

Original Research Article

The Effectiveness of Chlorhexidine 0.2% Mouthwash vs. Chlorhexidine 0.2% Mouthwash and Toothbrush in Preventing Ventilator Associated Pneumonia a Randomized Controlled Trial

ABSTRACT

Back ground

Intensive care unit patients are fragile and highly subject to infections. Respiratory infections and especially ventilator-associated pneumonia are the most frequent infectious complications in critically ill patients. Evidence Based Patients care treatment practices has been developed by center for disease control & prevention to decrease VAP cases. Sixty percent cases of VAP have been reduced by simple oral routine care.

Aims

To assess the effectiveness of 0.2% chlorhexidine mouthwash solution and tooth brush, their comparison and the association in demographic variables in patient admitted in critical care unit.

Methodology

A RCT was conducted from November 2020 to February 2021 in the patient under mechanical ventilation. Ethical clearance and written consent was obtained before collecting information. 30 participants in each control and experimental group were selected by applying the convenient sample technique method. Data was collected by using the self-created Performa and the main tool CPIS to detect the VAP.

Analysis

The data gathered were analyzed and interpreted according to the objective of the study by using SPCC 20 version. Descriptive statistics were used to find out the demographic result, where non-parametric Chi-square test were used to compare the data.

Result

Out of 60 participants, majority of patient belongs to 51-60 years, i.e. 11 (36.67%) in control group and 61-70 years, i.e. 13 (43.33%) experimental group. Patients who received chlorhexidine with tooth brushing intervention had higher CPIS values and higher rate of VAP occurrence in experimental group 3(10%) than in control group 1(3.33%).

Conclusion

Combining tooth brushing with 0.2% chlorhexidine did not provide additional benefit over 0.2% chlorhexidine alone. There is no any significant reduction in the rate of VAP by applying 0.2% chlorhexidine with toothbrushing. Thus, VAP remains an important clinical problem in intensive care unit.

Keywords: Chlorhexidine, VAP, Mechanical Ventilation, Toothbrushing

1. INTRODUCTION

Intensive care unit (ICU) patients are fragile and highly subject to infections. Respiratory infections and especially ventilator-associated pneumonia (VAP) are the most frequent infectious complications in critically ill patients. The use of ventilators more than 48 hours may result in ventilator associated pneumonia which is a potential serious complication in intensive care unit. Globally, 86 % of nosocomial pneumonias are associated with mechanical ventilation. The National Nosocomial Infections Surveillance system (NNIS) of the US study shows that the second most common nosocomial infection in intensive care units is nosocomial pneumonia. The incidence of VAP ranges from 13 to 51 per 1000 ventilator days. VAP increases the rate of death, rate of illness, hospital, and ICU stay, and by this increasing healthcare cost, making it to be a serious medical condition, with attributable risk for mortality of 33–50%. In the USA alone, there are between 250,000 and 300,000 cases per year, at an incidence rate of 5–10 per 1000 admissions.⁽¹⁾

The International Nosocomial Infection Control Consortium (INICC) has done the studies on nosocomial infection in 8 countries for 4 years on VAP which found 41.5% or 24.1 cases per thousand mechanical ventilation days. The incidence rates of VAP are higher in developing countries with limited resources. Australia, South Korea and Singapore which belongs to Asian –Pacific countries has 2nd highest incidence of VAP (16%) followed by Colombia, Mexico and Chile which comes under Latin America countries (13.8%). Studies published in China from 2010 to 2015 were selected for comprehensive review and meta-analysis which demonstrated an incidence density of 24.14 episodes per thousand ventilator days. Likewise, another meta-analysis done in 2019 for the VAP rates in 22 Asian countries stated a higher VAP rates in low income countries compared to higher income countries.⁽²⁾⁽³⁾

