

**An-Najah National University**

**Faculty of Graduate Studies**

**Pre- and Post-Operative Use of 0.2% Chlorhexidine  
Gluconate Oral Rinse for the Prevention of  
Ventilator -Associated Pneumonia in Patients  
Undergoing Cardiac Surgery**

**By**

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**This Thesis is Submitted in Partial Fulfillment of the Requirements for  
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## **Dedication**

This thesis work is dedicated to the sake of ALLAH, my Creator and my Master. My great teacher and messenger; Prophet Mohammed (May Allah bless and grant him), who taught us the purpose of life,

To my beloved father, Hossin, who had always loved me unconditionally and whose good examples had taught me to work hard for the things that I aspire to achieve.

To my beloved mother; Ola, who has been a constant source of support and encouragement during the challenges of graduate school and life. I am truly thankful for having you in my life.

This work is also dedicated to my darling wife, Lena

To my precious son; Amro

To my admired sisters and brothers, and

To my supervisors and all who supported me in completing this work

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Thank you GOD for the chance to learn...

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## الإقرار

أنا الموقع أدناه مقدم الرسالة التي تحمل العنوان:

**Pre- and Post-Operative Use of 0.2% Chlorhexidine Gluconate Oral  
Rinse for the Prevention of Ventilator -Associated Pneumonia in  
Patients Undergoing Cardiac Surgery**

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**Declaration**

The work provided in this thesis, unless otherwise referenced, is the  
researcher's own work and has not been submitted elsewhere for any other  
degree or qualification.

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## List of Acronyms and Abbreviations

Symbol	Abbreviation
bqBAL	Blind Quantitative Bronchoalveolar Lavage
BSIs	Bloodstream Infections
CCU	Coronary Care Unit
CDC	Centers for Disease Prevention and Control
CHX	Chlorhexidine Gluconate
CI	Confidence Interval
CVS	Cardiac Vascular Surgery
d	day
ETT	Endotracheal tubes
FiO <sub>2</sub>	Fraction of inspired oxygen
HAIs	Healthcare-associated infections
HAP	Hospital-Acquired Pneumonia
HICAPAC	Healthcare Infection Control Practices Advisory Committee
ICU	Intensive Care Unit
LoS	Length of Stay
MV	Mechanical Ventilation
NICUs	Neonatal Intensive Care Units
OR	Odds Ratio
PaO <sub>2</sub>	Partial pressure of arterial oxygen
PICU	Pediatric Intensive Care Unit
PRPs	Potential respiratory bacterial pathogens
RR	Relative Risk
RRR	Relative risk reduction
ARR	Absolute risk reduction
NNT	Number need to treat
VAP	Ventilator-Associated Pneumonia
CPIS	Clinical pulmonary infection score

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**Abstract**

**Background:** Scant oral hygiene in coronary care units (CCUs) has been documented as a precarious issue, given the fact that it is an imperative risk factor for ventilator-associated pneumonia (VAP). VAP is an aspiration pneumonia that befalls in mechanically ventilated patients. It is considered the second most common nosocomial infection and the leading cause of complications and death in mechanically ventilated patients. It has been advocated that improvement of oral hygiene in CCU patients undergoing cardiac surgery could steer to a lowered incidence of VAP by using 0.2% chlorhexidine gluconate oral rinse.

**Aim:** This study aimed at appraising the effect of employing a so-called designated “bundle” on the incidence of VAP and length of stay in the (CCU) on mechanically ventilated patients undergoing cardiac surgery at An-Najah National University Hospital , Nablus \ Palestine.

**Method:** A quasi-experimental study was conducted in patients undergoing elective cardiovascular surgery (CVS). The study was carried out at An-Najah National University Hospital (NNUH), located on the north west

bank at the coronary care unit (CCU), between October 2018 and October 2019. Patients of the chlorhexidine (CHX) (experimental group) were enrolled into a protocol, with 0.2% chlorhexidine gluconate oral rinse (15 mL) gargle for 30 seconds, 12 hourly for 3 days preoperatively and postoperatively until discharge. They were compared to a historical (control group), by reviewing the hospital's records of patients who underwent cardiac surgery between October 2017 and October 2018, who underwent elective cardiovascular surgery (CVS). A total of 90 patients (45 for the experimental group and 45 patients' files retrospectively) were targeted for recruitment into the study. However, all adult subjects (18+) undergoing elective CVS requiring sternotomy were included in this study, as well as all patients in experimental group who signed an informed consent forms. Clinical Pulmonary Infection Score (CPIS) was used to assist in diagnosing ventilator-associated pneumonia.

**Results:** Both the groups had approximate similar demographic characteristics in age ( $58.24 \pm 7.42$  (26-73)) years in the chlorhexidine (CHX) group Vs ( $56.8 \pm 11.18$  (27-77)) years in the control group. The mean (SD) age of participants was 57.52 (9.47) years and ranged between (26-77). Most of the patients (93.3%) and (91.1%) were in the age group of ( $20 \leq \text{age} < 70$ ) for the CHX and the control groups respectively. Among the 90 participants, (n = 53) 58.9% were males, 29 (64.4%) in the CHX group, Vs 24 (53.3%) in the control group, having a non-significance predominance of male population ( $p=0.662$ ). The most frequent comorbid disease was hypertension (HTN) (57.8%). There was a solitary (2.2%)

mortality in the control group; nevertheless, none in the chlorhexidine gluconate group was died. The VAP rate per 1000 ventilator days decreased from 17.8% to 4.4% with implementation of the new ventilator bundle. During the pre-intervention period, there were eight (8) VAPs in 154 ventilator days (mean = 3.42 infections per 1000 ventilator days). After the implementation of the bundle, there were two (2) VAPs in 132 ventilator days, resulting in lower rate of 2.96 infections per 1000 ventilator days. The MV time was significantly lengthier in the VAP (+) CHX as well as the control groups. The relative risk ( $RR = 0.23$ ), with a relative risk reduction ( $RRR = 77\%$ ) and absolute risk reduction ( $ARR = 13\%$ ); signify that out of every 100 patients treated with this bundle; there will be thirteen (13) fewer VAPs than if we had used the control treatment bundle. Moreover, the number needed to treat (NNT) analysis showed that one (1) extra VAP can be banned if eight (8) patients are decontaminated with our new bundle treatment.

A significant risk reduction of VAP was found in patients undergoing cardiac surgery and treated with chlorhexidine gluconate in decontaminating the nasopharynx and oropharynx, resulting in less VAP incidence, moreover, the new bundle was significantly beneficial in reducing the CCU stay.

**Conclusions:** Oral care with CHX trims down the VAP risk development on MV patients. This bundle reduces the VAP incidence resulted in a prolonged length of stay in the CCU. Two daily oral self-treatments with

0.2% chlorhexidine gluconate may reduce the risk of VAP in intubated patients approximately one-fourth less frequently in the experimental group than in the controls.

**Recommendations:** Nursing compliance to VAP bundle may lead to better results, while additional research with a larger sample size, longer duration, and in miscellaneous institutions with larger-scale intervention studies should be conducted to verify the proficiency of current protocols and propose conceivable improvements. Furthermore, care providers should consider the impact of oral care along with diverse preventive measures for VAP.

Hopefully, this study will be duly incorporated by reference and optimistically to be considered legally binding upon all hospitals and organizations in Palestine.

# **Chapter One**

## **Introduction**

### **1. Introduction**

#### **1.1 Overview**

Per annum, nosocomial infections are in charge for 17-29 billion dollars cost, and 44-98 thousand deaths in the United States of America. Bergmans et al. (1997) stated that ventilator-associated pneumonia (VAP) is the second most common nosocomial infection, while Strausbaugh (2000) denoted that it is the first popular infection in the intensive care unit (ICU).

Postoperative pneumonia is a common and critical impediment after cardiovascular surgery (CVS). It forms a factual risk and turns a successful surgery to a life-threatening situation. Moreover, ventilator-associated pneumonia (VAP) is a life-threatening postoperative snag that has an extreme effect on health care and hospital stay (Rello et al., 2002). However, mechanically ventilated patients may develop ventilator-associated pneumonia (VAP) ranging 9%-27%, catalyzing an eightfold rise in the death risk in patients submitting CVS (Chastre and Fagon, 2002).

Consequently, it is imperative to make additional determinations to avert VAP and to detect inclining risk factors to manage them, while mortality rates for patients who acquire VAP are prominent, which may



range 33-50% of ventilated patients dying (American Thoracic Society and Infectious Diseases Society of America, 2005).

Pre-emptive methods might be either pharmacologic or non-pharmacologic. Hygiene and oral defense facilitate avoiding pneumonia in non-sick persons (Terpenning, 2005). Nevertheless, intrusive anaesthesia as well as the operations raise the risk of chest infection through distressing the oral defense. The furthestmost significant contrivance is aspiration of oropharyngeal organisms into distal bronchi. Diverse approaches were employed to reduce bacterial stress through oral cleansing, containing the use of antiseptics. Even though commonly reliable, chlorhexidine has some side effects. VAP studies were carried out in the ICU sittings with seriously ill patients, thus; besides to the assortment of the fundamental patients bear further VAP risk factors as well as time of endotracheal intubation and immunological settlement. A few data is available on VAP preclusion in patients undertaking voluntary cardiac surgery and thus the effectiveness of using single antiseptics to reduce the occurrence of VAP in patients is uncertain. The most significant mechanism to decrease the prevalence of the post-operative pneumonia is the use of oral chlorhexidine in ICUs with encouraging results. Its function before the operation is to sanitize the oral cavity, thus dipping the incidence of pneumonia after operation (Tantipong et al., 2008). In this current study, we will attempt to promote to an approach for oral decontamination in patients experiencing elective CVS, which includes a protocol for oral hygiene and 0.2% chlorhexidine gluconate oral rinse. The aim of the study is to evaluate the effect of

employing the described protocol of VAP on the incidence of VAP and LoS in the coronary care units (CCUs) in mechanically ventilated patients undertaking cardiac surgery as well as to prevent/decrease the incidence of VAP.

## 1.2 Problem Statement

Developments in medicine have increased the use of mechanical ventilation in (ICUs) (Bernard et al., 1994). (VAP) denotes to bacterial pneumonia matured in mechanically ventilated patients for more than 48 hours (Davis, 2006). It vacillates from 6% to 52% and may extend to 76% in other definite situations (Koenig and Truwit, 2006). Hospital-acquired pneumonia (HAP) is the pneumonia next 48 hours after admission or more, which does not look being incubated when admitted. However, the HAP existence upturns hospital stay 7–9 days for every patient as well as imposing an extra financial burden to the hospital (Chastre and Fagon, 2002; Rello et al., 2002). Furthermore, (VAP) maintains as one of the chief sources of morbidity and mortality cardiac care units (CCUs)<sup>1</sup> patients (Raghavendran et al., 2007). When patients are mechanically ventilated, the VAP risk is uppermost in the primary lodging, is 0.03/day projected throughout the 1<sup>st</sup> 5 days of MV, 0.02/day during days five to ten of ventilation and 0.01/day later (Rello et al., 2002).

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<sup>1</sup> CCU: Abbreviation for coronary care unit, used interchangeably with critical care unit and cardiac care unit.

Nevertheless, absence of a rudiment benchmark for diagnosis is the key cause of humble outcome of VAP. The irrefutable diagnosis based on pus-filled sputum could result in intubation or secretion leakage nearby airway, while radiography of chest variations assumed of VAP can be a facet of respiratory oedema, pulmonic infarction or ARDS. Furthermore, leukocytosis and fever are indefinite and can be related to any situation that liberates cytokines. Though microbiology facilitates in diagnosis, it is not empty of drawbacks. Indeed, it was verified that airway colonization is regular, and pathogenic incidence in tracheal secretions in the lack of quantifiable results do not propose VAP (Niederman, 1990; Diaz et al., 2005). This current study aims at reviewing the incidence and outcome; detect numerous risk factors as well as to determine particular actions that should be embarked to avert VAP. The researcher has noticed -over years of practice in hospitals in Palestine- that the postoperative pneumonia escorts to an escalated morbidity and prolonged length of hospital stay. For this reason, the importance sits in the deterrence of the post-operative pneumonia, leading to decrease morbidity and mortality rates. Although some information exist on mechanical ventilation and related issues, limited data are available from Palestine

### **1.3 Significance of the Study**

Postoperative pneumonia is a really and critical impediment post cardiovascular surgery (CVS). It produces an actual risk and turns a successful surgery to a life-threatening situation. Literature review aiming oral care in critically ill patients, especially with the coexisting use of chlorhexidine, have not supported with adequate confirmation of VAP prevention. Hitherto, such study -to the knowledge of the researcher- has not been formally or informally investigated in Palestine. The CDC advocates that health care services improve and apply all-inclusive oral hygiene schedule for patients in acute-care backgrounds or residents in long-term care facilities who are at high risk for health care-associated pneumonia (Tablan et al., 2004). ICU nurses can use an oral care protocol and scores developed by this research to thwart VAP and improve oral health in critically ill adult patients.

There is a trend from the Palestinian Ministry of Health (MoH) to adapt this technique, and expecting, this study will be fittingly integrated by reference and positively to be considered legally binding upon all hospitals and organizations in Palestine.

## **1.4 Aims of the Study**

The aims of the study are to assess the effect of utilizing the so designated protocol of VAP on the VAP incidence, and LoS in (CCU) in mechanically ventilated patients undergoing cardiac surgery as well as to prevent/decrease the incidence of VAP.

## **1.5 Research Hypotheses**

1. There is a significant difference at a level of 0.05 related to the decontamination protocol of VAP and reducing bacterial colonization in patients undergoing elective cardiac surgery admitted to CCU.
2. There is a significant difference at a level of 0.05 related to the decontamination protocol of VAP and reducing length of stay in CCU in patients undergoing elective cardiac surgery.

## **Chapter Two**

### **Background**

#### **2. Background**

##### **2.1 Definition of Ventilator-Associated Pneumonia (VAP)**

While the term “VAP” has been used frequently in the literature, it is unluckily not uniformly defined from study to study. Most of the studies deal with the development of pneumonia in patients on mechanical ventilation for greater than or equal to some set period of time, as defined by the authors and researches (Zachary et al., 2013).

Augustyn (2007) argued that critically ill patients who are mechanically ventilated for intervals within 48 hours might develop VAP easily. Pathogenesis (the manner of the development of the disease) encompasses the access of bacteria to the lower respiratory tract of the patient and devastating of the patient’s defenses (Powers, 2006). (VAP) is termed as nosocomial pneumonia in mechanically ventilated patients that grows within more than 48 hours after introduction of mechanical ventilation (MV) (Gadani et al., 2010). Moreover, it is identified as pneumonia that happens 48–72 hours post endotracheal intubation and subsidizes all cases of hospital-acquired pneumonia (HAP) to the half (American Thoracic Society and Infectious Diseases Society of America, 2005).

VAP remains to confound the 8 to 28% course of patients obtaining (MV). Adjacent to infections of more commonly convoluted organs (for instance, skin and urinary tract), when mortality is stumpy, fluctuating from 1% to 4%, the mortality rate for VAP vacillates from 24% to 50% and can reach 76% in some particular situations, or while high-risk pathogens causing lung infection (Chastre and Fagon, 2002). Although the mortality rate for VAP is still questioned, good evidence designates that VAP elongates the interval of MV and ICU stay (Chastre and Fagon, 2002). About 50% of antibiotics prescribed in an ICU are administered for VAP treatment (Hunter, 2012).

