.67	30	100	7	df = 2
6	Duration of illness						
	a)< 1 Year	8	26.66	7	23.33	0.09	0.952
	b)1 – 5 Years	16	53.35	17	56.67	6	df = 1
	c)5 Years and above	6	20	6	20		
7.	Previous experience of surgery	12	40	14	46.66	0.27	0.602

	a)Yes	18	60	16	53.33	1	df = 1
	b)No						
8.	Co morbid illness						
	a)Diabetes mellitus	5	16.67	3	10	2.66	0.446
	b)Hypertension	3	10	4	13	6	df=3
	c)Obesity	0	0	2	6.67		
	d)None	22	73.33	21	70.00		

Table 2 represents the frequency and percentage distribution of oral cancer patients with selected clinical variables such as family history of cancer, previous exposure of knowledge regarding oral mucositis, treatment modalities, habits, dietary pattern, duration of illness, previous experience of surgery, and co-morbid illness,

with regard to family it was found that patients have no family history of cancer 27(90%) in experimental group and 29 (96.67%) in control group .3 had family history of cancer in experimental group and 2 in control group.

With regard to previous exposure of knowledge regarding oral mucositis majority of them have no previous exposure 24 (80%) in experimental group and 26(86.66%) in control group.

With regard to treatment modalities majority, of the patients had undergone radiation therapy 27(90%) in experimental group and 28(93.33%) in control group.

With regard to habits, majority of the patients had the habits of alcoholism 12(40%) in experimental group and 10 (33.35%) in control group.

With regard to dietary pattern, majority of them are non vegetarian 29 (96.67%) in experimental group and 30 (100%) in control group

Regarding the duration of illness, the majority of them are in suffering from oral cancer for 1 to 5 years 16(53.35%) in experimental group and 17(56.67%) in control group.

With regard to previous experience of surgery, majority of them had not undergone the surgery comes 18(60%) in experimental group and 16 (53.33%) in control group

Regarding to co morbid illness, majority of them were having diabetes mellitus 5(16.67%) each in experimental group and control group.3(10%) of them had hypertension in experimental group,4(13%) in control group,2(6.67%)were obesity

in control group and 22(73.33%) patients were not having anyother co morbid illness in experimental were 21(70%) in control group.

SECTION-II

Testing of hypothesis

H₁: There will be a significant difference between the pre and post interventional level of oral mucositis among oral cancer patients in experimental group and controlgroup .

Table 3: Data Pertaining to frequency and percentage distribution of pre test and post test level of oral mucositis oral cancer patients in experimental group

N = 30

S. No	Grades of oral mucositis	Pre test		Post test		χ^2	P value
		f	%	f	%		
1.	Normal	0	0	4	13.33	21.155	df=4 0.000 29 ***
2.	Mild	3	10	8	26.67		
3.	Moderate	5	16.67	12	40		
4	Severe	12	40	6	20		
5	Extreme	10	33.33	0	0		

(***P<0.001)

Table 3 shows the frequency and percentage distribution of pre-test and post-test interventional level of oral mucositis among oral cancer patients in experimental group. During pretest, majority of the oral cancer patients had severe oral mucositis of 12(40%).10 (33.33%) had extreme level of oral mucositis, 5(16.67%) had moderate level of oral mucositis. 3(10%) had mild oral mucositis. During post test there is a marked improvement 12(40%) of them have moderate level of oral mucositis, 8(26.67%) had mild level of oral mucositis and 6(20%) had severe level of oral mucositis, 4(13.33%) became normal and none of them had extreme level of oral mucositis.

Table: 4 Data pertaining to frequency and percentage distribution of pretest and post test level of oral mucositis among oral cancer patients in control group.

N=30

				χ^2	P

S. No	Grades of oral mucositis	Pre test		Post test		value
		f	%	f	%	
1.	Normal	0	0	0	0	9.426 df=3 0.024 *
2.	Mild	5	13	8	26.67	
3.	Moderate	7	23.33	8	26.67	
4.	Severe	10	33.33	14	46.67	
5.	Extreme	8	26.66	0	0	

Table 4 shows the frequency and percentage distribution of pre-test and post-test level of oral mucositis among oral cancer patients who are undergoing radiation therapy in control group. With regard to pre-test, majority of the sample subject 10(33.33%) had severe oral mucositis, 8 (26.66%) had extreme level of oral mucositis, 7 (23.33%) had moderate oral mucositis and 5 (13%) had mild oral mucositis. During the post-test much improvement was seen in the level of oral mucositis; 14(46.67%) had severe level of oral mucositis, 8 (26.66%) in each had mild and moderate level of oral mucositis and none of them had extreme level of oral mucositis. Hence H_1 was accepted

Testing of hypothesis

H₂: There will be a significant difference between the post interventional level of oral mucositis among oral cancer patients in experimental and control group.