Beginning stage Ventilator associated pneumonia is typically less serious, related with a superior guess, and is bound to be brought about by antibiotic delicate microorganisms. Late-beginning Ventilator associated pneumonia, is normally brought about by multi-drug resistant (MDR) microorganisms and is related with expanded mortality and morbidity. Numerous examinations from India have explored the causative microorganisms of Ventilator associated pneumonia. *Klebsiella pneumoniae*, *Acinetobacter* spp., *Pseudomonas* spp., *Staphylococcus aureus* and *Escherichia coli* were recognized as the basic Ventilator associated pneumonia microorganisms. The normal VAP rates described by Indian studies extended from 8.9 to 46 ventilator associated pneumonia rates for every thousand Mechanical ventilation days. Ventilator associated pneumonia infection is common in the ICU affecting 8-20 percentage of all ICU patients and up to 27 percentage of Mechanical ventilation patients.⁽⁴⁾⁽³⁾

In a study done in Karnataka, they have 44% VAP incidence. Researcher David D.M Rosario from Medical Sciences and research Centre perform research on the non-tracheostomy patients admitted in ICU where he found 31 (53.44%) out of 58 patients developed VAP. VAP is increasing daily at a rate of 1-3% per day of intubation and 30-60 % death associated with infection is related to VAP. There will be difficulty weaning from the

ventilators and longer stay to the hospital which is considered as financial burden to patients as well as family members. ⁽⁵⁾

In Belagavi, many studies were performed related to VAP. The studies done by group of expertise on topic VAP in medical ICU found out that ; out of 54 patients, early onset of VAP was 39.62% whereas late on set was 60.38%. ⁽⁵⁾

VAP is constantly connected with raise in morbidity and mortality, clinical length of stay and expenses. VAP can occur at any moment during ventilation, however develop frequently in the initial days after intubation. This is on the grounds that the intubation cycle itself adds to the advancement of VAP. Despite the fact that VAP has different risk factors, applying proper intervention at a time can help in reducing the VAP rates. The concept of proper mouth wash and tooth brush is based on the fact that delivering evidence-based interventions reliably and consistently will improve patient care.

The primary goal in health institution especially in intensive care unit is to decrease the pace of Ventilators Associated Pneumonia. Among precisely ventilated patient, 20 % create Ventilator Associated Pneumonia. To control the Ventilated Associated Pneumonia most of the health institution primarily go for sedation, spontaneous breathing trails, deep vein thrombosis prophylaxis, stress ulcers prevention, head elevation of bed and mouth wash management.

Proper mouth wash or oral care is the first line of defense in preventing the VAP. The researcher found that together with other health care procedure, oral care play a key role in preventing VAP because, many of the interventions are part of routine care. VAP is the preventable illness and if prevented in time can diminish the hospital stay, cost, rate of death and rate of illness. So, here applies the statement" prevention is better than cure".

Similarly, while observing the patients on mechanical ventilation, we can frequently notice that patient have a dry mouth. In normal healthy people, oral health is basically maintained by saliva which has antibacterial, lubricating or moistening the oral cavity and buffering properties. But patient who are on mechanical ventilations have low rate of saliva production because of the side effect of the treatment they are receiving in terms to recover their health.

VAP is occurred because of the aspiration of the oral colonization as a result of poor mouth wash care. After intubation most of the defense capacity to bacteria is been reduced. If proper care is not done there will be collection of secretion which enter into trachea & aspirate into lungs. Within 72 hours, there will be dental plaque depositions on the teeth which are considered as reservoirs for respiratory pathogens. Saliva has important enzymes lysozyme which helps to stop bacterial growth. But, in ICU, because of external stressors there is xerostomia which increases the risk of carries and periodontal disease.

Most of the research showed that oral care with chlorhexidine solution has been seen effective diminishing the incidence of ventilator associated pneumonia. Yet, the role of oral care with tooth brushing has sparse consideration and stays indistinct.