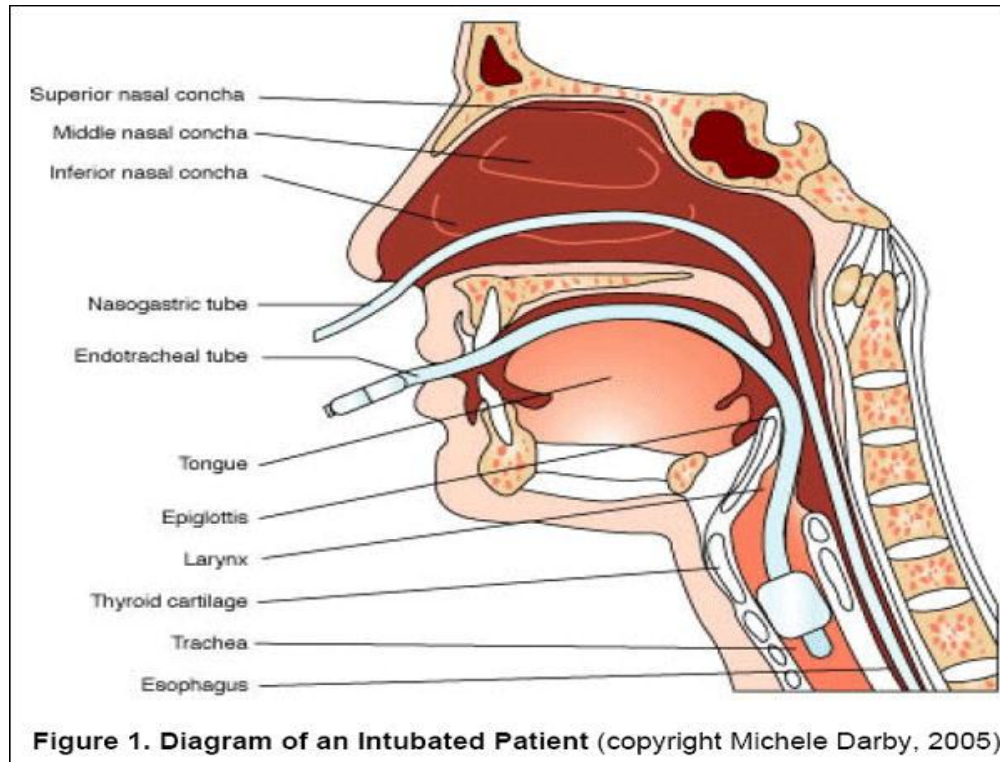
When there is an incursion bacterium of the parenchyma, VAP ascends in patients accepting MV. Nonetheless, immunization of the hygienic lower respiratory tract stereotypically rises from secretional aspirations, colonization of the digestive tract, or the use of contaminated tools or medicines. However, risk factors for VAP contain extended intubation, nutrition, observed aspiration, and fundamental illness and prodigality of age (Bergmans et al., 2001).

The ventilator-associated pneumonia pathogenesis commonly involves two imperative courses to come about: bacterial colonization of the aerodigestive tract, and the contaminated secretions aspiration into inferior airway (Estes and Meduri, 1995).

However, VAP diagnosis is an objective distrust. The incidence of a pulmonary infiltration on chest x-ray, besides two of the three measures: leukocytosis, purulent respiratory secretions and fever is the most accepted clinical definition for notion of pneumonia (Fathi et al., 2013).

On x-ray, VAP can be recognized when a chest x-ray shows a fresh or advanced infiltration, consolidation, cavitation or pleural effusions. Symptomatically, the patient may have in any case one of the followings: an alteration in sputum colour, high temperature, high or low white blood cells, organisms cultured from blood, and segregation of an aetiological cause by transtracheal aspirate, or biopsy (Centers for Disease Control and Prevention (CDC), 2009)). However, about one-third (1/3) of patients in ICUs uses mechanical ventilation as a backing treatment (Munro and Grap, 2004). CDC defined VAP as a lung infection that acquires in a patient on a ventilator. A ventilator is an apparatus used to assist a patient breathe by yielding oxygen within an endotracheal tube positioned in a patient's mouth or nose, or through tracheostomy. Subsequently, an infection may ensue if germs pass in through the tube and penetrate the patient's lungs. Furthermore, VAP is a pneumonia that takes place within a patient who is ventilated and intubated directly or during 48 h previously the inception of the pneumonia (Chastre and Fagon, 2002). (See Figure 2.1).





**Figure 2.1:** Diagram of an intubated patient.

## 2.2 How Chlorhexidine Might Work

Pronnier et al. (2005) revealed that 0.2% oral rinse Peridex chlorhexidine is an antimicrobial agent effectual versus aerobic and anaerobic bacteria. However, it is a functional solution that is absorbed onto soft tissues and emitted subsequently. Once administration, in one minute, aerobes and anaerobes are lowered 87% and 84%, respectively.

Mohammadi and Abbot (2009) maintained, “Chlorhexidine is a broad-spectrum biocide operative opposed to gram-positive bacteria, gram-negative bacteria and fungi. Chlorhexidine disables microorganisms with a wide-ranging band than other antimicrobials (e.g. antibiotics) and has a faster eradicating speed than other antimicrobials (e.g. povidone-iodine). It

has both bacteriostatic (hinders bacterial evolution) and bactericidal (destroys bacteria) mechanisms of action, relying on its concentration. Chlorhexidine exterminates by upsetting the cell membrane. Upon application in vitro, chlorhexidine could kill approximately 100% of Gram-positive and Gram-negative bacteria within 30 seconds.” There is restricted risk for the development of devious infections since chlorhexidine constructions can extinguish the mainstream of classifications of microbes. However, O'Reilly (2003) conducted a study demonstrating that using chlorhexidine as an addition to mechanical panel elimination conquers dental plaque colonisation via possible pathogens.

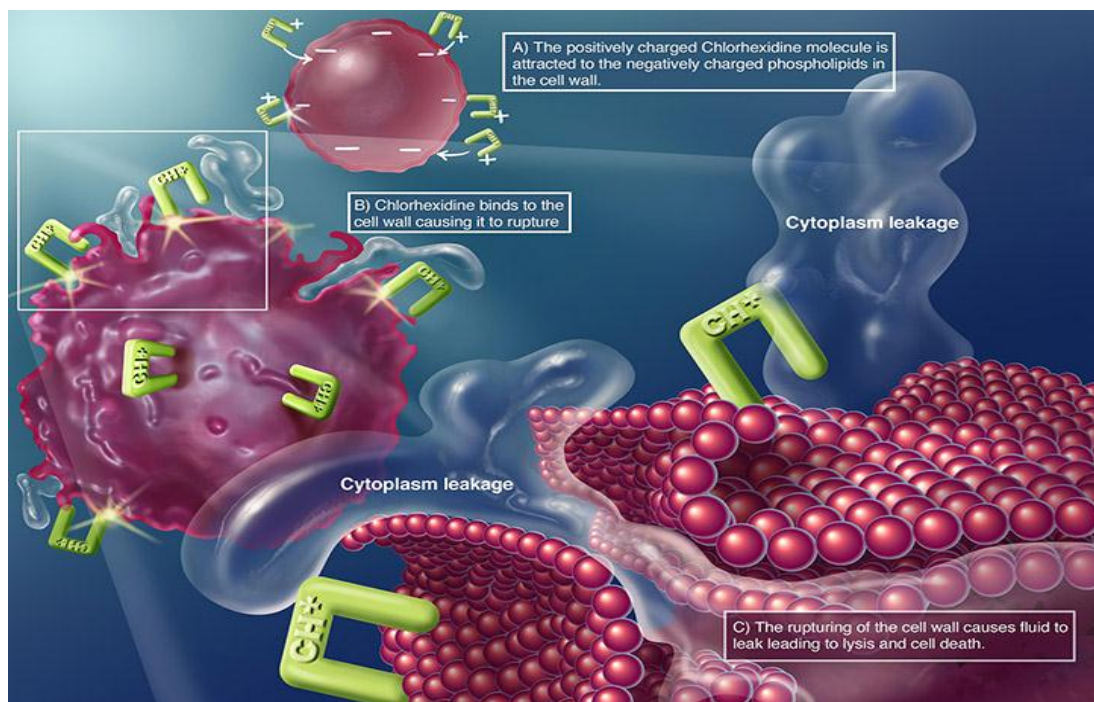
Nevertheless, oropharyngeal colonisation, gastric colonisation, aspiration and lung defences are the most aspects related with the occurrence of VAP (Morton et al., 2005). It (chlorhexidine) is being employed in place of an oral antiseptic in mechanically ventilated patients due to its capability to join to oral tissues with succeeding gentle discharge of antiseptic characteristic, hence, an extended duration of antibacterial act (Scannapieco et al., 2009). (Figure 2.2).

Chlorhexidine has the capability to combine to the proteins existing in human tissues for example skin and the mucous membranes with physically fascination (WHO, 2009). Protein combined chlorhexidine liberates gradually, conducting to sustained action. The substantivity prodigy permits for a lengthier time of antimicrobial engagement alongside a comprehensive spectrum of bacteria and fungi, which can continue at

least 48 hours on the skin (Mohammadi and Abbott, 2009). Chlorhexidine is not disturbed by the existence of fluids in the body such as blood contrasting povidone-iodine (Lim et al., 2015).

Orally, chlorhexidine attaches the teeth, mouth tissue and oral mucosa. Afterward, it is emancipated along the time to destroy fungi and bacteria (Buig et al., 2008). This prevents dental plaque, and helps to lessen the bacterial count. Chlorhexidine, when applied in medical apparatuses (for instance dental implantations, antimicrobial dressings and catheters), it eradicates organisms and shields against microbial colonization, and consequently biofilm development (Mermel, 2001).

Moreover, Koeman and colleagues (2006) concluded that relevant mouth sanitization with CHX or CHX/COL decreases the VAP incidence.



**Figure 2.2:** Mechanism of action.

## **Chapter Three**

### **Literature Review**

### **3. Literature Review**

#### **3.1 Overview**

A study accomplished by Tantipong and colleagues. (2008) in a university hospital in Thailand. The study aimed at identifying the efficiency of oral sanitization with 2% chlorhexidine suspension for the deterrence of (VAP). However, patients were randomized to take oral decontamination with 2% chlorhexidine suspension or normal saline four (4) times/day up until the removal of endotracheal tubes. They pointed that meta-analysis was achieved by merging their study results with the results from a different randomized experiment which used 2% chlorhexidine. Nonetheless, VAP incidence with the other group was (12 of 105) 11.4% ( $P=0.08$ ), while in the CHX group the VAP incidence was (5 of 102) 4.9%. It was noticed that in the chlorhexidine group, oropharyngeal colonization with gram-negative bacilli was one or the other delayed or reduced. Generally, mortality has not any dissimilarity of the patients among groups. Two meta-analysis randomized experiments discovered that the VAP relative risk in the chlorhexidine group of 53%. The study concluded that 2% chlorhexidine suspension for oral decontamination is an operational and innocuous mode to avert VAP in patients obtaining mechanical ventilation.

Özçaka and coworkers (2012) conducted a randomized study to evaluate conceding that oral swabbing with 0.2% (CHX) gluconate drops the (VAP) risk in (ICU) patients. Sixty-one (61) cogged participants retained for invasive mechanical ventilation for at least 48 hours by mopping the oral mucosa four (4) times/d were involved in this. They split into two groups. The gums dimensions were documented. Using normal culture methods, pathogens were recognized by measuring gatherings. However, results pointed out that VAP matured within 6.8 d in 34/61 patients (55.7%). VAP has substantial ratio, which was lower in the trial group than in the control one. Of all kinds recognized, the utmost conjoint pathogen was acinetobacter baumannii (64.7%). Moreover, no significant differences between the two groups in clinical periodontal measurements were obtained, neither VAP development time nor mortality rate or pathogens detected. It was concluded that CHX swabbing with the oral care shrinks the VAP risk development in (MV) patients.

Nonetheless, Zhang and coworkers. (2013) have appraised the chlorhexidine efficacy for the preclusion of VAP, and reconnoitered the CHX ideal concentration by conducting eighteen (18) randomised experiments in a meta-analysis study. The results denoted that chlorhexidine could significantly avert and demote VAP incidence. Nine (9) studies displayed 0.12% CHX developed a momentous outcome. Nonetheless, three (3) studies evidenced the influence of the 2% CHX on the VAP hindrance. However, the study concluded that chlorhexidine could stop and decrease the VAP incidence. Along with the meta-analysis, drug

resistance analysis and opposing reactions, 0.12% chlorhexidine ensures the unsurpassed upshot on the impediment of VAP. Hence, Zhang and colleagues. (2013) recommended 0.12% chlorhexidine usage in this study.

Beiswanger and colleagues. (1992), determined how 0.12% chlorhexidine rinse affect gingival healing. Measurements were documented, using 15 mL chlorhexidine two/d for about 30 seconds, and 2 weeks before/2 after on one side of the mouth. Subjects with chlorhexidine rinse had significantly improved gingival healing matched with the control groups, who used placebo. Individuals in the CHX group had 54% fewer plaque, 48% less bleeding spots and 29% fewer gingivitis.

In a prospective study conducted by Abbas and Mir Ahmad (2016), data were gathered using a two group categorization; (group A; n= 190, a pre-operative CHX mouthwash; 15/09/2008-15/10/2008) and (group B; n=195 patients received a pre-operative chlorhexidine mouthwash; 16.10.2008-15.11.2008). As a standard procedure in the department, patients had received 750mg pre-operative cefuroxime accompanied by the two postoperative doses. Moreover, they were given 10ml of 0.2% chlorhexidine mouthwash for 10 minutes as a preoperative medication the day of operation. Results indicated that the postoperative pneumonia incidence was pointedly trimmed down in patients preserved in (group A 10.52% vs. group B 2.56%  $p=0.003$ ). However, the LoS was significantly longer in the non-chlorhexidine group. Accordingly, using preoperative chlorhexidine before thoracic surgery produces a drop in the VAP progress.

Nevertheless, there were reviews reconnoitering CHX effectiveness dwindled for the demonstration of VAP decline. Results of Bellissimo-Rodrigues et al. (2009) showed that both groups had exhibited alike characteristics. The whole incidence of respiratory tract infections and the rates of VAP/1,000 ventilator days were comparable in both groups. Duration of MV, and LoS did not vary in-between both groups. It was deduced that 0.12% CHX does not thwart respiratory tract infections in ICU patients, though it can slow down their inception.

Moreover, the randomized study of Panchabhai and Dangayach (2009), reported that pneumonia settled in (7.1%) patients in the CHX group, and (7.7%) patients in the control set, while revealed that there was no significant difference between the CHX and control sets in the median day of pneumonia development. Moreover, primary and secondary results revealed there was no significant difference on MV and tracheal intubated patients. In the course of the study, pneumonia had developed in few patients (7.4%) than in the 3 months foregoing and following the study (21.7%). However, the study concluded that 0.2% chlorhexidine suspension was not outstanding related to the control suspension. Nevertheless, the declined incidence of pneumonia in the course of the study proposes a potential advantage of scrupulous oral hygiene in ICU patients.

