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Potential Change in Central Line-Associated Bloodstream Infections (CLABSIs) at UC San Diego Health Hospitals After Adoption of SecurAcath for Peripherally Inserted Central Catheters (PICCs)

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Potential Change in Central Line-Associated Bloodstream Infections (CLABSIs) at UC San Diego Health Hospitals After Adoption of SecurAcath for Peripherally Inserted Central Catheters (PICCs)

A Thesis submitted in partial satisfaction of the requirements for the degree Master

of

Public Health

by

Veen Doski

Committee in charge:

Professor Richard S. Garfein, Chair Professor Kimberly C. Brouwer Professor Francesca Torriani

The Thesis of Veen Doski is approved, and it is acceptable in quality and form for publication on microfilm and electronically.

University of California San Diego

DEDICATION

This Thesis is dedicated to,

My parents for their love, trust, and support.

My brothers, Jewar, Peshwar, Hasar, and Reyan for always being there for me.

My daughters, Anna and Luna for giving me the strength to persevere.

My relatives and friends in Duhok, Kurdistan Region for cheering me on thousands of miles

away.

I am forever grateful for them.

TABLE OF CONTENTS

THESIS APPROVAL PAGE iii
CABLE OF CONTENTS v
LIST OF TABLES vi
LIST OF ABBREVIATIONS
ACKNOWLEDGEMENTSviii
ABSTRACT OF THE THESIS ix
NTRODUCTION 1
METHODS
RESULTS
DISCUSSION
CONCLUSION
REFERENCES

LIST OF TABLES

Table 1. Demographics of Sample Population	18
Table 2. SIR for Pre-intervention and Intervention Periods with 2-months WO Exclusion and Inclusion.	20
Table 3. CLABSI Rate (per 1000 line-days)	23
Table 4. Comparison of CL Types During Pre-intervention and Intervention Periods Using 2x Contingency Tables (Chi-square Test with 1 degree of freedom and Fisher's Exact Test at least one expected value is < 5)	:2 st if 24
Table 5. Overall Single and Multiple CL Comparison Using CLABSI Rate (per 1000 line-day	/s) 24

LIST OF ABBREVIATIONS

HAIs	Healthcare-associated infections
CLABSIs	Central line-associated bloodstream infections
LCBIs	Laboratory-confirmed bloodstream infections
CLs	Central lines
CVCs	Central venous catheters
PICCs	Peripherally inserted central catheters
IJ	Internal jugular
FEM	Femoral
SUB	Subclavian
PORT	Port-a-cath device
IR	Interventional radiology
WO	Washout period
ICU	Intensive care unit
ONCU	Oncology unit
CDC	Centers for Disease Control and Prevention
NHSN	National Healthcare Safety Network
UCSDH	University of California San Diego Health

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ABSTRACT OF THE THESIS

Potential Change in Central Line-Associated Bloodstream Infections (CLABSIs) at UC San Diego Health Hospitals After Adoption of SecurAcath for Peripherally Inserted Central Catheters (PICCs)

by

Veen Doski

Master of Public Health

University of California San Diego, 2023

Professor Richard S. Garfein, Chair

Objective: Central line-associated bloodstream infections (CLABSIs) are associated with high morbidity and mortality, longer hospital stays, and increased healthcare costs. It was hypothesized that the adoption of a new anchoring device (SecurAcath) for peripherally inserted central catheters (PICCs) in May 2021 had contributed to a reduction in CLABSI incidence at University of California San Diego (UCSD) hospitals in La Jolla and Hillcrest. This study aimed to investigate if the overall decline in CLABSI incidence was associated with a decline in PICC CLABSI using SecurAcath. **Methods:** We conducted a retrospective cohort study involving 106 patients with CLABSI who had one or more central lines (CL) in place more than two calendar days before the onset of CLABSI from January 1st, 2020, to July 31st, 2022, at UCSD hospitals. Data was divided into intervention (exposed to SecurAcath) and pre-intervention (unexposed to SecurAcath) groups. The variables of interest were CLABSI event date, CL types, and CL insertion and removal dates and location. Standardized infection rate (SIR) and CLABSI incidence rate (per 1000 line-days) were calculated to compare the two groups. **Results:** The SIR was not significantly changed (Pre = 0.54 vs. Intervention = 0.46, P-value = 0.3827), and CLABSI rates (per 1000 line-days) by CL type did not find significant differences between the two groups. When all patients were examined irrespective of time, the CLABSI rate for single internal jugulars (IJs) was higher than other single CLs (1.7/1000 line-days, P-value = 0.0002). In contrast, the CLABSI rate for multiple CLs: PICC and port-a-cath (PORT) was lower than other multiple CLs (0.09/1000 line-days, P-value = 0.0264). Conclusion: This study did not find evidence of a decrease in CLABSI following the universal adoption of SecurAcath devices for PICCs at UCSD hospitals. However, we found that single high-risk CLs were associated with a higher CLABSI rate, while combined use of low-risk CLs was associated with lower CLABSI rate. Surveillance of bloodstream infections inclusive of all CL types is needed to identify impactful interventions and assess other benefits associated with SecurAcath.