2. MATERIAL AND METHODS / EXPERIMENTAL DETAILS / METHODOLOGY

The present study was undertaken to compare the effectiveness of chlorhexidine mouth wash and chlorhexidine mouth wash with tooth brush in KLE Dr. Prabhakar Kore hospital and MRC, Belagavi, Karnataka. The detail research methodology adopted for the study including the methods, tools and techniques, study area and procedure in the selection of samples, collection of data and data analysis is described below:

2.1 Research approach: Evaluative approach

2.2 Study Design: Randomized Controlled Trail

2.3 Variables under the study:

- Independent Variables: 0.2% chlorhexidine mouth wash solution and tooth brush
- Dependent Variables: Ventilator Associated Pneumonia.

2.4 Research setting: The study will be conducted in KLES Dr. Prabhakar Kore Hospital & MRC Belagavi.

2.5 Study Period: November 2019 – March 2021

2.6 Data Collection Period: 19th November 2020 – 19th Feb 2021

2.8 Study Population: Patients who were admitted in Critical Care Unit of Selected Tertiary Care Hospital, Belagavi.

2.9 Sample Size: 60 (30 Control group and 30 Study group)

2.10 Sampling technique: convenient sampling technique

2.11 Inclusion Criteria:

Patients;

- Age between 18 to 70 years.
- being initiated on mechanical ventilation
- relatives who are willing to give consent for research study.

2.12 Exclusion Criteria:

- Allergic to the study drug.
- Contraindication for oral care (severe facial trauma, oral injuries/surgery)
- Pregnant women
- Death within one week of inclusion in the study

2.13 Sources:

- **Primary sources:** Patients who are admitted in Critical Care Unit of KLE Dr. Prabhakar Kore Hospital and MRC, Belagavi, Karnataka.
- **Secondary Sources:** Review of literature collected from various journals, internet and reference books related to mouth wash.

2.14 Tools for data collection:

Section A: It consists of demographic variables like Age, Gender, Diagnosis, on ventilator more than 48 hours.

Section B: Clinical Pulmonary Infection Score (CPIS)

2.15 Confidentiality: All information collected about Participants during the course of the study will be kept Confidential. The code numbers will be used in this Study records and the information from this study may be published but participants identity will be confidential in any publication.

2.16 Data collection method:

- Permission will be obtained from the concerned authority.
- The investigator will introduce and explain the purpose of the study to the patient's relatives and the care giver.
- Obtain consent from the participants/Family Members.
- Data will be collected, tabulated and analyzed..

2.17 Data collection Procedure:

After obtaining the approval of the Ethical committee and written informed consent, a total of 60 patients confirming to the inclusion and exclusion criteria were included in the study. The investigator introduced and explains the purpose of the study to the patient's relatives and the care giver.

Patients were randomly divided into two groups, Group A who would be receiving 0.2% chlorhexidine mouth wash and Group B who would be receiving 0.2% mouth wash with tooth brushing, by using convenient sampling technique.

Group A will be given 0.2% chlorhexidine mouth wash twice a day. Here, simple method of mouth wash was followed using sterile swabs. Whereas Group B will receive an equal volume of Chlorhexidine with tooth brush twice a day. Here, tooth brush was dipped into the chlorhexidine solution which was further applied for brushing the patient tooth.

Every day (on 1, 3, 6, 9, 12 and 15 days), CPIS scoring system was applied for both the groups and followed up by microbiological test including ET gram stain and culture sensitivity.

3. RESULTS AND DISCUSSION

In control group, majority of patient belongs to 51-60 years, i.e. 11 (36.67%) and minority from less than 30 years, i.e. 3(10). Similarly, in experimental group majority of patient belongs to 61-70 years, i.e. 13 (43.33%) and minority from <30 and 41-50 years, i.e.2 (6.67%).