Pineda and coworkers. (2006) executed randomized controlled trials aimed at identifying the outcome of CHX on the pneumonia incidence. They argued that the nosocomial pneumonia incidence in the control group was higher (41 out of 615; 7%) related to (24 out of 587; 4%) in the treatment group. LoS and duration of MV were similar concerning the two groups. However, the study concluded that CHX oral decontamination neither improved mortality rate, nor caused a noteworthy markdown in the pneumonia incidence in MV patients.

On the other hand, Munro and Grap (2004) evaluated in their randomized clinical trial study the advantages of pre- and post-intubation CHX doses addition to know the reduction of the VAP risk. Moreover, to detect the effect of a CHX preintubation oral addition on early endotracheal tube (ETT) colonization. The results determined that the addition of a preintubation dose of CHX did not provide advantages over the intervention period by daily oral CHX succeeding intubation. No significant difference was detected for the ETT colonization at extubation in both groups, while the mean CPIS lingered below six (6) in both groups. Furthermore, study results r concluded that it is practicable to provide CHX earlier to intubation. The study suggested that preintubation CHX doses might be irrational when the ventilator bundle, with the daily oral CHX, is in position.



## **Chapter Four**

### **Methodology**

#### **4. Methodology**

##### **4.1 Overview**

In this section, methodology was determined for both experimental and control groups. In addition, a bundle was proposed for the CHX group.

##### **4.2 Design**

This was a quasi-experimental study carried out in patients undergoing elective cardiovascular surgery (CVS).

##### **4.3 Site and Setting**

The study was conducted at An-Najah National University Hospital (NNUH), cardiac care unit.

##### **4.4 Study Period**

Between October 2018 and October 2019 for experimental group (CHX).

##### **4.5 CHX (Experimental) Group**

An oral decontamination protocol was employed to be subjected to patients, and 0.2% chlorhexidine gluconate appearing most effective chlorhexidine gluconate oral rinse protocol (15 mL) 12 hourly for 3 days

preoperatively and two daily until the tracheostomy, extubation, death, or the diagnosis of pneumonia. The patients have obtained simply two (2) doses of the chlorhexidine gluconate oral rinse. They were told to robustly whoosh and slurp the solution for about 30 seconds to make certain to be interaction with the buccal sides of the molars, gingivalis, pharynx, as well as tooth surfaces. Moreover, patients were instructed avoiding drinking, eating or swallowing for at least half an hour subsequently mouth cleansing. Fifteen (15) mL of oral rinse were given out postoperatively to intubated patients two daily through fully mopping the oral cavity surfaces in the patients.

Along with the two (2) postoperative doses, patients have taken cefuroxime 750 mg pre-operative antibiotic prophylaxis as standard protocol in the CCU section of An-Najah National University Hospital. In addition, 30 minutes before surgery, a third-generation cephalosporin was dispensed unremitting for 24 hours post surgery. However, all the patients were intubated with Evac Endotracheal Tube<sup>2</sup>. Moreover, at the time of extubation, sputum samples were gathered. Nonetheless, sputum samples would be achieved consistently each 48 hours up until extubation if subjects were not extubated during 24 hours of surgery. Moreover, sputum samples were referred to the laboratory at An-Najah National University Hospital, and handed over in line with standard procedures. Samples were

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<sup>2</sup> Evac ETT: “is a new and special tracheal tube with a separate dorsal suction lumen, which is used for evacuation of subglottic secretions. The suction lumen of Evac ETT has two ports: a subglottic port located 15 mm above the cuff with an elliptical shape (major axis: 6 mm, minor axis: 3 mm) and an external port for connection to suction” (Dragoumanis et al., 2007).

examined after a day and two (2) days for the growth of pathogens. Infections were diagnosed by using an instrument based on the criteria for nosocomial pneumonia called Clinical Pulmonary Infection Score (CPIS). This scoring tool includes tracheobronchial secretions, fever, degrees of leukocytosis, microbial culture, and pulmonary infiltrate (Zilberberg and Shorr, 2010).

#### **4.6 Historical (Control) Group**

This group includes patients who experienced CVS between October 2017 and October 2018 in the same hospital, same workers, and personnel throughout both intervals. This was achieved by reviewing the hospital records of all patients with CVS admitted to the same CCU during the same period one year earlier (October 2017 to October 2018) to minimize the impact of seasonal variations on indications for VAP between the two groups.

#### **4.7 Inclusion Criteria Included**

- Respondents in the current study are all adult patients (18+) undertaking elective CVS requiring sternotomy.

#### **4.8 Exclusion Criteria Included**

- Patients who were pregnant.
- Patients having respiratory infection pre-operatively that had been documented.

- Patients requiring emergency surgery.
- Patients receiving immunosuppressive therapy.
- Patients who were hypersensitive to chlorhexidine gluconate.
- Entirely edentulous patients.
- Endotracheal re-intubation, re-operation.

#### **4.9 Protocol for the Experimental Group (Bundle)**

Even though several approaches and means for oral hygiene in ICUs targeted VAP deterrence designated in the literature, still there is no proof that could spotlight the most effectual evidences (Berry et al., 2011). Though the necessity of forming a wide-ranging protocol of oral hygiene in critically ill patients is frequently accentuated in the literature, there is still no unanimity concerning the best operative VAP preclusion approach of oral care to assimilate within exceptional inclusive rules. Yet, numerous conventions were suggested that are frequently built on mechanical plaque exclusion, like using tooth brushing (Stonecypher, 2010). However, while there are protocols that restrict using in cardiac surgery, CHX use is occasionally incorporated in normal oral care [Halm and Armola, 2009; Tablan et al., 2004]. Not with standing new improvements, oral care of the critically ill is achieved incompatibly and differently, mostly harmonized with separable team practice and existing resources (Lambert et al., 2013). Constructive outcome of standardized protocol implementation on

dropping VAP incidence was verified in several clinical evaluations (Beraldo and Andrade, 2008; Roberts and Moule, 2011), however, the conventions employed contrasted among researchers. Nevertheless, this approves the positive conclusion of several oral care observes in ICUs, along with a written protocol. Even if studied oral care observes differed, they are mostly concentrated on brushing as well as rinsing whereas examination of other oral care actions is moderately uncommon. However, the results are unreliable, though up keeping the proposition that upgrading of oral care diminishes VAP incidence. Wide-ranging oral care procedures have been issued (Prendergast et al., 2012; Sona et al., 2009), and oral care measures are becoming unified into care bundles for the critically ill (Heck, 2012). Many of the present evidence-based protocols comprise tooth brushing, while some of them embrace CHX rinsing. However, it was indorsed to routine brush polishing no less than two daily using a soft pediatric or adult toothbrush, but CHX use is restricted to cardiac surgery patients (Ali, 2013).

A recently published meta-analysis conducted by Alhazzani and his colleagues. (2013) highpointed the absence of high-level evidence for effectiveness of tooth brushing as a technique of VAP preclusion. Furthermore, most of the present recommendations are resulting from low-level evidence, therefore, additional surveys are necessary to approve the efficacy of present protocols and propose conceivable improvements.

**4.9.1 However, our study bundle is as follows (New Bundle):**

A. The patients are instructed to use the modified Bass technique (Bass, 1954) which involves slanting the toothbrush at a 45° angle while brushing not extra than three (3) teeth together, with soft vibratory/circular movements for 10–15 seconds, guaranteeing that every tooth is brushed at surface apiece. Moreover, hygiene is accompanied with dental floss or fibrilla and interdental brushes.

B. 10-15 ml of chlorhexidine mouthwash solution 0.2% (w/v), gargle for about 30 seconds, are given every 12 hours for 3 days before surgery to patients undergoing cardiac surgery admitted to CCU and twice daily postoperatively until discharge.

C. All patients were considered as stated by the local open-heart surgery protocol.

D. On admittance, preparations before surgery entailed two (2) baths with (40 mg/mL) antiseptic chlorhexidine gluconate soap a day preoperatively, while unnecessary hair is removed in the operation room with an electric clipper device.

E. 750 mg or 1.5 g antibiotic with cefuroxime preoperative along with the two (2) postoperative doses every twelve (12) hours for 24 hours are given to patients undergoing aortocoronary bypass, or vancomycin 1.0 g preoperatively, and two (2) doses every 12 hours postoperatively for valve surgery patients.

F. 1.0 g vancomycin preoperatively and two (2) doses every 12 hours postoperatively are given to patients undergoing valve surgery.

G. A third-generation cephalosporin is administered prophylactically (1.5 g intravenously) half an hour prior incision, while additional dose is appended to the preparing fluid of the extracorporeal circulation. Furthermore, if operating actions surpassed 4 hours, an extra dose was processed. Cephalosporin sustained for 24 hours postoperatively. Moreover, skin was sterilized with a chlorhexidine-alcohol solution (0.5%/70%). However, all surgeons independently of the trial protocol performed surgical procedures.

H. Evac Endotracheal Tubes are inserted into patients undergoing cardiac surgery admitted to CCU.

I. Moreover, at the time of extubation, sputum samples are collected, and are attained regularly every 48 hours until extubation if subjects are not extubated within 24 hours of surgery. They are sent to the microbiology laboratory at An-Najah National University Hospital.

J. The development of VAP cases diagnosed within 48 hours of intubation or 72 hours after extubation is the end point of the study.

K. VAP incidence is recorded in reference to gauges of the Clinical Pulmonary Infection Score (CPIS). Criteria for diagnosis of VAP are the substantiation of a new-fangled lung infiltration on chest x-ray and at any rate two of the followings: leukocytosis, fever, or purulent tracheobronchial

secretion. The entire infections post-surgery are documented, and VAP pathogens are detected at the bacteriology and microbiology laboratory of the hospital.

L. Furthermore, mortality rate and length of CCU stay are documented in both experimental and control groups.

#### **4.10 Clinical Pulmonary Infection Score (CPIS) for the Prediction of Ventilator-Associated Pneumonia (VAP)**

This is a humble means for the identification of VAP; therefore, a scoring scheme was settled in 1991 that comprised six (6) quantifiable parameters for VAP diagnosis termed as Clinical Pulmonary Infection Score (CPIS) (Table 5.10). However, in this system, case is assessed with endotracheal culture and radiological chest x-ray. Moreover, VAP diagnosis was built testing body temperature, white blood cells, tracheal secretion, oxygenation ( $\text{PaO}_2/\text{FiO}_2$  ratio (mmHg), existence of pulmonary infiltration in chest radiography, and culture of tracheal aspirate specimen. Scoring six (6) points or more proposes VAP. These values were assented as primary CPIS. (Zilberberg and Shorr, 2010).

During the initial evaluation of the patient, physicians have to have speedy management decisions if there was a distrust of VAP coming from the yardsticks or the (CPIS), considering clinical outcomes and chest x-radiography (Zilberberg and Shorr, 2010).



Clinical Pulmonary Infection Score (CPIS) values were premeditated 24h after intubation. Nonetheless, endotracheal aspirate samples were taken with three (2) days of interludes. Moreover, culture results were obtained two (2) days following taking the samples. While blood tests besides chest radiography were executed throughout the patients' CCU stay, more than one physician examined symptoms and signs of pneumonia. It is deliberated that VAP was doubted when a new, continual infiltrating outline was detected on chest x-ray no less than 48 h post the onset of MV, moreover, when at least two of the resulting criteria were encountered: temperature higher than 38°C, leukocyte count higher than 10,000/mm<sup>3</sup>, or existence of purulent respiratory tract secretions. VAP was ultimately spotted when a specimen of bronchoscopic tracheobronchial secretions displayed a result of 2 (Large ( $\geq 14+$  plus purulent secretion) or ( $>25$  PNL/LPF)(presence and purulent; =color: yellow, green or brown)) (Woske et al., 2001). The VAP diagnosis was formulated consistent with these results. Conversely, the patients' CPIS values who were not diagnosed as VAP and remained to be censored were considered along with these culture results as well.

Klompas and Platt, (2007); Luyt and coworkers. (2004) designated VAP analysis along these lines: the clinical pulmonary infection score (CPIS) takes in consideration radiographic, clinical, microbiological and physiological indications to consent an arithmetic value to forecast the VAP existence or absenteeism. Furthermore, counts can vacillate amidst

zero (0) and 12 scores, using a score of  $\geq 6$  viewing decent correspondence with the VAP manifestation.

#### **4.11 Ethical Consideration**

Our current study was steered in agreement with international standards of data fortification and concealment, as detailed in the Helsinki<sup>3</sup> Declarations. This study was a retrospective and experimental design, permitted by the Institution's Review Board of An-Najah National University. Moreover, the Ethics Committee of An-Najah National University Hospital approved this study.

All patients agreed to participate by indorsing the consent forms obtained from in the experimental group after explaining all the details of the study's purpose and procedure.

#### **4.12 Statistical Analysis**

Analyses concerning variances connecting the groups were carried out using a two-sided chi-square test with a significance level of 0.05; t-test, as well as risk factors affecting VAP incidence. Statistical significance was assessed at  $p \leq 0.05$  level (95% CI), proving by adopting Pocock's sample size formula. Furthermore, analyses were executed employing (SPSS 21, SPSS, Chicago, Illinois).

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<sup>3</sup> Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964.

#### 4.13 Sample Size Calculation

This was a controlled clinical trial, which entitled registered patients connecting October 2018 and October 2019 in An-Najah National University Hospital, School of Nursing, Respiratory ICU (Nablus/Palestine).