Table: 5 Data pertaining to comparison of post test level of oral mucositis among oral cancer patients in experimental and control group

N=30

S. No	Grades of oral mucositis	Pre test		Post test		χ^2	P value
		f	%	f	%		
1.	None	4	40	0	0	8.000 df=3 0.046 *	
2.	Mild	8	20	8	26.67		
3.	Moderate	12	23.33	8	26.67		
4.	Severe	6	16.66	14	46.67		
5.	Extreme Level	0	0	0	0		

Table 5 shows the comparison of post-test level of oral mucositis among oral cancer patients in experimental and control group. It depicts that the chi-square value was (8.000) and P value was (0.046), which was significant. Hence there was a difference between experimental group and control group on level of oral mucositis among oral cancer patients. Hence the research hypothesis H2 accepted.

Table: 6 Data pertaining to effectiveness of sodium bicarbonate mouth wash in reducing oral mucositis by comparing the post test level of oral mucositis in experimental and control group

N=60

S.No	POST TEST	MEAN	SD	t-test	P-value
1	ExperimentalGroup	1.433	1.145	2.52	df(58)
2	Control group	1.166	0.933		0.002 **

(** p<0.005)

Table: 6 reveals data pertaining to effectiveness of sodium bicarbonate mouth wash in reducing oral mucositis. It shows that in experimental group, the mean post test score was 1.433 with standard deviation of 1.145 where as in control group the mean post test is 1.166 with standard deviation of 0.933. The obtained t-test value is 2.52 and the p value was 0.02**. Hence the research hypotheses H₂ was accepted and it was inferred that sodium bicarbonate mouth wash effective in reducing oral mucositis.

SECTION-III

Testing of hypothesis

H₃: There will be a significant association between the post interventional level of oral mucositis among oral cancer patients with the selected socio demographic and clinical variables.

Table 7: Data Pertaining to association of Post test level of oral mucositis with social demographic variables in Experimental group

N = 60

S. No	Sociodemographic variables	Experimental group					χ ²	P value
		Normal	Mild	Moderate	Severe	Extreme		
1.	Age (in Years)						13.99	df = 6 0.0304 *
	a) <20	0	0	0	0	0		
	b) 21-25	0	2	0	0	0		
	c) 26-30	3	1	3	0	0		

	d) >30	1	5	9	6	0		
2	Sex							df=3
	a) Male	3	5	7	5	0	1.313	0.126
	b) Female	1	3	5	1	0		
3.	Education							
	a) Illiterate	0	0	0	2	0		
	b) Primary School certificate	0	3	2	2	0		
	c) Middle school certificate	4	2	3	0	0		
	d) High school certificate	0	2	4	2	0		
	e) Intermediate or post high	0	1	3	0	0	22.54	df=12
	f) School diploma	0	0	0	0	0	5	0.0318
	g) Graduate or Post Graduate	0	0	0	0	0		*
	h) Professional or Honours	0	0	0	0	0		
	i) Others	0	0	0	0	0		
4	Occupation							
	a) Profession	0	0	0	0	0		
	b) Semi Profession	0	0	0	0	0		
	c) Shop owners	1	3	0	1	0	15.60	df=2
	d) Skilled worker	2	0	4	0	0	4	9.2100
	e) Semi skilled worker	1	0	2	1	0		
	f) Unskilled worker	0	3	3	1	0		
	g) Unemployed	0	2	3	3	0		
5	Religion							
	a) Hindu	4	3	4	4	0	21.27	df=9
	b) Christian	0	0	2	0	0		0.3155
	c) Muslim	0	5	6	2	0		

	d)Others	0	0	0	0	0		
6	Family Monthly Income							
	a)>25000	0	0	0	0	0		
	b)20000 – 24999	0	0	0	0	0		
	c)15000 – 19999	1	2	5	5	0	10.44	df=9
	d)10000 – 14999	2	3	5	0	0	6	0.3155
	e)5000 – 9999	0	2	2	0	0		
	f)<5000	1	1	0	1	0		
7.	Place of Living							
	a)Rural	3	1	3	2	0		df=3
	b)Semi Rural	0	0	0	0	0	5.198	0.157
	c)Urban	1	7	9	4	0		
	d)Semi Urban	0	0	0	0	0		

***P<0.05**

Table 7 Shows that there was significant association between the level of oral mucositis and selected socio demographic variables such as Age (0.304*) ,educational status (0.0318*) and there is no association between the level of oral mucositis and selected socio demographic variables such as sex,occupational status, family monthly income, religion and place of living Hence research hypothesis H₃ was partially accepted.