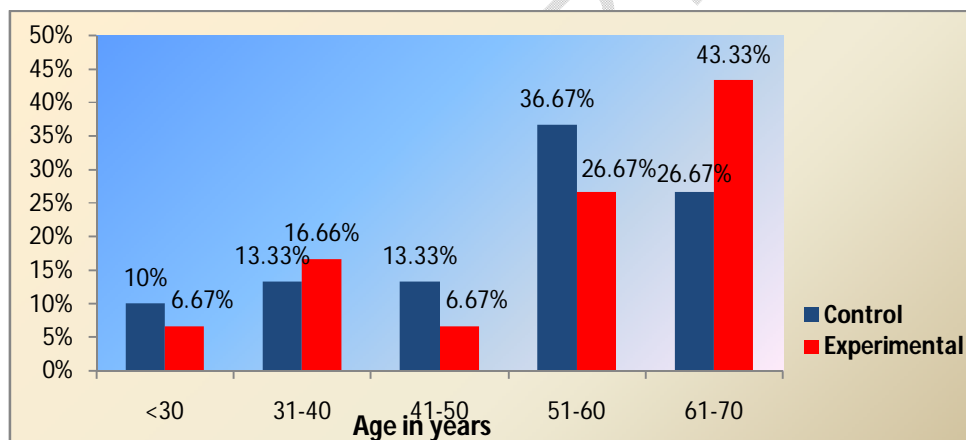
Out of 30 participants, 24 (80%) patients were male and 6 (20%) patients were Female in Control group. Similarly, 23 (76.67%) Male and 7 (23.33%). In both group female participants were less than male.

Age in years and gender does not had any significant difference in the result of mouth wash effectiveness with the p value 0.619 and 0.754 respectively which was more than level of significance 0.05. Thus, this result shows hypothesis H_{02} is accepted.

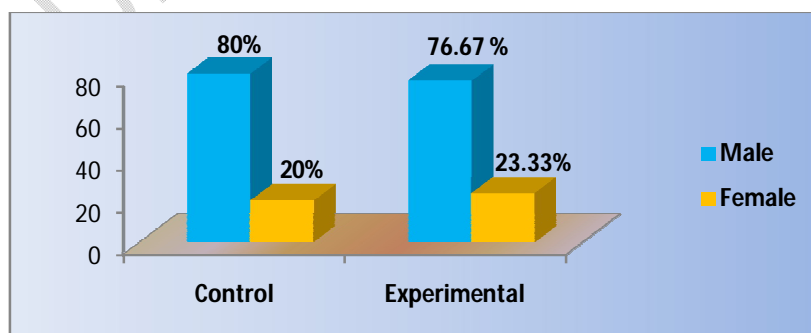
Table .1: Distributions of the study participants according to the age in years
n= 30+30

S.no	Variables	Control		Experimental		df	P
		F	%	F	%		
1.	Age in years						
	<30	3	10	2	6.67		
	31-40	4	13.33	5	16.66		
	41-50	4	13.33	2	6.67	4	0.615
	51-60	11	36.67	8	26.67		
	61-70	8	26.67	13	43.33		
2.	Gender of Patient						
	Male	24	80	23	76.67	1	0.754
	Female	6	20	7	23.33		
	Total	30	100	30	100		

Graph.1: Bar graph of the study participants according to the age in years



Graph.2: Bar graph of the study participants according to the gender



The microbiology test of endotracheal (ET) tube tips came positive more in experimental group 3 (10%) than in control group 1 (3.33%). The p value is 0.301 which shows p value greater than 0.05 level of significance ($p > 0.05$). Hence, H_{01} is accepted.

Table.2. Distributions of the study participants according to the microbiology test of ET tube tips

Microbiology test of ET tube tips	Control				Experimental		Df	P
	Control		Experimental					
	f	%	F	%				
Negative	29	96.7	27	90	1	0.301		
Positive	1	3.33	3	30				
Total	30	100	30	100				

Graph.03: A cone chart of the study participants according to microbiology test.