Pocock's sample size formula was used. This equation assumes that the comparison is to be made across two equally sized groups. However, comparisons in observational studies are mainly made across two unequally sized groups. In this case, the sample size should be adjusted according to the actual ratio of the two groups in order to reflect the inequality (Pocock, 1983). In line with efficacy analysis, 39 patients in each group are recommended. However, the researcher recruited 45 patients in each group to cover any drop out from the study. Overall, we have recruited 90 patients in the current study.

$$n = \frac{[0.40(1-0.40) + 0.70 (1-0.70)]}{(0.40-0.70)^2} (1.96+ 0.84)^2$$

$$(0.40-0.70)^2$$

$$n = \frac{[0.40 (0.60) + 0.70(0.30)]}{(0.30)^2} (2.8)^2$$

$$(0.30)^2$$

$$n = \frac{[0.24 + 0.21]}{0.09} (7.84)$$

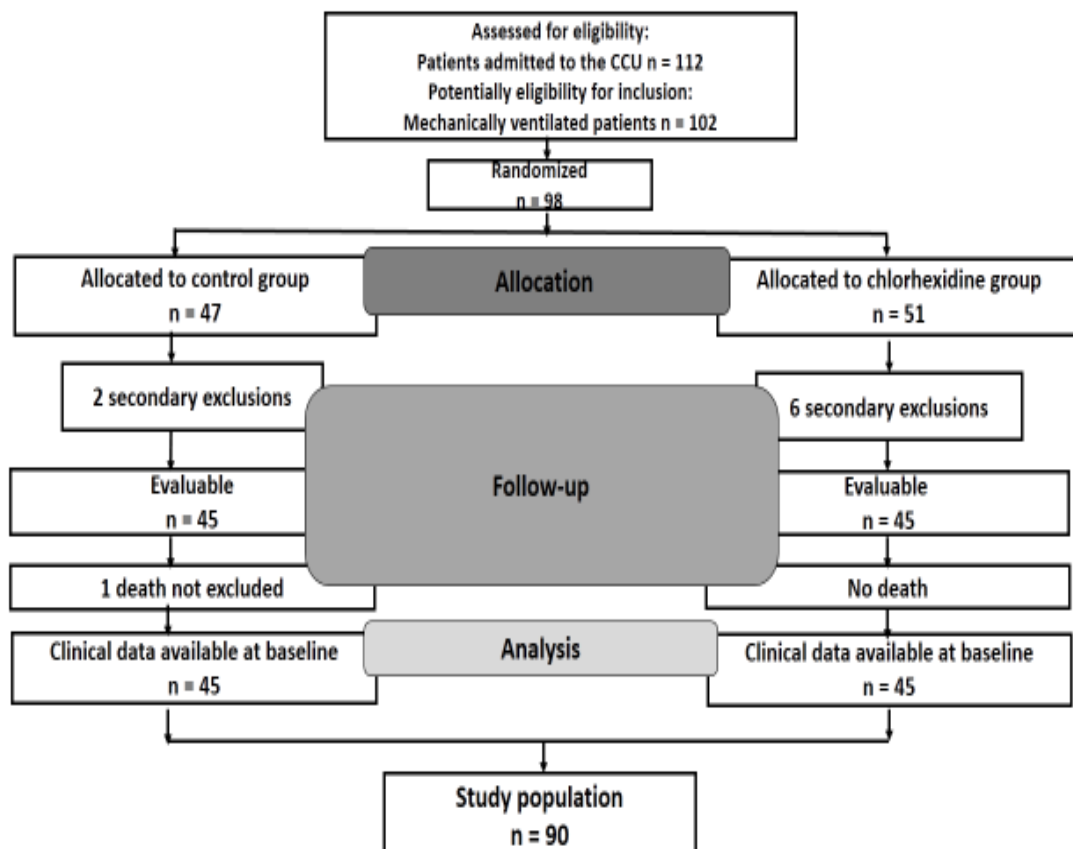
$$0.09$$

$$n = \frac{[0.45]}{(7.84)}$$

$$0.09$$

$$n \approx 39 \text{ patients}$$

Therefore, a total of 90 patients (45 for the experimental group (CHX group) and 45 patients' files (control group) retrospectively between October 2017 and October 2018) were targeted for the recruitment into the study. According to the analysis of power, 39 patients were recommended. Nevertheless, 45 were recruited in each group to account for the possibility of dropout (Figure 4.1).



**Figure 4.1:** Flow chart of the study.

## **Chapter Five**

### **Results**

#### **5. Results**

##### **5.1 Overview**

This chapter presents the study results containing the features of the respondents and the average percentages of the responses for each of the survey's items.

##### **5.2 Characteristics of the Study Population**

In this study, we were able to recruit 90 patients (45 for the experimental group (CHX group) and 45 patients' files (control group) retrospectively between October 2017 and October 2018). In this table (5.1), Chi-Square tests, frequencies and percentages, ranges, means and standard deviations were used.

Table 5.1 below showed that among the 90 participants, ( $n = 53$ ) 58.9% were males, 29 (64.4) in the CHX group, Vs 24 (53.3) in the control group, having a non-significance predominance of male population ( $p=0.662$ ). Moreover, the table below showed that both the groups had approximate similar demographic characteristics in age ( $58.24 \pm 7.42$  (26-73)) years in the CHX group Vs ( $56.8 \pm 11.18$  (27-77)) years in the control group, while all patients were above 18 years; the mean (SD) age of participants was 57.52 (9.47) years and ranged between (26-77). Most of the patients (93.3%) and (91.1%) were in the age group of ( $20 \leq \text{age} < 70$ )

for the CHX and the control groups respectively. The groups were levelheaded with regarding gender, age, and comorbidities. The most frequent comorbid disease was hypertension (HTN) (57.8%), followed by myocardial infarction (17.8%) and congestive heart failure (13.3%) disorders. Kózka et al. (2020) reported that there was a statistically significant found between VAP and co-morbidities, e.g., obesity, chronic obstructive pulmonary disease, diabetes, the occurrence of VAP and multi-organ trauma, hemorrhage/hemorrhagic shock, and fractures as the reasons for admitting ICU patients. Variances were not momentous for social, demography of individuals, neither clinical or laboratory features amongst groups, suggesting that the sample was homogeneous. No correlations were witnessed between comorbidities and group assignments.

Analysis of the secondary outcomes (mean length of time intubated, CCU stay (d), and mortality) was executed on the data from 90 patients (Figure 4.1). Correspondingly, differences were not significant to the individual characteristics and laboratory involving the two groups (Table 5.1). CCU stay ( $2.93 \pm 0.688$  d in the CHX group, while the total days spent was 132 days) and  $3.42 \pm 1.840$  d in the control group while the total days spent was 154 days). However, the total days of (MV) was ( $1.07 \pm 0.330$  d, while the total days spent was 48 days in the CHX group, and  $1.47 \pm 1.254$  d, with a 66 total days spent in the control group).

**Table 5.1: Patients' demography and characteristics.**

Characteristics	Sub group	CHX group (n=45) n (%)	Control group (n=45) n(%)	P-value
Gender	<i>Male</i>	29 (64.4)	24 (53.3)	0.284
	<i>Female</i>	16 (35.6)	21 (46.7)	
Age Mean age $\pm$ SD, range	$20 \leq \text{age} < 70$	42 (93.3) (58.24 $\pm$ 7.42)	41 (91.1) (56.8 $\pm$ 11.18)	0.694
	$70 \leq \text{age}$	3 (6.7)	4 (8.9)	
Result of CPIS (VAP)		2 (4.4)	8 (17.8)	0.001
Comorbidities (n) (%)*				
HTN		26 (57.8)	24 (53.3)	0.756
Smoking (habit)		21 (46.7)	21 (46.7)	0.671
Renal failure (acute or chronic)		5 (11.1)	5 (11.1)	1.000
Peripheral vascular disease		2 (4.4)	5 (11.1)	0.238
Myocardial infarction		8 (17.8)	4 (8.9)	0.215
Congestive heart failure		6 (13.3)	5 (11.1)	0.748
Ejection Fraction (EF) Mean $\pm$ SD		53 $\pm$ 6.16 (35-60)	55.33 $\pm$ 7.02 (20-60)	0.6764
Operation				
If need re-intubation		1 (2.2)	2 (4.4)	0.501
Intra-aortic balloon pump		0 (0)	0 (0)	---
Return to surgery		3 (6.7)	0 (0)	---
Tracheostomy		0 (0)	1 (2.2)	0.638
> 24 h of inotropic support		22 (48.9)	32 (71.1)	0.047
Transfusion > 5 units		5 (11.1)	3 (6.7)	0.022
Sputum Culture result		0 (0)	0 (0)	--
Secondary outcome variables				
CCU Stay (d)		132 (2.93) $\pm$ 0.688 (2-5)	154 (3.42) $\pm$ 1.840 (1-10)	0.001
Length of time intubated (d)		48 (1.07) $\pm$ .330 (1-3)	66 (1.47) $\pm$ 1.254 (1-7)	0.041
Mortality		0 (0)	1 (2.2)	

\*Some percentages may be less or more than 100% due to rounding. Continuous variables are presented as mean $\pm$  SD. Categorical variables are presented as counts and percentages in parentheses. €Some patients had multi-comorbidities. IMV: invasive mechanical ventilation.

### 5.3 VAP Incidence

This current study was sub-partitioned into VAP negative [VAP (-)] together with VAP positive [VAP (+)] (Table 5.2). In this table, Chi-Square tests, frequencies and percentages, ranges, means and standard deviations

were used. There were a total of 10 VAP episodes; 2 patients (4.4%) in the CHX group, and eight (8) patients (17.8%) in the control group, analyzed with VAP during CCU stay. The VAP rate incidence (number of infected patients or infections per 1,000 ventilator days , or per 100 CCU days) in the control group was significantly higher than in the CHX group with an odds ratio of 22 (95% confidence interval = 15.09–29.91,  $P = 0.03$ ). In total, ventilator-associated pneumonia was developed in 10/90 patients (11.1%) within 3.20 days during the CCU stay.



**Table 5.2: Secondary outcome variables and standard features of the control and chlorhexidine gluconate (CHX) groups in line with the status of being ventilator-associated pneumonia VAP negative [VAP (-)] or (VAP) positive [VAP (+)].**

Parameter	CHX group (n=45)			Control group (n=45)		
	VAP (+) (n=2)	VAP (-) (n=43)	p-value	VAP (+) (n=8)	VAP (-) (n=37)	p-value
Clinical or biochemical parameters						
Age (years)	43 (26-59)	59 (50–73)	0.001*	53 (46–62)	58 (27–77)	0.264
Result of CPIS (VAP)	7 (6–7)	4 (2–5)	0.000*	6 (6–6)	4 (2–5)	0.142
Comorbidities (n) (%)*						
HTN	2 (1–2)	2 (1–2)	0.925	2 (1–2)	2 (1–2)	1.000
Smoking	2 (1-2)	1 (1–2)	0.825	2 (1-2)	1 (1–2)	0.183
Renal failure (acute or chronic)	2 (2–2)	2 (1–2)	0.619	2 (1–2)	2 (1–2)	0.176
Peripheral vascular disease	2 (2–2)	2 (1–2)	0.762	2 (2–2)	2 (1–2)	0.281
Myocardial infarction	2 (2–2)	2 (1–2)	0.512	2 (1–2)	2 (1–2)	0.081
Congestive heart failure	2 (2–2)	2 (1–2)	0.581	2 (2–2)	2 (1–2)	0.281
Ejection Fraction (EF)	55 (50-60)	53 (35–60)	0.644	54 (50–55)	56 (20–60)	0.488
Secondary outcome variables						

Parameter	CHX group (n=45)			Control group (n=45)		
	VAP (+) (n=2)	VAP (-) (n=43)	<i>p</i> -value	VAP (+) (n=8)	VAP (-) (n=37)	<i>p</i> -value
CCU stay (d)	4 (3-5)	3 (2-4)	0.023*	5 (3-9)	3 (1-10)	0.040*
IMV (d)	2 (1-3)	1 (1-2)	0.000*	2 (1-3)	1 (1-7)	0.935
Mortality	0 (0.0)	2 (2-2)	0.021*	2 (1-2)	2 (2-2)	0.030*

Data are given as mean (range); Statistically significant at  $\alpha \leq 0.05$ .

In table (5.3) below, Chi-Square tests, frequencies and percentages, ranges, means and standard deviations were used. They were statistically significant at  $\alpha \leq 0.05$ .

A 3.4% of male and 6.3% of female suffered from VAP in the CHX group, while 8.3% of male and 28.6% of female suffered from VAP in the control group. Moreover, 4.8% of patients who were in the CHX group were in the  $20 \leq age < 70$  years old who developed VAP, while 19.5% with the same age category who developed VAP in the control group. Along the same lines, 4.8% of patients with hypertension (HTN) who developed VAP were in the CHX group, while 19% who developed VAP were in the control group. Moreover, 3.8% and 25% of patients with smoking history suffered from VAP in the CHX and control groups respectively with no statistically significant differences. Besides, 0.0% of patients with myocardial infarction who have not developed VAP were in the CHX group, while 50% who developed VAP were in the control group (Table 5.3).

**Table 5.3: Standard features of the control and (CHX) groups related to the status of being ventilator-associated pneumonia VAP negative [VAP (-)] or (VAP) positive [VAP (+)].**

Parameter		CHX group		Control group		
		(n = 45)		(n = 45)		P-value
		VAP (+)	VAP (-)	VAP (+)	VAP (-)	
		(n = 2)	(n = 43)	(n = 8)	(n = 37)	
Gender						0.076
Male	1 (3.4)	28 (96.6)	.662	2 (8.3)	22 (91.7)	
Female	1 (6.3)	15 (93.8)		6 (28.6)	15 (71.4)	
Age						0.330
20 ≤ age < 70	2 (4.8)	40 (95.2)	0.699	8 (19.5)	33 (80.5)	
70 ≤ age	0 (0.0)	3 (100)		0 (0.0)	4 (100)	
HTN	1 (4.8)	20 (95.2)	0.923	4 (19.0)	17 (81.0)	1.000
Smoking	1 (3.8)	25 (96.2)	0.820	6 (25.0)	18 (75.0)	0.176
Renal failure (acute or chronic)	0 (0.0)	5 (100)	0.609	2 (40.0)	3 (60.0)	0.168
Peripheral vascular disease	0 (0.0)	2 (100)	0.755	0 (0.0)	5 (100)	0.270
Myocardial infarction	0 (0.0)	8 (100)	0.501	2 (50.0)	2 (50.0)	0.077
Congestive heart failure	0 (0.0)	6 (100)	0.570	0 (0.0)	5 (100)	0.270
Ejection Fraction (EF) Mean ± SD	2 (55 ± 7.07)	43 (52.91 ± 6.19)	0.644	8 (53.75 ± 2.31)	37 (55.68 ± 7.65)	0.488

Data are presented as percentages (%).

## 5.4 Risk Factors

It is noted that the "exposure" of interest was low-VAP occurrence, and the experimental and control groups are summarized in the top row of the 2x2 table shown below (Table 5.4).

Incidence in the exposed group ( $I_e$ ):  $a/a + b = 2/45 = 0.04$ , or 4 per 100

Incidence in the unexposed group ( $I_u$ ) or ( $I_o$ ):  $c/c + d = 8/45 = 0.17$ , or 17 per 100.

The cumulative incidence (relative risk<sup>4</sup>) (RR) is used in the statistical investigation of the experimental data, cross-sectional and cohort studies, to guesstimate the relationship forte concerning risk factors or treatments, and outcomes (Sistrom and Garvan, 2004; Riegelman, 2005). For instance, it is used to match the menace of an adverse aftermath when partaking a medical treatment set against placebo, or when imperiled to an environmental risk factor contrasted with not exposed.

The (RRR)<sup>5</sup> is the risk difference between the two groups concerning "the control ( $RRR = [I_e - I_o] / I_o$ ), which means that  $RRR = (0.04-0.17)/0.17 = -0.77$ .

The ARR<sup>6</sup> is unpretentious: it is the difference between the risks of exposed and controls ( $ARR = I_e - I_o$ ), which means that  $ARR = 0.04 - 0.17 = -0.13$  or 13% (ignore the negative sign).

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<sup>4</sup> **Relative risk (RR): risk ratio** is "the ratio of the possibility of an outcome in an exposed group to the possibility of an outcome in an unexposed group. It is computed as, where is the frequency in the exposed group, and is the frequency in the unexposed group" (Porta, 2014). "Together with risk difference and odds ratio, relative risk measures the association between the exposure and the outcome" (Sistrom and Garvan, 2004).

<sup>5</sup> **Relative risk reduction (RRR):** the relative decrease in the risk of an adverse event in the exposed group compared to an unexposed group (Ranganathan et al., 2016).