Table 8: Data Pertaining to association of Post test level of oral mucositis with clinical variables in Experimental group

N = 60

Sl. No	Clinical Variables	Experimental group oral mucositis					χ^2	P value
		Normal	Mild	Moderate	Severe	Extreme		
1.	Family History of cancer							df=2
	a)Yes	0	0	0	8	1	0.82	0.24
	b)No	7	0	14	0	0		
2.	Previous exposure of knowledge regarding oral mucositis							df=2
		0	0	4	4	0	12	0.001 ***

	a)Yes	8	0	14	0	0		
	b)No							
3.	Treatment modalities							
	a)Radiation Therapy	0	0	0	5	0	10.82	df=2 0.004 ***
	b)Chemotherapy	3	3	0	5	0		
	c)Both	4	0	0	0	1		
4	Habits							
	a)Alcoholism	0	0	0	0	2	0.825	df=3 0.84
	b)Smoking	1	2	3	2	1		
	c)Betel leaves chewing	3	2	6	7	1		
	d)None	0	0	0	0	0		
5	Dietary Pattern							
	a)Vegetarian	0	0	0	8	0	19.8	df=5 0.001 ***
	b)Non vegetarian	8	0	14	0	0		
6	Duration of illness							
	a)< 1 Year	0	0	0	3	4	1.797	0.77 df=4
	b)1 – 5 Years	1	2	4	2	2		
	c)5Years and above	9	3	0	0	0		
7.	Previous experience of surgery							
	a)Yes	0	0	4	4	4	0.153	df=2 0.92
	b)No	4	6	8	0	0		
8.	CO morbid illness							
	a)Diabetes mellitus	0	0	0	0	1	3.82	df=6 0.70
	b)Hypertension	1	0	6	1	2		
	c)Obesity	0	5	1	1	2		
	d)None	10	0	0	0	0		

***P<0.001

Table 8 Shows that there was significant association between the level of oral mucositis and selected clinical variables such as previous exposure of knowledge regarding oral mucositis(0.001***) ,treatment modalities (0.004***) and dietary pattern (0.001***)and no significant association between the level of oral mucositis in

selected clinical variables such as family history of cancer, duration of illness, previous experience of surgery ,habits and co morbid illness Hence research hypothesis H₃ was partially accepted.

Table 9: Data Pertaining to association of Post test level of oral mucositiswith social demographic variables in Control group

N = 60

Sl. No	Socio demographic variables	Control group					χ^2	P value
		Normal	Mild	Moderate	Severe	Extreme		
1.	Age (in Years)							
	a)<20	0	0	0	0	0	6.414	df=4
	b)21-25	1	3	4	0	1		0.170
	c)26-30	2	5	0	0	1		
	d)>30	3	0	0	0	0		
2.	Sex							df=2
	a)Male	0	0	5	3	5	10.82	0.004
	b)Female	1	4	0	0	0		***
3.	Education							
	a) Illiterate	0	0	0	0	0	3.33	df=8 00.91
	b)Primary School certificate	0	0	0	0	2		
	c)Middle school certificate	1	2	2	3	0		
	d) High school certificate	0	0	0	2	2		
	e) Intermediate or post high	2	2	0	0	0		
	f)School diploma	0	4	2	3	3		
	g) Graduate or Post Graduate	0	0	0	0	0		
	h)Professional	2	0	0	0	0		

	or Honours							
	I) Others	0	0	0	0	0		
4	Occupation							
	a)Profession	0	0	0	0	0		
	b)Semi Profession	0	0	0	2	1		
	c) Shop owners	1	2	2	0	0		
	d)Skilled worker	2	1	0	2	1	1.362	0.99
	e)Semi skilled worker	0	0	3	2	4		df-8
	f)Unskilled worker	2	0	0	0	0		
	g) Unemployed	0	0	3	0	0		
5	Religion							
	a) Hindu	0	0	0	0	3		df=4
	b) Christian	5	0	0	2	6	6.121	0.19
	c) Muslim	0	0	8	4	2		
	d) Others	0	0	0	0	0		
6	Family Monthly Income							
	a) >25000	0	0	0	0	0		df=6
	b)20000– 24999	0	0	0	3	3	5.893	0.43
	c)15000 – 19999	2	0	0	0	3		
	d)10000– 14999	3	2	0	0	0		
	e) 5000 – 9999	6	6	0	2	0		
	f) <5000	0	0	0	0	0		
7.	Place of Living							
	a) Rural	0	0	0	0	6		df=6
	b) Semi Rural	0	2	0	2	0	14.65	0.006
	c) Urban	6	0	0	0	14		***
	d) Semi Urban	4	0	0	0	0		