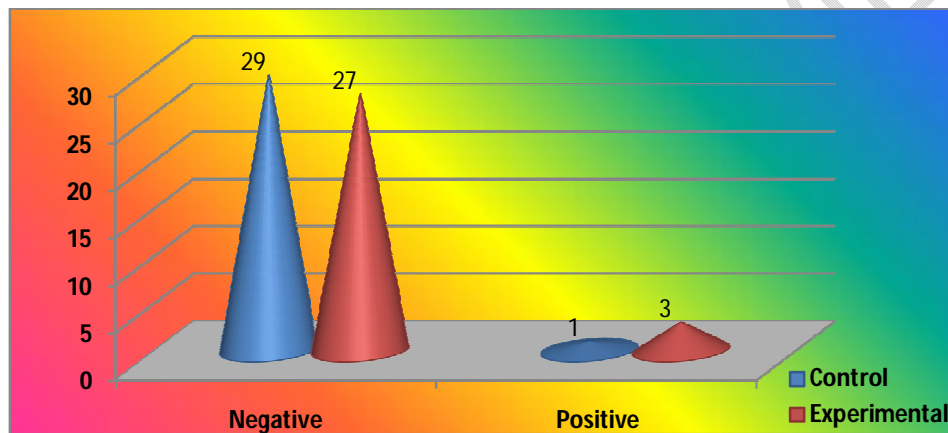


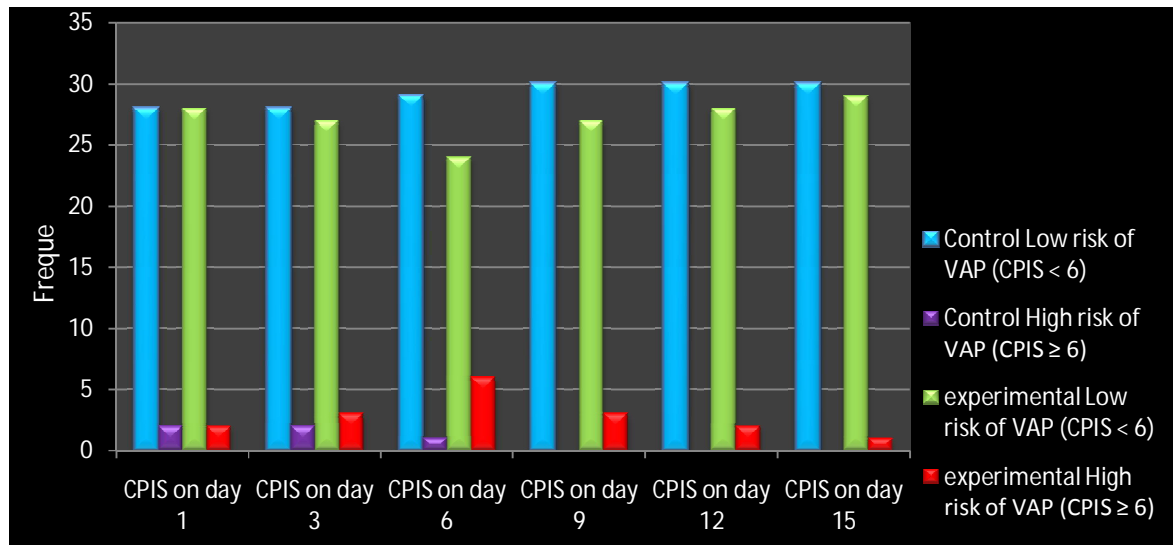
Table 3 clearly explained the comparison between the chlorhexidine group and chlorhexidine with tooth brush on the basis of CPIS score on day 1, 3, 6, 9, 12, 15 and their risk to get VAP. According to the result of Chi-square test, the CPIS score on day 3 was found to be insignificant than in others day with p value more than 0.05. VAP risk was high in Experimental group compare to Control group as the day progressed.

Table.3. Comparing CPIS score and risk of VAP between two groups in days.

Days of CPIS	Control		Experimental		Chi-square test value	df	P
	Low risk of VAP (CPIS < 6)	High risk of VAP (CPIS ≥ 6)	Low risk of VAP (CPIS < 6)	High risk of VAP (CPIS ≥ 6)			
1	28	2	28	2	13.5	6	0.036
3	28	2	27	3	7.6	5	0.180
6	29	1	24	6	35.200	7	0.000
9	30	0	27	3	167.167	4	0.000

12	30	0	28	2	108.300	2	0.000
15	30	0	29	1	56.067	1	0.000

Graph.04. A bar graph comparing CPIS score and risk of VAP between two groups in days.