<sup>6</sup> **Absolute risk reduction (ARR) or risk difference:** "The difference in the incidence of poor outcomes between the intervention group of a study and the control group. For example, if 20 per cent of people die in the intervention group and 30 per cent in the control group, the ARR is 10 per cent (30–20 per cent" (Ranganathan et al., 2016).

The number needed to treat (NNT)<sup>7</sup>; is the antithetical of the ARR. Thus, the  $NNT = 1 / ARR = 7.7$ .

The table below illustrates the connotation of the binary exposure and binary trait. Controls and cases, unexposed and exposed individuals, are summed up in the four-cell table below.

**Table 5.4: Contingency (or 2x2) Table: Relative risk reduction, relative risk, number needed to treat and absolute risk reduction.**

Group	VAP	NO VAP	Total	Cumulative incidence	I <sub>e</sub> = 0.04 I <sub>u</sub> = 0.17 RR = 0.04/0.17 = 0.23 RRR = (0.04-0.17)/0.17 = -0.77 ARR = 0.04-0.17 = -0.13 NNT = 1/0.13 = 7.7
Experimental	2 (a)	43 (b)	45	2/45=0.04	
Control	8 (c)	37 (d)	45	8/45=0.17	

## 5.5 CCU Stay

In the current study, t-tests, df, means, 95% confidence interval of the difference, std. deviation, sig. (2-tailed), std. error means were carried out to see the VAP effect on CCU-LoS (days) in both groups. (Tables: 5.5, 5.6, and 5.7).

In the current study, the total number of days spent in the CCU for the CHX group was 132 days and vacillated from 2 days to 5 days, with a mean of  $2.93 \pm 0.688$  days. However, the total number of days spent in the CCU for the control group was 154 days and ranged from 1 day to 10 days, with a mean of  $3.42 \pm 1.840$  days.

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<sup>7</sup> **Number needed to treat (NNT):** “the number of people who must be treated to result in benefit in one person. It is the inverse of absolute risk reduction” (Ranganathan et al., 2016).

**Table 5.5: Effect of VAP on CCU length of stay (days) in the CHX group.**

Experimental Group						
CCU stay	VAP		N	Mean	Std. Deviation	Std. Error Mean
	No		43	2.88	.625	.095
	Yes		2	4.00	1.414	1.000
	t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
	-2.358-	43			Lower	Upper
					-2.071-	-.162-
	-2.358-	43	.464	-1.116-	-13.352-	11.119

**Table 5.6: Effect of VAP on CCU length of stay (days) in the control group.**

Control Group						
CCU stay	VAP		N	Mean	Std. Deviation	Std. Error Mean
	No		37	3.16	1.708	.281
	Yes		8	4.63	2.066	.730
	t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
	-2.118-	43			Lower	Upper
					-2.856-	-.070-

**Table 5.7: Total effect of VAP on CCU length of stay (days) in the both groups.**

VAP	(with VAP) (mean)	(without VAP) (mean)	P-Value
Duration of CCU stay (mean days)	4.12	2.16	0.021

## 5.6 Ventilation

In our study, it was shown that MV time was declined from 66 days (mean = 1.47) to 48 days (mean = 1.07) (Table 5.1). The MV interval was significantly lengthier in the VAP (+) CHX group and control group ( $p = 0.002$  and  $p < 0.0001$ , correspondingly). However, the mean time of MV in

this study in the CHX group was  $1.07 \pm 0.330$  day with a 48 ventilation days. Nonetheless, it was  $1.47 \pm 1.245$  day for patients in the control group ranging from (1-7) with a 66 ventilation day period (Table 5.1).

## **5.7 Mortality**

In the current study, total CCU mortality was 2.2%. No significant differences were found between groups.

A 57-year-old female solitary mortality with a history of hypertension, renal failure, and myocardial infarction with an ejection fraction of 55%, which was on admission in chest pain. In the control group, the patient (2.2%) was diagnosed with IHD, MR, NSTEMI, CABG and BIVAD. She needed > 24 h of inotropic support and more than five (5) blood unit transfusion. Nevertheless, none in the chlorhexidine gluconate group was died. However, mortality rate among VAP patients was significantly higher related to non-VAP patients (12.5% vs. 0.0%,  $P < 0.001$ ).

## **5.8 Research Hypotheses**

1. There is a significant difference at a level of 0.05 related to the decontamination protocol of VAP and reducing bacterial colonization (frequency of VAP in patients undergoing elective cardiac surgery admitted to CCU).



To make sure of this hypothesis, cross tabulation, percentages and frequencies tests Sig. (2-sided) were made. Later the VAP implementation bundle, the VAP incidence had decreased from 17.8% to 4.4% (VAP rate per 1000 patients).

**Table 5.8: Incidence of VAP**

Group * Result of CPIS: Cross tabulation					
			Result of CPIS:		Total
			No	Yes	
Group	Control	Count	37	8	45
		% within Group	82.2%	17.8%	100.0%
	Experimental	Count	43	2	45
		% within Group	95.6%	4.4%	100.0%
Total		Count	80	10	90
		% within Group	88.9%	11.1%	100.0%
Pearson Chi-Square		Value	DF	Asymp. Sig. (2-sided)	
		4.050 <sup>a</sup>	1	.044	

2. There is a significant difference at a level of 0.05 related to the decontamination protocol of VAP and reducing length of stay in CCU in patients undergoing elective cardiac surgery.

In the current study, t-tests, DF, means, 95% confidence interval of the difference, std. deviation, sig. (2-tailed), and std. error means were carried out to see decontamination protocol of VAP and the reduction length of stay in CCU in patients undergoing elective cardiac surgery.

The length of CCU stay was abridged in patients without VAP in this study. This new bundle reduced the CCU stay from 154 days (mean 3.42) to 132 days (mean 2.93).

**Table 5.9: CCU stay related to VAP**

Group Statistics					
	Group	N	Mean	Std. Deviation	
Duration of CCU stay	No VAP	80	3.01	1.248	
	With VAP	10 <sup>9</sup>	4.50	1.900	
t-test for Equality of Means					
Duration of CCU stay	t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference
					Lower
	-3.336-	88	.001	-1.488	-2.34-

<sup>9</sup> Among the patients who developed VAP: CHX (n = 2), control (n = 8)

### 5.9 Results of Clinical Pulmonary Infection Score (CPIS)

In the current study, none of the patients was detected with pneumonia during the first 12 hours. Each factor studied in CPIS was distinctly examined in the experimental and control groups, and then, matched. Nevertheless, as the entire score of the variables was important to CPIS, the two (2) groups were compared with respect to both their scores and the presence or absence of infection. Patients were monitored day-to-day after institution of MV for the development of VAP using clinical, radiological and microbiological criteria. The pertinent data were chronicled from within medical records, next to radiographic reports, flow sheets and statements of microbiological studies.

Diagnostic criteria of studied cases with clinical suspicion of VAP was established using clinical pulmonary infection score (CPIS) as displayed in Table 5.10. VAP was detected when a score  $\geq 6$ , and was attained in the (CPIS) requiring 6 variables and a maximum score of 12,

and was considered positive VAP. Participants were scrutinized from the inclusion date in the study to the last result in the CCU. VAP was spotted on clinical grounds relied on the CPIS system (Table 5.10) giving 0–2 points for each parameter while these values were accepted as basal CPIS.

In this study, tracheal secretion was the most predictable parameter in the control group, which scored the highest levels (2 points) (24.4%), (Table 5.11), while in the experimental group, the most predictable one was the  $\text{PaO}_2/\text{FiO}_2$  ratio, which was analyzed and was found to be  $\leq 240$  mmHg in 22.2% (2 points). Nonetheless, the residual was 77.8% while the ratio was superior ( $>240$  mmHg) (Table 5.11). In the present study, two (2) cases had scored  $\geq 6$  scores of CPIS levels in the CHX group patients with VAP (+), they were significantly higher than the patients with VAP (–) were. Likewise, eight (8) cases had scored  $\geq 6$  scores of CPIS; nonetheless, CPIS levels in the control group were also higher in the VAP (+) patients. The parameters, which included the CPIS: body temperature, leukocyte number, tracheal secretions,  $\text{PaO}_2/\text{FiO}_2$  levels and the presence of infiltrates on the chest radiograph, were significantly higher in VAP (+) patients ( $P < 0.001$ ). The cutoff point had a sensitivity of 80% and a specificity of 53.75% for diagnosing VAP.

**Table 5.10: Clinical pulmonary infection scoring system (CPIS).**

No:	Element	Assessment	Point
<b>1</b>	<b>Temperature °C</b>		
	≥36.5 and ≤38.4		0
	≥38.5 and ≤ 38.9		1
	≥39.0 and ≤ 36.0		2
<b>2</b>	<b>Blood leukocytes (mm<sup>3</sup>), microscopy</b>		
	White blood cell count ≥ 4000 or ≤ 11.000		0
	< 4000 or > 11.000		1
	<4,000 or >11,000 + Rod (band) form ≥ 50%		2
<b>3</b>	<b>Tracheal secretions</b>		
	Few (≤ 14+) (absence)		0
	Moderate (≥ 14+) (presence and non-purulent; =color: white or light-yellow)		1
	Large (≥ 14+ plus purulent secretion) or (>25 PNL per LPF)(presence and purulent; =color: yellow, green or brown)		2
<b>4</b>	<b>Oxygenation (PaO<sub>2</sub>/FiO<sub>2</sub> ratio (mmHg))</b>		
	>240 or presence of ARDS (No need for oxygen)		0
	≤240 and absence of ARDS (Increase need for oxygen)		2
<b>5</b>	<b>Pulmonary infiltration in chest radiography</b>		
	No infiltrate		0
	Patchy or diffuse infiltrate		1
	Localized infiltrate		2
<b>6</b>	<b>Culture of tracheal aspirate specimen</b>		
	Negative		0
	Positive		2

ARDS, Acute Respiratory Distress Syndrome; BAL, Bronchoalveolar Lavage; CFU, Colony Forming Unit; CHF, Congestive Heart Failure; CPIS, Clinical Pulmonary Infection Score; FiO<sub>2</sub>, Fraction of inspired oxygen; LPF, Low Power Field; PaO<sub>2</sub>, Partial arterial oxygen; PNL, Polymorphonuclear Neutrophils.

**Table 5.11: Results of clinical pulmonary infection scoring CPIS**

CPIS parameter	Group											
	Control						Experimental					
	0		1		2		0		1		2	
	Count	Row N %	Count	Row N %	Count	Row N %	Count	Row N %	Count	Row N %	Count	Row N %
Temperature °C	33	73.3%	10	22.2%	2	4.4%	38	84.4%	5	11.1%	2	4.4%
Blood leukocytes (mm <sup>3</sup> ), microscopy	7	15.6%	29	64.4%	9	20.0%	13	28.9%	32	71.1%	0	0.0%
Tracheal secretions	8	17.8%	26	57.8%	11	24.4%	11	24.4%	26	57.8%	8	17.8%
Oxygenation	1	2.2%	36	80.0%	8	17.8%	1	2.2%	34	75.6%	10	22.2%
Pulmonary infiltration in chest radiography	14	31.1%	26	57.8%	5	11.1%	20	44.4%	25	55.6%	0	0.0%
Pulmonary bacteria in tracheal aspirate culture	43	95.6%	2	4.4%	0	0.0%	41	91.1%	4	8.9%	0	0.0%

**Table 5.12: Results of clinical pulmonary infection scoring CPIS related to VAP**

CPIS parameter	Group											
	Control						Experimental					
	0		1		2		0		1		2	
	Count	Row N %	Count	Row N %	Count	Row N %	Count	Row N %	Count	Row N %	Count	Row N %
Temperature °C	6	75.0%	2	25.0%	0	0.0%	0	0.0%	2	100.0%	0	0.0%
Blood leukocytes (mm3), microscopy	2	25.0%	0	0.0%	6	75.0%	0	0.0%	2	100.0%	0	0.0%
Tracheal secretions	0	0.0%	2	25.0%	6	75.0%	0	0.0%	0	0.0%	2	100.0%
Oxygenation	0	0.0%	6	75.0%	2	25.0%	0	0.0%	0	0.0%	2	100.0%
Pulmonary infiltration in chest radiography	0	0.0%	6	75.0%	2	25.0%	1	50.0%	1	50.0%	0	0.0%
Pulmonary bacteria in tracheal aspirate culture	8	100.0%	0	0.0%	0	0.0%	2	100.0%	0	0.0%	0	0.0%

### **5.10 Reason of Admission and Diagnosis**

It was noted that chest pain was the utmost reason of admission for patients in both groups (Table 5.13).

Fourteen potential risk factors are summarized in Table 5.13 as frequencies and percentages.

**Table 5.13: Reason of patient admission**

Reason * Group Cross tabulation					
	Reason	Count	Group		Total
			Control	Experimental	
Reason	Tightness	Count	1	0	1
		% within Group	1.3%	0.0%	0.7%
	Chest Pain	Count	32	35	67
		% within Group	40.5%	50.7%	45.3%
	Shortness of Breath	Count	26	20	46
		% within Group	32.9%	29.0%	31.1%
	Dizziness	Count	3	0	3
		% within Group	3.8%	0.0%	2.0%
	Dyspnea	Count	3	0	3
		% within Group	3.8%	0.0%	2.0%
	Retrosternal	Count	5	0	5
		% within Group	6.3%	0.0%	3.4%
	Nausea	Count	1	0	1
		% within Group	1.3%	0.0%	0.7%
	Flue like Illness	Count	2	0	2
		% within Group	2.5%	0.0%	1.4%
	General Weakness	Count	2	0	2
		% within Group	2.5%	0.0%	1.4%
	Productive Cough	Count	1	0	1
		% within Group	1.3%	0.0%	0.7%
	Palpitation	Count	2	4	6
		% within Group	2.5%	5.8%	4.1%
	IHD	Count	0	3	3
		% within Group	0.0%	4.3%	2.0%
	MVD	Count	1	3	4
		% within Group	1.3%	4.3%	2.7%
	CABG	Count	0	4	4
		% within Group	0.0%	5.8%	2.7%
Total		Count	79	69	148
		% within Reason	53.4%	46.6%	100.0%
		% within Group	100.0%	100.0%	100.0%

It was noted that coronary artery bypass grafting (CABG) was the utmost diagnosis for patients in both groups (Table 4.14).