***P<0.001

Table 9 Shows that there was significant association between the level of oral mucositis and selected socio demographic variables such as sex(0.004***),place of living (0.006***) and no significant association between level of oral mucositis in

selected socio demographic variables such as age, educational status occupational status, religion, family monthly income and place of living. Hence research hypothesis H₃ was partially accepted.

Table 10: Data Pertaining to association of Post test level of oral mucositis with clinical variables in Control group

N = 60

Sl. No	Clinical Variables	Control group oral mucositis					χ^2	P value
		Normal	Mild	Moderate	Severe	Extreme		
1.	Family History of cancer a)Yes b)No	0 27	0 8	1 11	2 4	0 0	5	df=3 0.17
2.	Previous exposure of knowledge regarding oral mucositis a)Yes b)No	6 24	1 3	2 6	0 12	0 0	6.563	df=3 0.087
3.	Treatment modalities a)Radiation Therapy b)Chemotherapy c)Both	4 0 0	6 0 2	1 0 1	6 0 0	0 0 0	3.148	df=3 0.036 *
4	Habits a)Alcoholism b)Smoking c)Betel leaves chewing d)None	2 1 0 1	3 2 1 2	7 4 1 0	0 3 3 0	0 0 0 0	14.02 1	df=9 0.012 **
5	Dietary Pattern a)Vegetarian b)Non vegetarian	0 4	0 8	1 11	0 6	0 0	1.552	df=3 0.67
6	Duration of illness a)< 1 Year b)1 – 5 Years c)5 Years and above	1 2 1	1 4 3	3 8 1	3 2 1	0 0 0	4.844	df=6 0.56
7.	Previous						6.042	df=3

	experience of surgery							0.109
	a)Yes	1	2	8	1	0		
	b)No	3	6	4	5	0		
8.	CO morbid illness							
	a)Diabetes mellitus	1	1	2	1	0		
	b)Hypertension	0	0	1	2	0	4.51	df=6
	c)Obesity	0	0	0	0	0		0.608
	d)None	3	7	9	3	0		

***P<0,005**

Table 10, Shows that there was significant association between the level of oral mucositis and selected clinical variables such as treatment modalities (0.036*)and no significant association between the level of oral mucositis in selected clinical variables such as family history of cancer, duration of illness, dietary pattern , previous exposure of knowledge regarding oral mucositis , previous experience of surgery and co morbid illness

Table 7,8,9,10 shows that there was a significant association between post interventional level of oral mucositis and selected socio demographic variables and clinical variables in experimental group and control group .Hence the research hypothesis H₃ was partially accepted.

SUMMARY

This chapter dealt with analysis and interpretation of data obtained by the researcher. The analysis of the result showed that the effectiveness of sodium bicarbonate mouth wash in reducing oral mucositis among oral cancer patients

CHAPTER V

DISCUSSION

This chapter deals with the discussion of the data analyzed based on the objective and hypothesis of the study. The problem statement was **“A Quasi experimental study to assess the effectiveness of sodium bicarbonate mouth wash in reducing oral mucositis among oral cancer patients undergoing radiation therapy in C.S.I mission hospital at neyyoor”**

Objectives of the study

- To assess the level of oral mucositis before and after administration of sodium bicarbonate mouth wash among oral cancer patients in experimental and control group.
- To compare the effectiveness of sodium bicarbonate solution with existing practices in reducing oral mucositis among oral cancer patients undergoing radiation therapy in experimental and control group.
- To determine the association between post interventional level of oral mucositis among oral cancer patients undergoing radiation therapy with selected socio demographic variables and clinical variables.

Data pertaining to Socio Demographic variables among oral cancer patients in Experimental group and control group

socio demographic variables such as Age, Sex, Education, Occupation, Religion, Family monthly Income and Place of residence.

With regard to age, majority of 21 (70%) falls under age group of less than 30 years in both Experimental group and control group. 7(23.33%) were in the age group of 26-30years in experimental group and 5(16.67%) were in control group,2(6.67%) were in the age group of 21-25 in experimental group and only 3(10%) were in control group and none of them are in the age group of less than less than 20 in experimental group and control group.