DISCUSSION:

The aim of the study was to assess the effectiveness between 0.2% chlorhexidine mouth wash and 0.2% chlorhexidine with tooth brush on the patient who were under Mechanical ventilation admitted in intensive care unit of selected hospital in Belgaum.

Generally, tooth brushing is a simple activity for health promotion. Tooth brushing has been recommended as a standard care in critically ill patients even though very few evidence to support this practice. Strong evidence supporting the benefit of tooth brushing in intubated, critically ill patients is lacking. Conversely, tooth brushing may allow bacteria to enter the bloodstream because of potential breakdown of mucosal and gingival tissue, especially in the patient with poor dental health. Therefore, most of the researchers concluded that additional research needed in order to explore association between oral care and bloodstream infection in patient receiving mechanical ventilation.

However, it is essential to remove the plaque and debris from the oral cavity while performing the mouth care for the patient. This is done to avoid the aspiration of the contaminated fluids in the respiratory tract. While giving mouth care, focusing on important aspect like elevating the head of bed and careful use of suction that might be opened or closed fitted with cuff of endotracheal tube is needed most to treat critically ill patient in critical care unit.

Therefore, in order to reduce cases of VAP & to improve the condition of the patient with mechanical ventilators, every health institution must have written oral care protocol & trainings plans to get comprehensive care by patients. The aim of mouth wash and tooth brushing is; regular cleaning of plaque from the teeth twice a day to protect gingivitis, to prevent periodontal disease, for the treatment of xerostomia, ulcers & candidiasis to prevent VAP.

On study done by Mohanty et al. who showed that gender insignificantly influenced incidence of VAP. Despite, Rello et al. detected that VAP was higher among males while Srinivasan et al. concluded that VAP was found to be higher in females. ^(6, 7)

A study conducted on Ventilator Associated Pneumonia in a ICU of a Tertiary Care Hospital in India by Debaprasad Mohanty and Et al found that age did not affected the development of VAP (p- value= 0.929) which was not significant and also the disease had no preference for gender and not significant (p value=0.372). ⁽⁶⁾

Although there were many researches done in 0.2% chlorhexidine, the effectiveness of chlorhexidine in preventing VAP incidence is still in controversial. One study done by Koeman M and Et al demonstrated that there is decrease in VAP rate by using 0.2% chlorhexidine because it will help in decreasing the pathogenic colonization in the oral cavity. The same researcher further conducted another randomized double blind study using the same solution 0.2% chlorhexidine and found chlorhexidine help in reducing the pathogens but not the rate of VAP. ⁽⁸⁾

Furthermore, recent studies revealed that tooth brushing may not have any effectiveness in preventing VAP and reducing oral pathogens. Munro et al. conducted RCT in the adult patient admitted in intensive care unit using 2X2 factorial design CPIS was used to determine the VAP. The result shows that, from 547 only 249 patients were left for the study by the third day. 24 % developed VAP in the group treated by chlorhexidine with CPIS ≥ 6 . After analyzing the data, it shows there was no any effect of combination care. In addition, they also declared that chlorhexidine group with CPIS < 6 have the incident of decreased VAP by the third day. Tooth brushing doesn't show any effect on CPIS. The study concluded that chlorhexidine somehow help in reducing VAP whereas tooth brushing have no any relation. ⁽⁹⁾

In this study, we have evaluated the clinical diagnosis of VAP assessed by simplified CPIS using endotracheal tip culture as the reference standard. CPIS more than six has found to be most sensitive for VAP than CPIS less than six. To the best of our knowledge, no data exist regarding the best oral-hygiene technique to employ, and our results confirm the fact that more studies on this topic are necessary.