**Table 5.14: Diagnosis of patients at admission**

<b>Main Diagnosis * Group Cross Tabulation</b>					
	<b>Main Diagnosis</b>	<b>Count</b>	<b>Group</b>		<b>Total</b>
			<b>Control</b>	<b>Experimental</b>	
<b>Main Diagnosis</b>	IHD	Count	31	36	67
		% within Group	22.5%	27.9%	25.1%
	MVD	Count	32	40	72
		% within Group	23.2%	31.0%	27.0%
	CABG	Count	33	39	72
		% within Group	23.9%	30.2%	27.0%
	TAR	Count	10	3	13
		% within Group	7.2%	2.3%	4.9%
	NSTEMI	Count	3	3	6
		% within Group	2.2%	2.3%	2.2%
	BIVAD	Count	2	0	2
		% within Group	1.4%	0.0%	0.7%
	AORTIC STENOSIS	Count	5	2	7
		% within Group	3.6%	1.6%	2.6%
	AVR	Count	6	6	12
		% within Group	4.3%	4.7%	4.5%
	AF	Count	3	0	3
		% within Group	2.2%	0.0%	1.1%
	CHF	Count	2	0	2
		% within Group	1.4%	0.0%	0.7%
	ACS	Count	1	0	1
		% within Group	0.7%	0.0%	0.4%
	AORTIC ANEURYSM	Count	2	0	2
		% within Group	1.4%	0.0%	0.7%
	UNSTABLE ANGINA	Count	2	0	2
		% within Group	1.4%	0.0%	0.7%

	MVR	Count	4	0	4
		% within Group	2.9%	0.0%	1.5%
	RESIDUAL MEMBRANE RESECTION	Count	1	0	1
		% within Group	0.7%	0.0%	0.4%
	TV REPLACEMENT	Count	1	0	1
		% within Group	0.7%	0.0%	0.4%
Total		Count	138	129	267
		% within main diagnosis	51.7%	48.3%	100.0%
		% within Group	100.0%	100.0%	100.0%

IHD: Ischemic heart disease; CABG: Coronary artery bypass grafting NSTEMI: Non ST Segment Elevation Myocardial Infarction; BIVAD: Biventricular Assist Device Implantation; AF: Atrial fibrillation; MVR: Mitral valve replacement; ACS: Acute coronary syndrome; CHF: Congestive Heart Failure; MVD: mitral valve disease; TAR: total arterial revascularization; TV Replacement: tricuspid valve replacement.

## **Chapter Six**

### **Discussion**

#### **6. Discussion**

##### **6.1 Overview**

In this chapter, patient data and outcome variables are introduced, more prominently, to put into action the recommendations that are based on the yielded findings. This, in turn, will optimistically lead the pathway for the planners and decision makers to employ the recommendations for all nurses and professionals in the West Bank, which in turn will yield better health results and be more efficient and effective to their patients and institutions.

##### **6.2 Outcome Measures**

Outcomes procedures were termed as influence of chlorhexidine mouthwash on prevalence of post-operative pneumonia and length of hospital stay (LoS) comparing (treatment CHX group) who received chlorhexidine mouthwash and (historical control group) who did not receive preoperative chlorhexidine mouthwash. However, we examined whether the decontamination protocol of VAP (bundle) reduced the bacterial colonization (frequency of VAP in patients experiencing optional cardiac surgery admitted to CCU).

### 6.3 Participant Flow and Demographic Characteristics

The study scheme and patient employment outcomes are illustrated in (Fig. 4.1). Commencement of patient employment commenced in October 2017 and ended in October 2018.

In this study, the mean age of patients identified with VAP was considerably smaller than that of the non-VAP group. However, cases ( $70 \leq age$ ) in the control group were slightly older than the patients were in the experimental one, which could similarly explicate why one individual in the control group acquired nosocomial pneumonia. Defensive measures aiming at the risk factors are significant. Our study found multiple valuable preoperative risk factors. Before surgery, we support antagonistic therapies for prevailing diseases to lessen the risks for VAP; for instance, mend cardiac and renal function, alleviate pulmonary hypertension, treat COPD or peripheral vascular diseases. Nevertheless, not all preoperative diseases can be treated effectively, and some aspects such as age or gender are undeniable. Therefore, creating a quantitative guide for patients seems a promising technique of prevention. We can categorize patients based on this confirmation and offer solutions for each feature.

Though MV is an indispensable module of contemporary CCU care, it is concomitant with a substantial risk of VAP (Arora et al., 2002). Accurate gratitude of high-risk patients and of likely adaptable risk factors may shape deterrent procedures and systematized strategies to lessen the

infection (Jaimes et al., 2007). Nonetheless, the incidence of VAP varies along with the studied population and type of ICU (Rosenthal et al., 2012).

Craven and Steger (1998) informed that host elements, such as primary diseases and progressive age, significantly raise the risk of pneumonia and colonization of the upper respiratory tract, but are often not operational goals for inhibition. However, Sartzi and colleagues (2008) argued that age does not influence the clinical response to therapy.

#### **6.4 VAP Incidence**

We introduced a new bundle for preclusion of VAP for the first time at An-Najah National University Hospital CCU department. The current study validates a diminution in the prevalence and VAP risk post the application of the new bundle. However, study groups were sub-sectioned into VAP negative [VAP (-)] and VAP positive [VAP (+)] (Table 5.2). In our study, the imperative variance between the control and CHX groups may be reported to the utilization of CHX excessive concentration, and attributed to management timetable (see new bundle); (gargle the solution for 30 seconds, given every 12 hours for 3 days prior to surgery and twice daily postoperatively until discharge).

The low incidence may be explained because of the period of innovative diagnosis and timely management of conceivable hitches. Furthermore, it can be ascribed to the fact that the study duration and the sum of cases in the study were comparatively accepted time (a year) as

matched to other studies, displaying subdued incidence. It can be concluded that one more reason for this lower incidence could be the sufficiency of reasonably abundant nursing staff (i.e. nurse to patient ratio should ideally be 1:1 as compared to 1:2 in our department) which may have auspiciously shaped positively the excellence of care offered to patients. Nonetheless, there is nowadays a rising testimony that high workload and low nursing staffing point redouble the risk for negative patients' outcomes for instance death and healthcare concomitant infections (Hugonnet et al., 2007).

In the present study, VAP was more common in women in the control group, inconsistent with the study of Elkolaly and colleagues. (2019), who pointed that VAP was more common in men (66.7%) than in women (33.3%), as well as the findings with those of Sharpe et al. (2014), who found that VAP was common in men (79%) than women (21%) among ventilated patients. Furthermore, Eom et al. (2014) argued that, in six studies counting 6319 patients, there was no relationship between age and the occurrence of VAP post cardiac surgery (random effect model;  $P = 0.57$ ; 95% confidence interval [CI]. Nonetheless, VAP was more prospective to occur in elderly patients more than 70 years of age (fixed effect model  $P < .01$ ; 95% CI, 2.17, 3.94). This could be attributed to old age, with higher VAP incidences, or may have been due to the mainstream of patients had primary comorbidities and risk factors such as COPD and cardiac deficiency. This was coinciding with Hawe et al. study (2009) who denoted VAP incidence decreased significantly from 19.2 to 7.5 per 1,000

ventilator days with a rate difference (99% CI) = 11.6 (2.3–21.0) per 1,000 ventilator days.

In the current study, the MV time was connotatively lengthier in the VAP (+) CHX and control groups ( $p = 0.002$  and  $p < 0.0001$ , respectively). Moreover, the VAP (+) control group had a significantly lengthier CCU duration than the VAP (-) rivals ( $p = 0.0001$ ) (Table 5.2).

Saliva has been displayed to preserve the antibacterial properties two (2) hours after the presentation of 0.2% CHX overwhelming the bacterial amount over twelve (12) hours, which consecutively met the aim of our study to reduce VAP, which in turn was matching with the studies of [Hope and Wilson, 2004; Abbas and Mir Ahmad, 2016]. These studies have compared the use of the postoperative chlorhexidine gel with mouthwash, and inferred that gel was more applicable in dropping the oral infections.

Our study outcomes are auspicious where the addendum of 0.2% CHX oral mopping, twice daily, to the ordinary oral-care system might be operational in dipping bacteria, consequently, tumbling the VAP growth. This is conformable to the Tantipong et al. (2008) and Pineda et al. (2006) studies who pointed that 0.2% chlorhexidine mouthwash preparation had encouraging results to prevent the post-operative pneumonia.

However, **VAP incidence** was estimated this way: (number of patients with VAP/Total number of patients who obtained MVx100) = VAP rate per 100 patients (Galal et al., 2016).

$8/45 \times 100 = 17.8\%$  (VAP rate per 100 patients). (For control cases).

$2/45 \times 100 = 4.4\%$  (VAP rate per 100 patients). (For CHX cases).

While **VAP incidence density (VAP rate)** was computed this manner: (Number of patients with VAP/Number of ventilator days) x 1000 = VAP rate per 1000 ventilator days (Khattab et al., 2014).

VAP rate per 1000 ventilator days =  $8/66 \times 1000 = 121.21$  per 1000 ventilator day (for control cases).

While VAP rate per 1000 ventilator days =  $2/48 \times 1000 = 41.7$  per 1000 ventilator day (for CHX cases).

The rate of VAP per 100 ventilator days decreased from 17.8% to 4.4% with the implementation of the new ventilator bundle. During the pre-intervention period, there were eight (8) infections (VAPs) in 154 ventilator days (mean = 3.42 infections per 1000 ventilator days). Subsequent to the implementation of the bundle, there were two (2) infections (VAPs) in 132 ventilator days, leading to lesser rate of 2.96 infections per 1000 ventilator days.

This cutback in VAP corresponds to previously reported studies, and shows that the bundle can be effective in An-Najah National University Hospital. Bundling the preventive strategies as a default practice proved to be a successful approach that warrants consideration by other CCU practices. The involvements are supported by scientific evidence; give no



additional risk to patients. We advocate consideration of a trial of the ventilator bundle in all CCUs. Our current results have revealed substantial decline in postoperative pneumonia by plain use of preoperative oral chlorhexidine. Pooled with the postoperative oral care, chlorhexidine use preoperatively can have improved advantage in plummeting the morbidity and mortality linked with postoperative pneumonia in thoracic surgery patient.

Safdar and coworkers. (2005) pointed that VAP is considered the utmost widespread nosocomial infection in the (ICUs) and (CCUs). It has an estimation rate of (1–3%) per day after introduction of mechanical ventilation (MV), and the cumulative incidence increases if MV period is increased (Ibrahim et al., 2001). Despite wide variation of VAP incidence (5 to 67%), depending on the participants selected and the diagnostic criteria used, VAP is generally associated with more antibiotic intake, lengthier MV duration and ICU stay, and, eventually, higher ICU and hospital mortality (Safdar et al., 2005; Chastre and Fagon, 2002). Likewise, the study of Ranjan et al, (2014) showed that VAP incidence is directly proportional to the mechanical ventilation period. However, intubated patients are at risk to develop VAP, moreover, the longer the duration of MV, the higher the risk. Eom et al. (2014) and Lim et al. (2015) state that VAP cases are possibly avertable and VAP bundles are effectual to lessen the VAP rates. Hence, VAP preclusion has to initiate with circumventing or rescinding mechanical ventilation time whenever conceivable (Keyt et al., 2014).

Contemporary oral application of (CHX) has been assessed for the stoppage of VAP. CHX has specific attentiveness as an oral sanitizer in MV-CCU patients due to its objectivity (its ability to unite to oral tissues with succeeding discharge, and consequently, a quite elongated period of act) (Labeau et al., 2011). However, DeRiso et al. (1996) concluded that low-priced and effortlessly functional oropharyngeal cleansing with CHX oral solution lessens the entire rate of infection and general antibiotics the usage to those who are submitting to cardiac surgery. Moreover, Genuit et al. (2001) conducted that enhanced oral hygiene using relevant CHX treatment in combination with the use of a weaning protocol (WP) is efficient in dropping the VAP incidence and MV time in surgical ICU and CCU patients. They found that sanitization of the nasopharynx and oropharynx using CHX gluconate gives the impression to be an operational technique to lessen nosocomial infection following cardiac surgery. Eom and colleagues. (2014) conducted a similar trend in a multicenter study where the VAP incidence rate declined from 4.08 to 1.16/ 1,000 ventilator days. Moreover, the Mori and his colleagues' study (2006) publicized oral care could decrease the VAP incidence in ICU patients in addition to the risk of VAP development, and impede its onset.

Nevertheless, Pineda et al. (2006) argued that not all studies using CHX have revealed a drop in the incidence of pneumonia. Besides, issued studies exercised diverse CHX treating regimens did not evidently delineate the application method of CHX all the time. Consistency of the minutest rate of recurrence for CHX use necessary to lessen the PRPs

number on the teeth may endorse the repetitive use of this involvement for MV-ICU patients. Yet, the simplest manner for usage and the triflingly operative dosing regimen of CHX that mends oral hygiene to downgrade the PRPs number in dental plaque biofilms has not been verified.

## **6.5 Risk Factors**

The group (treated) assigned to use chlorhexidine mouthwash had an incidence of 4.4%, while the control (untreated) group had an incidence of about 17.8%. The cumulative incidence (relative risk) (RR) in the experimental group was divided by the cumulative incidence in the control one, whereas (RR= 0.23). An appropriate interpretation of this would be:

Risk of the outcome in the experimental group was reduced by those who use chlorhexidine mouthwash 77% (or occurred 23% less) relative to the control group who do not use chlorhexidine mouthwash, meaning that the VAP is about a fourth less frequent in the experimental group than in the controls.

However, what we are interested in is to know how much the risk of the VAP decreases with our bundle intervention to estimate how much effort is needed to prevent each one. For this, we can compute the absolute risk reduction (ARR) and the relative risk reduction (RRR). In our case, (RRR) is 77%, (we ignore the negative sign), those who assigned in the experimental group had a 77% reduction in risk of getting VAP, compared to those who assigned in the control group and did not have chlorhexidine

mouthwash pre- and post-cardiac surgery. This means that our bundle treatment intervention tested reduces the risk by 23% compared to the usual bundle treatment used at An-Najah National Hospital CCU department. This result promotes and is consistent with and close to the results of Fourrier et al, (2000) which were in harmony with a substantial deterrent effect of the antiseptic decontamination with a 53% relative risk reduction.

Nonetheless, this entails that the absolute difference in risk of having VAP in the two groups is  $0.04 - 0.17 = -0.13$  or 13% (ignore the negative sign). This means that out of every 100 patients treated with this bundle; there will be 13 fewer VAPs than if we had used the control treatment bundle. In other words, chlorhexidine mouthwash reduces the “absolute” risk of VAP by 13% as compared to the non-chlorhexidine mouthwash group. This is also known as the “(ARR)” or else “risk difference,” and represents “the proportion of patients who are past the worst the adverse outcome because of having obtained the experimental rather than the control therapy.”

Yet, we can know how many we have to treat with the new bundle to avoid a VAP by just calculating the number needed to treat (NNT); the inverse of the ARR. Thus, the  $NNT = 1 / ARR = 7.7$ . Along with our NNT analysis, one (1) extra VAP can be prevented if eight (8) patients are decontaminated with our new bundle treatment. This current result is in accordance with the results of Segers and colleagues. (2006) who

concluded that for the prevention of one (1) nosocomial infection, sixteen (16) patients required to be cured with chlorhexidine gluconate.

The CHX oral care value has been studied extensively. A meta-analysis study conducted by Labeau and colleagues. (2011), including 12 randomized studies encompassing 2341 participants, reported a significant overall risk reduction in VAP with CHX oral care [risk ratio (RR) 0.72, 95% confidence interval (CI) 0.55–0.94]. The stoutest outcomes were perceived in cardiac surgery patients (RR 0.41, 95% CI 0.17–0.98) and with greater (2%) CHX concentrations (RR 0.53, 95% CI 0.31–0.91) (Deschepper et al., 2018). Accordingly, CHX oral care has become conventional praxis, for which the Centers of Disease Control and Prevention (CDC) and the American Thoracic Society/Infectious Diseases Society of America (ATS/IDSA) (Healthcare Infection Control Practices Advisory Committee, 2005) has indorsed its usage for cardiac surgery patients. It is suggested as one of the five constituents of a principal set of intermediations in the ventilator bundle demarcated by the Institute for Healthcare Improvement (IHI) (Institute for Healthcare Improvement, 2012). Although not constantly backed by facts, CHX mouthwash is currently commonly used in a diversity of populations, whichever critically or non-critically ill (Mohr et al., 2015; Hollaar et al., 2015; Sharif-Abdullah et al., 2016).