Regarding educational status in Experimental group, 9 (30%) acquired middle school education, 8(26.67%) had high school education, 7 (23.33%) completed primary school educations, 4(13.33%) undergone post high school diploma course and none of them were graduate or professional. In control group, 8(20.00%) completed primary school education, 8 (20.00%) completed post high school diploma education, 7(20.00%) completed high school education, 5(16.66%) finished middle school education and 2 (6.67%) were graduates and none of them were professionals in control group

With regard to occupational status, among patients in Experimental group a proportion of 8(26.67%) were unemployed, 7(23.33%) were unskilled workers were 6(20%) skilled workers and shop owners were 5(16.66%) and none of them were in profession and semi professional. In control group 8(23.33%) were unskilled worker, 7(20.00%) were shop owners, 5(16.66%) were skilled workers; semi skilled workers and an employed .none of them were in professional and semi professional.

With regard to religious status in experimental group majority of 15(50%) were Hindus, 13(43.33%) were Christians only 2(6.67%)were in muslims and none of them were from other religion where as in control group, Christian religion hold the leading proportion of 15(50%), next Hindu with 13(43.33%). Muslims were found limited in number of 2(6.67%) respectively

Regarding Family monthly income, in Experimental group , 13(43.33%) were earning salary between Rs 15000-19999 per month 10(33.355) were earning salary of Rs 10,000-14999 per month 4(13.33%) persons are earning between Rs 5000-9999 per month , Also a least of 3(10%) are earning less than 5000 per month in both Experimental group. and control group were 12 (40%) were earning 15,000-1999 and 10,000-14999, 4 (13.33%) were earning 5000-9999 and only 2(6.67%) were earning below 5,000 and none of them were earning money above Rs 20,000 in experimental and control group .

Regarding place of living , majority of study participants in Experimental group and control group were from urban background of 21(70.00%) and 22(73.33%) respectively 9(30.00%) from rural area in experimental group 8(26.67%) in control group none of them were in semi rural or semi urban background

Data pertaining to Clinical variables among oral cancer in Experimental group and control group

represents the frequency and percentage distribution of oral cancer patients with selected clinical variables such as family history of cancer, previous exposure of knowledge regarding oral mucositis, treatment modalities, habits, dietary pattern, duration of illness, previous experience of surgery, and co-morbid illness, family it was found that patients have no family history of cancer 27(90%) in experimental group and 29 (96.67%) in control group .

With regard to previous exposure of knowledge regarding oral mucositis majority of them have no previous exposure 24 (80%) in experimental group and 26(86.66%) in control group.

With regard to treatment modalities majority, of the patients undergoes radiation therapy 27(90%) in experimental group and 28(93.33%) in control group.

With regard to habits, majority of the patients had the habits of alcoholism 12(40%) in experimental group and 10 (33.35%) in control group.

With regard to dietary pattern majority of them are non vegetarian 29 (96.67%) in experimental group and 30 (100%) in control group

Regarding the duration of illness, the majority of them are in suffering from 1to5 years 16(53.35%) in experimental group and 17(56.67%) in control group.

With regard to previous experience of surgery majority of them do not underwent the surgery comes 18(60%) in experimental group and 16 (53.33%) in control group

Regarding to co morbid illness majority of them were having diabetes mellitus 5(16.67%) each in experimental group and control group and some of them had hypertension 3(10%) were in experimental group,4(13%) were in control group,2(6.67%)were had obesity in control group and 22(73.33%) patients not having anyother co morbid illness in experimental were 21(70%) in control group.

OBJECTIVES: 1

To assess the level of oral mucositis among oral cancer patients before and after administration of oral cancer patients in experimental and control group:

Shows the frequency and percentage distribution of pretest and posttest interventional level of oral mucositis among oral cancer patients in experimental group .During pretest, majority of the oral cancer patients had severe oral mucositis of 12(40%).10 (33.33%) had extreme level of oral mucositis, 5(16.67%) had moderate level of oral mucositis. 3(10%) had mild oral mucositis. During post test there is a merued improvement 12(40%) moderate level of oral mucositis, 8(26.67%) had mild level

of oral mucositis and 6(20%) had in severe level of oral mucositis, 4(13.33%) became normal and none of them had extreme level of oral mucositis.

shows the frequency and percentage distribution of pretest and posttest level of oral mucositis among oral cancer patients who are undergoing radiation therapy in control group with regard to pretest majority of the sample subject 10(33.33%) had severe oral mucositis were 8 (26.66%) had extreme level of oral mucositis , were 7 (23.33%) had moderate oral mucositis and 5 (13%) had mild oral mucositis .