4. CONCLUSION

Based on the analysis of the study, we can conclude that combining tooth brushing with 0.2% chlorhexidine did not provide additional benefit over 0.2% chlorhexidine alone. Thus, VAP remains an important clinical problem in intensive care unit. Although the finding is not statistically significant, patients who received chlorhexidine with tooth brushing intervention tended to have higher CPIS values and higher rate of VAP occurrence in experimental group 3 (10%) than in control group 1 (3.33%).

Due to dislodgement of dental plaque micro-organism during tooth brushing could give a bigger pool of micro-organism for movement from the mouth to subglottic secretion or the lung, further examination of expected risk of tooth brushing is justified. Moreover, the technique of endotracheal tube adjustment and control in arrangement of oral care is a territory for future research. Thus, further research to prevent VAP is needed.

CONSENT (WHERE EVER APPLICABLE)

Written consent was obtained before collecting the information.

ETHICAL APPROVAL (WHERE EVER APPLICABLE)

Institutional review board approval was taken. Prior to data collection ethical clearance was obtained from ethical committee of KLE Academy of Higher Education and Research, Institute of Nursing Sciences, Belagavi, Karnataka. After obtaining ethical clearance, hospital permission was taken from the KLE Dr. Prabhakar Kore Hospital and MRC, Belagavi, Karnataka.

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DEFINITIONS, ACRONYMS, ABBREVIATIONS

VAP	Ventilated Associated Pneumonia
ICU	Intensive Care Unit
ICCU	Intensive Critical Care Unit
MICU	Medical Intensive Care unit

SICU	Surgical Intensive Care Unit
KLEs	Karnataka Lingayat Education Society.
MV	Mechanical Ventilation
CPIS	Clinical pulmonary Infection Score
NNIS	National Nosocomial Infections Surveillance
CDC	Centres for Disease Control and Prevention
RCT	Randomized control trials
SPSS	Statistical Package for Social Sciences
ET	Endo Tracheal Tube
d.f	Degree of Freedom
F	Frequency
P	Probability value

APPENDIX

ANNEXURE I - PROFORMA

TITLE- "EFFECTIVENESS OF CHLORHEXIDINE 0.2% MOUTHWASH VS.CHLORHEXIDINE 0.2% MOUTHWASH WITH TOOTHBRUSH IN PREVENTING VENTILATOR ASSOCIATED PNEUMONIA. A ONE YEAR HOSPITAL BASED RANDOMIZED CONTROLLED TRIAL."

Group: _____

Name & Address of the patient:

Age of the Patient: _____ IP. No. _____

Sex. _____

Date of admission:

Diagnosis:

Length of ICU stay:

Date of endotracheal intubation:

No. of days on mechanical ventilation:

Indication for mechanical ventilation: Pulmonary (_____/Non pulmonary (_____))

Past History:

General Physical Examination:

Pallor:

Icterus:

Cyanosis:

Edema:

Clubbing:

Lymphadenopathy

Pulse:

B.P:

RR:

Temperature:

Central Nervous system:

Per Abdomen:

SYSTEMIC EXAMINATION :

Respiratory System:

Cardiovascular System:

INVESTIGATIONS:

Test	Score					
	Day 1	Day 3	Day 6	Day 9	Day 12	Day 15
Tracheal secretion						
Chest X-ray infiltrates						
Temperature						
Leukocytes count						
PaO ₂ /FiO ₂						
Microbiology						
Total Score						

Adverse Effect (If any)

Signature of staff in charge

ANNEXURE II – GANTT CHART

STUDY PLAN AND PREPARATION	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY
TITLE SELECTION	✓	✓																	
REVIEW OF LITERATURE			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
SYNOPSIS DEVELOPMENT				✓	✓	✓	✓												
INTERNAL REVIEW							✓												
ETHICAL CLEARANCE							✓												
HOSPITAL PERMISSION												✓							
EXTERNAL REVIEW								✓											
PILOT STUDY												✓	✓						
DATA COLLECTION AND ENTRY													✓	✓	✓	✓			
DATA ANALYSIS																✓			
DISSERTION WRITING																✓	✓		