## 6.6 CCU Length of Stay

In our study, the VAP (+) control group has a significantly lengthier CCU period than the VAP (-) group ( $p = 0.0001$ ) (Table 5.5). Nonetheless, an independent sample T-test was carried out for the comparison of those who have total VAP and those who don't regarding CCU stay with a mean difference of 1.49 (95% confidence interval = 2.374-0.601,  $p = 0.001$ ). Similar results were obtained from the study of Özçaka et al. (2012).

It has been described that the occurrence of VAP raises the duration of hospital stay by approximately 6 days (Safdar et al., 2005), while Myny et al. (2005) argued that, the length of stay is a chief risk factor for the expansion of nosocomial infection. Eom and coworkers (2014) denoted that length of stay in the ICU was also affected by VAP according to data extracted from 5 studies involving 4475 participants (random effect model;  $P < .01$ ; 95% CI, 6.65, 39.91)

Generally, T-test analysis showed a significant difference impact (4.12 days v 2.16 days,  $p = 0.021$ ) in the CCU stay in patients developing VAP paralleled with those who haven't VAP (Table 5.7).

## 6.7 Ventilation

In our study, it was proved that MV time is an imperative VAP risk factor, which is alike to the study of Rello et al. (1999). (Table 5.1). In this current study, the interval of MV was more connotatively prolonged in the VAP (+) CHX group as well as in the control one, respectively. The mean

duration of ventilation for patients in the CHX group almost matches other studies such as the study of Özçaka and his colleagues. 2012.

Mechanical ventilation is linked with an ample risk for VAP, unfortunately (Arora et al., 2002). However, one of the most momentous VAP risk factors is prolonged MV time (Khattab et al., 2014). Yet, Houston and coworkers. (2002) concluded that even though pneumonia rate was greater in the Listerine (control) group than in the Peridex (CHX) one. Consequently, VAP hindrance has to initiate with eluding or restraining time of mechanical ventilation when conceivable (Keyt et al., 2014). Likewise, the risk of VP rises 3- to 10-fold in patients getting MV (Augustyn, 2007), while Shalini et al. (2010) reported that intubation into trachea is concomitant with a 3-21-fold risk for emerging pneumonia. Patients who experienced cardiac surgery and a stay in the (ICU) frequently require long-time MV; they epitomize a distinct subset at high risk for VAP (Rebollo et al., 1996).

DeRiso et al. (1996) and Houston et al. (2002) informed that CHX oral rinse as a deterrent measure for VAP has been gaged before in two trials among cardiac-surgical patients. DeRiso and colleagues. (1996) noticed a drop of respiratory tract infections of 69% that involved both lower and upper respiratory tract infections. In addition, Houston et al. (2002) matched CHX with a phenolic mixture in an open trial of 561 patients and conveyed a non-significant 52% fall of nosocomial pneumonia. Nevertheless, statistical significance was extended in a

subgroup of 37 patients intubated as a minimum 24 hours. Bearing in mind the particular patient population with low risks for developing VAP because of short time of intubation (in one study, 93% of the patients were extubated in 24 hrs (Houston et al., 2002)).

## **6.8 Mortality**

Our results are consistent with that of DeRiso (1996), who found that there was a decrease in mortality in the CHX-treated group (1.16% vs 5.56%), (24/180 vs 8/173;  $p < 0.01$ ). Numerous studies have publicized that instant origination of suitable antibiotics was related with decreased mortality (Iregui et al., 2002).

Nonetheless, our study results were contrariwise to the study of Kobayashi et al. (2017), who found that a ventilator-associated event (VAE) was related to hospital mortality in critically ill subjects with prolonged mechanical ventilation, and that VAP was not. VAP did not increase a hazard of hospital death (hazard ratio 1.08, 95% CI 0.44–2.66,  $P = 0.87$ ). Eom and colleagues (2014), in eight studies including 7612 participants, indicated that mortality was increased significantly in patients infected with VAP (random effect model;  $P < .01$ ; 95% CI, 5.81, 39.68).

## **6.9 Research Hypotheses**

1. There is a significant difference at a level of 0.05 related to the decontamination protocol of VAP and reducing bacterial colonization



(frequency of VAP in patients undergoing optional cardiac surgery admitted to CCU).

Instead of a complex bundle beyond our capability, we hypothesized that establishing a simplified VAP bundle based on our own CCU settings, with strict audit of bundle performance could reduce VAP incidence. We describe a quasi-experimental study that evaluates the effects of introducing a bundle of evidence-based interventions to reduce VAP.

In conclusion, our study found significant risk reductions of VAP in patients going through cardiac surgery and remedied with chlorhexidine gluconate. This secure and low-cost decontaminator is operational in disinfecting the nasopharynx and oropharynx, begetting less VAP incidence, and should be pondered in the preoperative planning of a patient undergoing cardiac surgery.

Monitoring VAP incidence and systematic implementation of VAP bundle is critical for improving quality of care; we fabricated this clinical trial and incorporated pre and post administration of chlorhexidine gluconate to appraise its value in reducing bacterial colonization.

Mogyoródi et al. (2016) introduced a bundle for stoppage and education on VAP. Their study demonstrated a lessening in the occurrence and VAP risk after the bundle application. They revealed that the phase following bundle was littler; ventilator days were lower, declined incidence rate, shorter mean ICU LoS (36 to 27 days), and lower number of ventilator

days (26 to 21 days). Furthermore, similar development was detected in a multicenter study by Eom et al. (2014), in which the VAP incidence dwindled from 4.08 to 1.16/1,000 ventilator days. Nonetheless, the study of Viana et al. (2013) in Brazil presented an educational model concerning VAP and used a bundle checklist. Before the intervention, the mean VAP rate was  $18.6 \pm 7.8/1,000$  ventilator days, declining to  $11.8 \pm 7.8/1,000$  ventilator days after the intervention. Hawe and her colleagues (2009) concluded that a functioning employment agenda improved employees' fulfillment with evidence-based interpositions and was linked with a substantial decrease in VAP possession.

2. There is a significant difference at a level of 0.05 related to the decontamination protocol of VAP and reducing length of stay in CCU in patients undergoing elective cardiac surgery.

This study advocates the application of 0.2% chlorhexidine preoperative is knowingly constructive in plummeting the CCU stay. Protracted period of action can safeguard the operation time until oral care is continued postoperatively. However, this pooled with postoperative oral care can have improved an advantage in dropping postoperative pneumonia. Mogyoródi et al. (2016) denoted that implementing a VAP bundle explored its usefulness on littler mean ICU LoS (lowered from 36 to 27 days).

### **6.10 Discussion of (CPIS)**

Through preliminary patient assessment, doctors have to make up their minds towards instantaneous treating decisions in the existence of irrefutable distrust of VAP in reference to traditional benchmarks or the clinical pulmonary infection score (CPIS) which aids in diagnosing VAP by forecasting advantage of pulmonary cultures and x-ray. Diagnosis of post-operative pneumonia necessitates all the criteria in the patients manifested.

In our study, in the interim of the primary phase of ventilation, patients were sufficiently sedated. At any rate, two of the followings evince VAP; leukocytosis, fever, or purulent tracheobronchial secretion, and a new lung infiltration on the chest radiation. Whilom VAP pathogens were recognized at the bacteriology and microbiology laboratory of the hospital, ventilator manner and settings to each patient; patients' vital signs, physical and general investigation, oxygen saturation, as well as infections befalling postoperatively were logged day-to-day and regularly. A sequence of repetitive examinations was executed, and sputum was assembled from the suction catheter and conveyed to the lab in a sterile tube as well. Bacteria matured at substantial medium ( $BAL \geq 10^4$  CFU/ml) were apportioned 1 point, while no growth or non-significant cultured applications allotted 0 points. Consequently, VAP was diagnosed in consonance with CPIS values.

In their study, Pugin et al. (1991) merged data on chest x-ray, tracheal aspiration culture, oxygenation, leukocytes, temperature, and secretion from the tracheal into (CPIS) which in turn he condenses the main structures applied to demonstrate pneumonia giving them prorated connotation. Furthermore, according to Rello et al. (2001), clinical doubt measures for VAP were demarcated as the manifestation of fever ( $\geq 38^{\circ}\text{C}$ ), white blood cells and pus-filled secretion, and newfangled or advanced spot in chest x-ray. In addition, Meduri and Chastre (1992) argued that blood cultures are attained twice after a 30 min-interval if there was a circumspection of VAP. BAL affirmative was consented as ratification of VAP.

Clinical Pulmonary Infection Score (CPIS) values were elaborated employing six (6) parameters:

1. Body temperature,
2. Leucocyte count,
3. Tracheobronchial secretion,
4. Oxygenation  $\text{PaO}_2/\text{FiO}_2$  ratio,
5. Presence of pulmonary infiltration,
6. In addition, microbiological culture.

## **6.11 Discussion of Reason of Admission and Diagnosis and Co-Morbidities**

We found that: tightness, pulmonary hypertension, chest pain, IHD: Ischemic heart disease; CABG: Coronary artery bypass grafting NSTEMI: Non ST Segment Elevation Myocardial Infarction; ACS: Acute coronary syndrome; BIVAD: Biventricular Assist Device Implantation; AF: Atrial fibrillation; CHF: Congestive Heart Failure; MVR: Mitral valve replacement; MVD: mitral valve disease; TAR: total arterial revascularization and TVR: tricuspid valve replacement were all tightly associated to VAP incidence.

In the study by Rajnan and colleagues. (2014), it was found that the relationship concerning co-morbidities and VAP incidence was more frequent in patients with co-existing COPD, diabetes, and obesity. VAP occurred in 57% of patients who were diagnosed with COPD, and in patients with trauma was 76%. In Kózka's et al. (2020) study, a connection between the cause for patient's admission to ICU and the VAP incidence was found. Patients with trauma to several organs, hemorrhage, and fractures more frequently underwent VAP.

Eom et al. (2014) indicated, in three (3) studies counting 3657 patients, that VAP was more probable to arise in patients with hypertension (fixed effect model. Moreover, in five (5) studies including 6416 patients, they designated that VAP was prospective to ensue in COPD patients.

## 6.12 Conclusions

- The findings of this study intensely corroborate the treatment of CHX in CCUs, and unquestionably the significance of passable oral cleanliness to avert hitches, and diminishes the VAP risk development in MV patients.
- VAP incidence in adult cardiac surgical patients is directly proportional to mechanical ventilation time; it rises dramatically, while it is a robust VAP risk factor development.
- A diminution in the  $\text{PaO}_2/\text{FiO}_2$  ratio is a primary prognosticator of VAP ( $\leq 240$  and no ARDS).
- Heart surgery patients usually need long CCU stay; this bundle reduces the VAP incidence resulted in prolonged length of stay in the CCU.
- Oropharyngeal decontamination with CHX seems to be an operational modus operandi to downgrade VAP before and after cardiac surgery. This simplified prevention bundle effectively reduces VAP incidence. We suggest this dual audit and consistent bundle performance that matters in quality-of-care VAP prevention.
- Preliminary findings, in our study, propose that two-circadian oral hygiene care with 0.2% CHX gluconate could lower the VAP risk about a fourth less frequent in the experimental group than in the controls.
- The foremost objectives of VAP supervision are timely, apposite antibiotics in ample doses subsequent to phasedown pertaining to

microbiological culture results and the clinical rejoinder of the patient. Unquestionably, this bundle shapes a credible fruition emanated from new policies and definitions of inspection of events associated with MV.

### **6.13 Recommendations**

- To weed out of mortality concomitant with mechanical ventilation, duration of ventilation should be abridged by managing an accurate weaning protocol and standardizing bundle, as patients need.
- Efficacious strategies to prevent VAP should be the standards of care in all CCUs. However, this study provides sound evidence that VAP is a complication we can safely preclude. Its incidence and the implementation of strategies to prevent its occurrence should be expedient measures followed by all surgeons and intensivists involved in providing care for these patients.
- Nursing compliance to VAP bundle may lead to better results.
- Additional research with a larger sample size, longer duration, and in miscellaneous institutions with larger-scale intervention studies should be conducted to authenticate the proficiency of present-day schedules and propose conceivable enhancements.
- Along with diverse deterrent measures for VAP, the impact of oral care should be considered by care providers.

- Hopefully, this bundle is to be adopted and duly incorporated by reference and enthusiastically to be considered legally binding upon all health bodies and educational organizations in Palestine.
- Moreover, nursing competent training, and stringent management of infection control practices are decisive.

#### **6.14 Limitations and Strengths of the Study**

The current study undergoes some restrictions:

- Enlistment in a solitary organization, as well as restricted data concerning the entrants could influence generalization.
- As for the rate of recurrence of repetitive oral care, treatment promulgation, and trial consequence may were not very powered.
- In the meantime, patients entered the hospital before to the presentation of oral care were used as study controls, there may a bias of the patients contributed in the study, entered selfsame hospital, selfsame CCU, whilom their features might be closely even.

Nonetheless, it has some strengths:

- This study attained that oral care comprising oral rinsing and tooth brushing lessened the incidence and VAP risk in CCU patients, and that it stopped the VAP onset.



- To the researcher's knowledge, this study may be the first to VAP preclusion by oral care in Palestine.
- Its results assure a wide-reaching multi-center trial on the capableness of oral care for VAP stoppage.

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## Annexes

### Annex (1): PERSONAL DATA SHEET

The CPIS score is based on sensible elements and the likelihood of VAP does seem to be somewhat higher when scores are  $\geq 6$ , and need for BAL or mini-BAL, or 3 days later was considered suggestive of pneumonia.

PERSONAL DATA SHEET	
HISTORICAL / EXPERIMENTAL	
<b>1. Subjective and demographic data</b>	
• Patient name:	
• File number:	
• Gender:	M / F
• Age:	
• Marital status:	
• Height:	
• Mobile:	
<b>2. Date of data collection:</b>	
<b>3. Admission:</b>	
• Date:	
• Reason:	
<b>4. Main Diagnosis:</b>	
<b>5. Medical history:</b>	
• HTN:	YES / NO
• Smoker:	YES / NO
• Renal failure (acute or chronic):	YES / NO
• Peripheral vascular disease:	YES / NO
• Myocardial infarction:	YES / NO
• Congestive heart failure:	YES / NO
• Ejection Fraction (EF):	
<b>6. Surgical history:</b>	
•	
•	
<b>7. Date of operation:</b>	
• Date of extubation:	
• Duration of intubation:	
• If need re-intubation:	YES / NO
• Intra-aortic balloon pump:	YES / NO
• Return to surgery:	YES / NO
• Tracheostomy:	YES / NO
• > 24 h of inotropic support:	YES / NO
• Transfusion > 5 units:	YES / NO
• Sputum Culture result:	
• Date of CCU discharge:	
• Result of CPIS:	
• Died:	YES / NO

## Annex (2)

### نموذج الموافقة على المشاركة في الدراسة

لقد تمت دعوتك للمشاركة في البحث الذي سيقام في وحدة العناية الفائقة كونك ستقوم بعملية جراحية في القلب المفتوح، بحيث ستكون مشاركتك طوعية ولك الحق في القبول أو الرفض، وقبل أن تقرر المشاركة في البحث يجب أن تدرك مضمون هذا البحث.