During the post test much improvement the level of oral mucositis 14(46.67%) were had severe level of oral mucositis, 8 (26.66%) had mild and moderate level of oral mucositis none of them in extreme level.

OBJECTIVES: 2

To compare the effectiveness of sodium bicarbonate solution with existing practices in reducing oral mucositis among oral cancer patients undergoing radiation therapy in experimental and control

In experimental group mean post test score was 1.433 with standard deviation Of 1.145 where as in control group the mean post test is 1.166 with standard deviation of 0.933.The obtained t-test value is 2.52.and the p value was 0.02 .Hence the research hypotheses H_1 was accepted and it was inferred that sodium bicarbonate mouth wash effective in reducing oral mucositis

OBJECTIVES: 3

To determine the association between post interventional level of oral mucositis among oral cancer patients undergoing radiation therapy with selected socio demographic variables and clinical variables.

The results shows that there was a significant association between post interventional level of oral mucositis and selected socio demographic variables and clinical variables in experimental group and control group .Hence the research hypothesis H_3 was accepted.

SUMMARY

This chapter dealt with the objectives of the study ,major findings of the selected socio demographic variables, clinical variables among oral cancer patients,description of effectiveness of sodium bicarbonate mouth wash ,association between post test level of oral mucositis among oral cancer patients , oral cancer patients with selected socio demographic variables and clinical variables

CHAPTER VI

SUMMARY, CONCLUSION, IMPLICATIONS & RECOMMENDATIONS

This chapter deals with the summary of the study and the conclusion drawn from the study, implication of the study for different areas like nursing practice, nursing education, nursing administration and nursing research it also includes the recommendation for future research in the field.

SUMMARY

The summary includes the objectives of the study, description of procedures used, major findings and conclusion and recommendations for the research study. ” **A Quasi experimental study to assess the effectiveness of sodium bicarbonate mouth wash in reducing oral mucositis among oral cancer patients undergoing radiation therapy in C.S.I mission hospital at neyyoor**”

Objectives

The objectives were

- To assess the level of oral mucositis before and after administration of sodium bicarbonate mouth wash among oral cancer patients in experimental and control group.
- To compare the effectiveness of sodium bicarbonate solution with existing practices in reducing oral mucositis among oral cancer patients undergoing radiation therapy in experimental and control group.
- To determine the association between post interventional level of oral mucositis among oral cancer patients undergoing radiation therapy with selected socio demographic variables and clinical variables.
- To assess the level of oral mucositis before and after administration of sodium bicarbonate mouth wash among oral cancer patients in experimental and control group.

HYPOTHESES

H₁: There will be a significant difference between the pre and post interventional

level of oral mucositis among oral cancer patients in experimental group and control group .

H₂: There will be a significant difference between the post interventional level of oral mucositis among oral cancer patients in experimental and control group.

H₃: There will be a significant association between the post interventional level of oral mucositis among oral cancer patients with the selected demographic and clinical variables.

The conceptual framework selected for the study was based on “**Wiedenbach’s prescriptive theory**“ which was described as a system of concept invented for a purpose. Prescriptive theory may also be described as one that conceptualizes both the desired situations and the perception by which it is to be brought about as an outcome.

The literature has been reviewed under the following headings

- I. Empirical studies related to prevalence of cancer.
- II. Empirical studies related to radiation therapy induced oral mucositis.
- III. Empirical studies related to sodium bicarbonate mouthwash for patients with oral mucositis

The content validity refers to the adequacy of the sampling of the domain being studied. Content validity of the tool was obtained after consulting with research guide and getting opinion from eight experts in the field of medical surgical nursing. One of the expert was a doctor, and other biostatistician. The validations has suggested some specific modifications in the clinical variable proforma. The modification and suggestions of experts were incorporated in the final preparation of the tool for assessing oral mucositis. Pilot study was conducted in C.S.I mission hospital, Neyyoor. Initial permission was sought from the institution and formal permission was sought from the chief medical officer for conducting the pilot study. Pilot study was conducted in the month of September for a period of one week. Content was found to be reliable and feasible. Reliability of the tool was calculated by test retest method. The study was conducted among oral cancer patients undergoing radiation therapy in C.S.I Mission Hospital, Neyyoor .At first a rapport was established with the patients and the purpose of the study was explained to them. Verbal and written consent was taken from the patients. Patients with oral mucositis among oral cancer patients who undergoing radiation therapy were selected as study participants ..The 60 samples were selected by using purposive sampling technique.