نموذج الموافقة هذا سيوضح لك أهمية إجراء البحث وما هي المنافع المنتظرة وهل سيكون هناك خطورة أو أي إزعاج يترتب على مشاركتك.

إذا أحببت المشاركة سيكون لك الخيار على ترك البحث والانسحاب في أي وقت ودون إبداء الأسباب، وفي حال انسحابك من المشاركة في البحث، لن تفقد أي رعاية طبية أو اهتمام.

رجاء اقرأ نموذج الموافقة هذا جيداً وبأريحية مطلقة، وناقش الأمر مع العائلة والأصدقاء أو الطبيب الخاص بك قبل اتخاذ القرار.

#### **المنفعة من المشاركة في البحث**

ليس هناك منفعة مرتقبة مباشرة، وأرجو أن تكون المعلومات المستفادة من البحث بعد إتمامه مفيدة لأشخاص آخرين سيخضعون لمثل هذه العملية الجراحية.

#### **المخاطر**

لا يوجد مخاطر أو مضاعفات مرتبطة بهذه الدراسة

#### **التكلفة**

لا يوجد تكلفه مترتبة على المشاركة في البحث

#### **جهة الاتصال عند الحاجة**

عند وجود أي استفسار أو توضيح بالإمكان الاتصال مباشرة بالباحث الرئيسي في البحث (غسان حسين زكارنة)

على الرقم 0568988953

#### **نموذج الموافقة**

أنا \_\_\_\_\_ قرأت وفهمت كل ما جاء من معلومات وأوافق على المشاركة في البحث، وقد فهمت أن مشاركتي في البحث بإرادتي وجميع المعلومات التي أصرح بها والتي يتم جمعها سيتم الاحتفاظ بسريتها، واستعمالها للأهداف العلمية فقط، وعليه أوقع.

التاريخ: \_\_\_\_\_

توقيع المريض: \_\_\_\_\_

## Annex (3)

## الخطوات الواجب اتباعها لتنظيف الفم والأسنان:

حضرة السيد(ة) الكريم (ة) ..

أنت مدعو(ة) للمشاركة ببحث علمي سيُجرى في مستشفى جامعة النجاح الوطنية، نرجوا من حضرتكم المشاركة في هذا البحث، عبر القيام بالخطوات التالية الواجب اتباعها لتنظيف الفم والأسنان في البيت مع الإلتزام التام بها:

1. الإلتزام الكامل باستخدام أسلوب "باس" المعدل والذي يتكون من إمالة فرشاة الأسنان بزاوية 45 درجة، باستخدام حركات اهتزازية / دائرية لطيفة لمدة 10-15 ثانية.
2. لا يتم تفريش (تنظيف الأسنان بالفرشاة) أكثر من ثلاثة (3) أسنان دفعة واحدة.
3. ضمان أن يتم تفريش كل سن على كل المسطح.
4. إستكمال النظافة بخطط تنظيف الأسنان وفرشاة بين الأسنان.
5. إستخدام 10-15 مل من غسول الفم الكلورهيكسيدين 0.2%.
6. الغرغرة بغسول الفم لمدة 30 ثانية، مرتان يومياً لمدة 3 أيام قبل الجراحة.
7. ومرتين يومياً بعد العمل الجراحي حتى الخروج من المستشفى.
8. إذا كان لديك أي تردد أو أي استفسار، يُرجى منك الإتصال على الباحث.
- 9.

الباحث: غسان حسين زكارنة

موبايل: 0568988953

بريد إلكتروني: [ghasan.zakarni@yahoo.com](mailto:ghasan.zakarni@yahoo.com) E-mail:

مع الشكر الجزيل

**Annex (4): Approval letter from IRB.**

An-Najah  
National University  
Faculty of medicine  
& Health Sciences  
Department of Graduate  
Studies



جامعة النجاح  
الوطنية  
كلية الطب وعلوم الصحة  
دائرة الدراسات العليا

REF:MAS

**Approval Letter**

**Study Title:**

"Pre- and Post-Operative Use of 0.2% Chlorhexidine Gluconate Oral Rinse for the Prevention of Ventilator -Associated Pneumonia in Patients Undergoing Cardiac Surgery"

**Submitted by:**

Ghassan Hossain Zakarni

**Supervisor:**

Dr. Aidah Abu Elsoud Alkaissi

Dr. Wael Sadaqa

**Date Reviewed:**

19<sup>th</sup> November 2018

**Date Approved:**

21<sup>st</sup> November 2018

Your Study titled "Pre- and Post-Operative Use of 0.2% Chlorhexidine Gluconate Oral Rinse for the Prevention of Ventilator -Associated Pneumonia in Patients Undergoing Cardiac Surgery" with archived number (20) November was reviewed by An-Najah National University IRB committee and was approved on 21<sup>st</sup> November 2018

Hasan Fitian, MD

IRB Committee Chairman

An-Najah National University



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**Annex (5):****Clinical pulmonary infection scoring system (CPIS)**

<b>No:</b>	<b>Element</b>	<b>Assessment</b>	<b>Point</b>
<b>1</b>	<b>Temperature °C</b>		
		≥36.5 and ≤38.4	0
		≥38.5 and ≤ 38.9	1
		≥39.0 and ≤ 36.0	2
<b>2</b>	<b>Blood leukocytes (mm3), microscopy</b>		
		White blood cell count ≥ 4000 or ≤ 11.000	0
		< 4000 or > 11.000	1
		<4,000 or >11,000 + Rod (band) form ≥ 50%	2
<b>3</b>	<b>Tracheal secretions</b>		
		Few (≤ 14+) (absence)	0
		Moderate (≥ 14+) (presence and non-purulent; =color: white or light-yellow)	1
		Large (≥ 14+ plus purulent secretion) or (>25 PNL per LPF)(presence and purulent; =color: yellow, green or brown)	2
<b>4</b>	<b>Oxygenation (PaO<sub>2</sub>/FiO<sub>2</sub>ratio (mmHg))</b>		
		>240 or presence of ARDS (No need for oxygen)	0
		≤240 and absence of ARDS (Increase need for oxygen)	2
<b>5</b>	<b>Pulmonary infiltration in chest radiography</b>		
		No infiltrate	0
		Patchy or diffuse infiltrate	1
		Localized infiltrate	2
<b>6</b>	<b>Culture of tracheal aspirate specimen</b>		
		Negative	0
		Positive	2

جامعة النجاح الوطنية

كلية الدراسات العليا

تنظيف الفم باستخدام مادة الكلوروكسيدين 0.2% قبل وبعد العملية  
للمرضى الذين يخضعون لعملية القلب المفتوح لمنع الإلتهاب الرئوي  
المصاحب لإستخدام جهاز التنفس الاصطناعي

إعداد

غسان حسين زكارنة

إشراف

د. عايدة القيسي

د. وائل صدقة

قدمت هذه الأطروحة استكمالاً لمتطلبات الحصول على درجة الماجستير في برنامج تمريض  
العناية المكثفة، بكلية الدراسات العليا، في جامعة النجاح الوطنية، نابلس-فلسطين.

2020



ب

تنظيف الفم باستخدام مادة الكلورهكسيدين 0.2% قبل وبعد العملية للمرضى الذين يخضعون لعملية القلب المفتوح لمنع الإلتهاب الرئوي المصاحب لإستخدام جهاز التنفس الإصطناعي

إعداد

غسان حسين زكارنة

إشراف

د. عايدة القيسي

د. وائل صدقة

الملخص

**الخلفية:** تعتبر عدم كفاية النظافة الفموية في وحدات العناية بالقلب (CCUs) مشكلة حرجية وشائعة لدى مرضى التهوية ميكانيكيا، حيث يعتبر عاملاً مسبباً للإلتهاب الرئوي المصاحب للتهوية (VAP). ويعرف الإلتهاب الرئوي المصاحب لأجهزة التنفس الصناعي بأنه التهاب الرئة المكتسب في المستشفى الذي يصيب المرضى الذين يخضعون للتهوية الميكانيكية (التنبيب) خلال 48 ساعة أو أكثر، والذين ليس لديهم علامات أو أعراض عدوى الجهاز التنفسي قبل التنبيب والتهوية الميكانيكية. وهي ثاني أكبر مسبب لحالات العدوى، والسبب الرئيسي للوفيات. وكعامل مساعد على العناية بالصحة الفموية لدى المرضى كإجراء تحضيرى للجراحة، فإن استخدام الكلورهيكسيدين 0.2% يؤدي إلى تقليل الإلتهاب الرئوي المصاحب للتهوية.

**الأهداف:** هدفت هذه الدراسة إلى تقييم تأثير الحزمة الوقائية الدوائية (Bundle) على انتشار الإلتهاب الرئوي المصاحب لأجهزة التنفس الصناعي وتقليله أو القضاء عليه، وعلى مدة المكوث في وحدات العناية بالقلب (CCUs) لدى المرضى الذين يخضعون للتهوية الميكانيكية.

**المنهجية والإجراءات:** تم استخدام المنهج البحثي شبه التجريبي للمرضى الذين يخضعون لعملية القلب المفتوح في وحدة العناية بالقلب في مستشفى جامعة النجاح الوطنية، في الفترة الواقعة بين تشرين أول 2018 وتشرين أول 2019. قسمت الدراسة إلى مجموعتين بما مجموعه (90 مريضاً): المجموعة التجريبية (45 مريضاً)، وهي المجموعة التي تم إعطاء المرضى فيها الحزمة الدوائية، وكذلك بإعطائهم الكلورهيكسيدين 0.2% بجرعة مضمضة تصل إلى 15 mL لمدة 30 ثانية، كل 12 ساعة، لمدة 3 أيام قبل وبعد العملية وحتى خروج المريض من المستشفى. أما المجموعة الثانية فهي المجموعة الضابطة، وذلك بمراجعة ملفات المرضى (45 مريضاً) الذين خضعوا لعمليات القلب المفتوح قبل سنة من بداية الدراسة في الفترة الواقعة بين تشرين أول 2017 وتشرين أول 2018. شملت الدراسة من كانت أعمارهم تزيد عن 18 عاماً، وكذلك من وقَّعوا على نموذج الموافقة للإشتراك في البحث.

استخدم الباحث المنهج الإسترجاعي والتجريبي، وقد تمت الموافقة عليه من قبل "لجنة أخلاقيات البحث العلمي في جامعة النجاح الوطنية" (IRB). علاوة على ذلك، وافقت لجنة الأخلاقيات في مستشفى جامعة النجاح الوطنية -مشكورة- على إجراء هذه الدراسة في المستشفى. تم استخدام أداة القياس الإكلينيكي للعدوى الرئوية (CPIS) للمساعدة في تشخيص الإلتهاب الرئوي المرتبط بالتهوية المصاحب لأجهزة التنفس الصناعي (المتنفس).

**النتائج:** أظهرت النتائج تشابه كلا المجموعتين من حيث العوامل الديموغرافية من ناحيتي العمر والجنس تقريباً؛ حيث كان متوسط العمر والانحراف المعياري والمدى للمجموعة التجريبية ((26-73)  $7.42 \pm 58.24$ )، في حين كان للمجموعة الضابطة ((27-77)  $11.18 \pm 56.8$ ) سنة، وقد كان متوسط العمر الكلي للمجموعتين (الانحراف المعياري) (9.47) 57.52 مع مدى (26-77) سنة. أشارت النتائج أيضاً إلى أن 93% من المشاركين كانوا ضمن عمر ( $20 > \text{age} \geq 70$ ) لكلا المجموعتين

تقريباً، 58.9% (n=53) كانوا في فئة الذكور. أكثر الأمراض المصاحبة كان ضغط الدم (HTN) حيث وصلت نسبته (57.8%)، غير أنه كانت هناك حالة وفاة وحيدة بنسبة (2.2%) في المجموعة الضابطة فقط. أظهرت النتائج انتشار 8 حالات مع 154 يوم تهوية في المجموعة الضابطة (متوسط=3.42) مقارنة مع 2 من الحالات مع 132 يوم تهوية (متوسط=2.96)، وقد انخفض معدل ال (VAP) من 17.8% إلى 4.4% لكل 1000 يوم تهوية ميكانيكية، وقد كان معدل أيام التهوية وأيام المكوث في العناية في المجموعتين اللتين تحتويان على ال (+VAP) أكثر منه في المجموعتين اللتين لا تحتويان على ال (-VAP). لوحظ هناك انخفاض كبير في انتشار ال (VAP) للمرضى الذين أجروا عمليات قلب مفتوح بعد تطبيق "الحزمة الدوائية"، والذين عولجوا بالكلورهيكسيدين في تطهير البلعوم، مما أدى إلى حدوث (VAP) أقل، بالإضافة إلى أن "الحزمة الدوائية" كانت فعالة ومؤثرة في تقليل أيام المكوث في وحدة العناية بالقلب.

وقد بدت مقاييس فعالية التداخلات الصحية مناسبة، حيث كانت نسبة الخطر (الإختطار) النسبي وهو نسبة حدوث المرض في المجموعة المتعالجة إلى نسبة حدوثه في المجموعة غير المعالجة (RR=32%)، والحد من المخاطر النسبية (RRR=77%)، كما أن إنقاص الخطر المطلق وهو الفرق بين احتمال حدوث ال (VAP) مع المعالجة واحتمال حدوثها بدون المعالجة (ARR=13%)، علاوة على ذلك، فإن العدد الواجب علاجه (NNT=8)؛ أي أنه لتجنب حدوث (VAP) واحدة، فإنه يجب معالجة 8 مرضى "بالحزمة الدوائية".

**الاستنتاجات:** خلصت النتائج إلى أن المعالجة الفموية بالكلورهيكسيدين "والحزمة الدوائية" الخاصة بهذه الدراسة تقلل من حدوث ال (VAP) في المرضى الذين يخضعون للتهوية الميكانيكية (التنبيب)، كما أنها تقلل من فترة المكوث في وحدة العناية بالقلب، وقد تكون مرتان يومياً كافية لتقليل الخطر بحوالي الربع تقريباً.

**التوصيات:** إلّتزام هيئة التمريض "بالحزمة الدوائية" قد يؤدي إلى نتائج جيدة، هناك حاجة إلى إجراء المزيد من الدراسات بعينة ومدة أكبر وفي أماكن متعددة للتحقق من كفاءة البروتوكول الحالي واقتراح التحسينات الممكنة، وعلاوة على ذلك، ينبغي لمقدمي الرعاية الطبية النظر في تأثير العناية بالفم إلى جانب التدابير الوقائية المتنوعة لـ (VAP).

وإنه من المأمول أن يتم دمج هذه الدراسة حسب الأصول والرجوع إليها، لتكون ملزمة قانوناً لجميع المستشفيات والمؤسسات في فلسطين.