Sociodemographic variables, clinical variables were collected. The pretest was done by using WHO oral mucositis assessment scale. Sodium bicarbonate mouth wash was given for 3 times for a period of two weeks. The post-test level of oral mucositis was evaluated by conducting a post-test on 4th day, 7th day, 10th day, 13th day, 16th day for both the groups with oral mucositis scale. Collected data were analyzed and interpreted as per objectives of the study by using descriptive statistics (frequency, percentage, mean and median) and also by using inferential statistics (chi-square) method after careful editing, coding and tabulation.

FINDINGS

Major findings of the study presented under the followings:

Findings related to Socio Demographic variables among oral cancer patients in Experimental group and Control group:

Socio demographic variables such as Age, Sex, Education, Occupation, Religion, Family monthly Income and Place of residence. With regard to age, majority of 21 (70%) falls under age group of less than 30 years in both Experimental group and control group. 7 (23.33%) were in the age group of 26-30 years in experimental group and 5 (16.67%) were in control group, 2 (6.67%) were in the age group of 21-25 in experimental group and only 3 (10%) were in control group and none of them are in the age group of less than 20 in experimental group and control group.

Regarding educational status, in Experimental group 9 (30%) acquired middle school education, 8 (26.67%) had high school education, 7 (23.33%) completed primary school education, 4 (13.33%) undergone post high school diploma course and none of them were graduate or professional. In control group, 8 (20.00%) completed primary school education, 8 (20.00%) completed post high school diploma education, 7 (20.00%) completed high school education, 5 (16.66%) finished middle school education, and 2 (6.67%) were graduates and none of them were professionals in control group.

With regard to occupational status, among patients in Experimental group a proportion of 8 (26.67%) were unemployed, 7 (23.33%) were unskilled workers, 6 (20%) skilled workers and shop owners were 5 (16.66%) and none of them were in profession and semi professional. In control group 8 (23.33%) were unskilled worker, 7 (20.00%) were shop owners, 5 (16.66%) were skilled workers, semi skilled workers and unemployed. None of them were in profession and semi professional.

With regard to religious status in experimental group majority of 15(50%) were Hindus, 13(43.33%) were Christians only 2(6.67%) were in Muslims and none of them were from other religion whereas in control group, Christian religion hold the leading proportion of 15(50%), next Hindu with 13(43.33%). Muslims were found limited in number of 2(6.67%) respectively

Regarding Family monthly income, in Experimental group, 13(43.33%) were earning salary between Rs 15000-19999 per month 10(33.33%) were earning salary of Rs 10,000-14999 per month 4(13.33%) persons are earning between Rs 5000-9999 per month, Also a least of 3(10%) are earning less than 5000 per month in both Experimental group. and control group were 12 (40%) were earning 15,000-1999 and 10,000-14999, 4 (13.33%) were earning 5000-9999 and only 2(6.67%) were earning below 5,000 and none of them were earning money above Rs 20,000 in experimental and control group.

Regarding place of living, majority of study participants in Experimental group and control group were from urban background of 21(70.00%) and 22(73.33%) respectively 9(30.00%) from rural area in experimental group 8(26.67%) in control group none of them were in semi rural or semi urban background

Findings related to clinical variables among oral cancer patients in experimental group and control group:

clinical variables such as family history of cancer, previous exposure of knowledge regarding oral mucositis, treatment modalities, habits, dietary pattern, duration of illness, previous experience of surgery, and co-morbid illness, family it was found that patients have no family history of cancer 27(90%) in experimental group and 29 (96.67%) in control group.

With regard to previous exposure of knowledge regarding oral mucositis majority of them have no previous exposure 24 (80%) in experimental group and 26(86.66%) in control group. With regard to treatment modalities majority, of the patients undergoes radiation therapy 27(90%) in experimental group and 28(93.33%) in control group.

With regard to habits, majority of the patients had the habits of alcoholism 12(40%) in experimental group and 10 (33.33%) in control group.

With regard to dietary pattern majority of them are non vegetarian 29 (96.67%) in experimental group and 30 (100%) in control group

Regarding the duration of illness, the majority of them are in suffering from 1 to 5 years 16(53.33%) in experimental group and 17(56.67%) in control group.

With regard to previous experience of surgery majority of them do not underwent the surgery comes 18(60%) in experimental group and 16 (53.33%) in control group

Regarding to co morbid illness majority of them were having diabetes mellitus 5(16.67%) each in experimental group and control group and some of them had hypertension 3(10%) were in experimental group,4(13%) were in control group,2(6.67%)were had obesity in control group and 22(73.33%) patients not having anyother co morbid illness in experimental were 21(70%) in control group.

Findings related to assess the level of oral mucositis among oral cancer patients before and after administration of oral cancer patients in experimental and control group:

Shows the frequency and percentage distribution of pretest and posttest interventional level of oral mucositis among oral cancer patients in experimental group .During pretest, majority of the oral cancer patients had severe oral mucositis of 12(40%).10 (33.33%) had extreme level of oral mucositis, 5(16.67%) had moderate level of oral mucositis. 3(10%) had mild oral mucositis. During post test there is a merued improvement 12(40%) moderate level of oral mucositis, 8(26.67%) had mild level of oral mucositis and 6(20%) had in severe level of oral mucositis, 4(13.33%) became normal and none of them had extreme level of oral mucositis

In control group the frequency and percentage distribution of pretest and posttest level of oral mucositis among oral cancer patients who are undergoing radiation therapy in control group with regard to pretest majority of the sample subject 10(33.33%) had severe oral mucositis were 8 (26.66%) had extreme level of oral mucositis , were 7 (23.33%) had moderate oral mucositis and 5 (13%) had mild oral mucositis .During the post test much improvement the level of oral mucositis 14(46.67%) were had severe level of oral mucositis, 8 (26.66%) had mild and moderate level of oral mucositis none of them in extreme level.

Findings related to effectiveness of sodium bicarbonate solution with existing practices in reducing oral mucositis among oral cancer patients in experimental and control group.

In experimental group mean post test score was 1.433 with standard deviation of 1.145 where as in control group the mean post test is 1.166 with standard deviation of 0.933.The obtained t-test value is 2.52.and the p value was 0.02 .Hence the research hypotheses H_1 was accepted and it was inferred that sodium bicarbonate mouth wash effective in reducing oral mucositis

Findings related to determine the association between post interventional level of oral mucositis among oral cancer patients with selected socio demographic variables and clinical variables.

The results shows that there was a significant association between post interventional level of oral mucositis and selected socio demographic variables and clinical variables in experimental group and control group .Hence the research hypothesis H₃ was accepted.

CONCLUSION

The chapter deal with the summary of the study and conclusion

IMPLICATION TO NURSING RESEARCH

- There is a need for extensive and intensive researchin this area so that strategies for education nurses.
- This study will serve a valuable reference material for future investigators.
- The study findings will motivate the initial researchers to conduct the same study on large scale.
- Disseminate the findings of research through conferences, seminars,and publishing in nursing journals.
- The study can be done with large sample for the generalization of the findings.

IMPLICATION TO NURSING PRACTICE

- The nurses must implement the use of sodium bicarbonate mouth wash for all patients receiving radiation to reducing oral mucositis
- The nurse must educate the care giver about the preparation of sodium bicarbonate mouth wash.
- Nurses are the health promoters. They must play an important role in educating public regarding this .

IMPLICATION TO NURSING EDUCATION

- With the emerging health care demands and newer trends in the field of nursing education must focus on the innovations to enhance the nursing care.
- Nurses has learn the assessment of oral mucositis.
- Institution should arrange workshops for students to participate ,so they gain information
- In- service education can given to the nursing personnels regarding common problems of radiation therapy

- Nurse educators must arrange facilities and opportunities for nursing personnel to attend workshops and conferences to update their knowledge regarding the importance of sodium bicarbonate mouth wash

NURSING ADMINISTRATION

- With technological advances and ever growing challenges, the health care administrators have the responsibility to provide continuing nursing education opportunities to understand the oral mucositis assessment .
- The Nurse administrators can initiate sodium bicarbonate mouth wash to reduce the oral mucositis through development programmes like in-service education and continuing nursing education programme. This enables the nurses to update the knowledge and to render the cost effective care to the public.
- The nurse administrators can train the nurses to identify level of oral mucositis, and to give counselling and teaching regarding effects of sodium bicarbonate mouth wash
- Nurse administrators can prepare written policies regarding application of sodium bicarbonate mouth wash and be practiced on patients with oral mucositis in international cancer centre.

RECOMMENATIONS

- A longitudinal study can be conducted to find out the long term effect of sodium bicarbonate mouth wash in reducing oral mucositis
- A study can be done to find out the role of nurse in assessment and management of oral mucositis among oral cancer patients
- Similar study can be conducted with a larger populations.
- A comparative study may be done between effectiveness of sodium bicarbonate mouth wash and other pharmacological methods

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