INTRODUCTION

Central Lines (CLs):

Central venous catheters (CVCs) are long, soft, thin, flexible tubes that can be inserted directly into the human body through a central vein in neck (internal jugular, IJ), chest (subclavian, SUB), or groin area (femoral, FEM). ^{1,2} CVCs end in or near the superior vena cava, which is a large vein that carries blood into the heart. ¹ The purpose of these catheters is to give healthcare professionals access to large blood vessels for easily taking blood samples and providing medication such as chemotherapy, where the drug can cause damage to the blood vessel if given through small veins. ^{1–3} CVCs are primarily used for patients in critical conditions who need immediate attention. ⁴ Generally, there are two types of CVCs: tunneled and non-tunneled catheters. ¹ Tunneled CVCs are more secured because they are placed into a vein and then tunneled under the skin to anchor the catheter in place beneath the skin for long-term venous access without the fear of catheter dislodgement. ^{5,6} Whereas non-tunneled CVCs are more commonly placed for short-term venous access in acute care settings for emergency situations. ^{1,7}

Peripherally inserted central catheters (PICCs) are another type of CVCs, but instead of inserting into a vein located in the IJ, SUB, or FEM, they are inserted into a peripheral vein in the upper arm (basilic or cephalic vein). ^{1,8} The tip of PICCs is placed in the superior vena cava, the right atrium of the heart, or the inferior vena cava. ^{1,8} PICCs are typically long (50-60 cm), and can stay inserted for weeks or even months and help avoid the need for repeated needle sticks. ^{9,10} In recent years, PICCs have been an integral part of patient care and are commonly recommended for patients who need cancer treatments. ^{8,11} Another reason why PICCs have increased significantly is because nursing staff can place and remove them at the bedside.⁵

Nonetheless, PICCs have some disadvantages including the need for frequent flushing, frequent dressing changes, and increased risk of dislodgement due to lack of a cuff. ^{7,12} Risks and complications of PICCs may include–bleeding, nerve injury, irregular heartbeat, damage to veins in the arm, blood clots, blocked or broken PICC, and infection. ⁸

Port-a-cath (PORT) is an implantable device that can be placed under the skin in the upper chest but can sometimes go in the arm or abdomen. ^{3,14} PORT can be indwelled for a prolonged period (weeks, months, or even years) and is primarily used for patients who need long-term treatments such as chemotherapy. ¹⁵ When not in use, PORT appears as a small bump. ¹⁵ Unlike PICCs, PORT is placed and removed in a short surgical procedure. ¹⁵ There are early (less than 30 days after the placement) and delayed (more than 30 days after the placement) risks and complications associated with PORT. ^{14,15} Early risks and complications include catheter dislocation, arterial injury, pneumothorax, hemothorax, thoracic duct injury, and cardiac tamponade, and delayed risks and complications include infection and catheter thrombosis. ¹⁴

Central Line-Associated Bloodstream Infections (CLABSIs):

According to the Centers for Disease Control and Prevention (CDC), Central Line-Associated Bloodstream Infections (CLABSIs) are serious infections that occur when pathogens colonize the catheter at the skin entry, produce a biofilm and then enter the bloodstream. CLABSIs result in increased patient morbidity and mortality as well as increased healthcare costs. They are defined as laboratory-confirmed bloodstream infections (LCBIs) that develop within 48 hours of central line (CL) insertion. ⁵ Symptoms include fever, chills, and soreness and redness around the catheter. ¹⁷ Each year, CLABSIs are responsible for thousands of deaths and billions of dollars in healthcare costs nationwide. ¹⁸ Of all the healthcare-associated infections

(HAI), CLABSI account for approximately \$46,000 per case. ⁵ While the risk of CLABSIs varies depending on the type of CL used and the location of insertion, there are independent factors that increase the risk of CLABSI such as, chronic diseases, compromised immunity, malnutrition, total parenteral nutrition, aging, loss of skin integrity, prolonged hospitalization before CL insertion, prolonged duration of catheterization, microbial colonization at CL insertion site, microbial colonization of the CL hub, multi-lumen catheters, concurrent catheters, neutropenia, BMI of greater than 40, prematurity, catheter manipulation, and transfusion of blood products. ¹⁹

According to the CDC, pathogen pathways for CLABSI can be extraluminal or intraluminal. ¹⁸ Extraluminal happens when pathogens migrate along the external surface of the catheter (usually within 7 days of CL insertion). ¹⁸ Whereas, intraluminal refers to pathogen migration along the internal surface of the catheter (Occurs after 7 days of CL insertion). ¹⁸ The most common microorganisms associated with CLABSI are *Coagulase-negative staphylococci*, followed by *Staphylococcus aureus, Candida species, Enterococci and Gram-negative bacilli*. ²

Acute Care Setting:

Bloodstream infections are common complications for patients in the ICU and result in longer hospital stays, higher costs, and high mortality. ²⁰ The risk of CLABSI is particularly high for patients in the ICU. ⁵ The CDC reports that there was an overall drop in CLABSI in hospitals nationwide; however, from 2008-2013, an estimated 30,100 CLABSIs still occurred in ICU each year. ^{5,17} In 2020, the CLABSI rate was 0.87/1000 line-days in ICU. ²¹ Patients in the ICU have a higher risk of CLABSI for several reasons including, the insertion of multiple CLs, the specific types of CL used, and the fact that inserted CLs are often accessed repeatedly over a long period of time. ^{22–24} Although acute care settings have been the primary focus of attention over the last

20 years, CLABSIs are prevalent in oncology units as well as other hospital units outside the ICU. ^{25–29}

Impact of COVID-19 Pandemic on CLABSIs:

The CDC's National Healthcare Safety Network (NHSN) defines Standardized Infection Ratio (SIR) as, "*a summary measure used to track healthcare-associated infections (HAIs) at a national, state, or local level over time*". ³⁰ The SIR adjusts for several risk factors (such as healthcare facilities and/or patients) that have been found to be significantly associated with differences in CLABSI incidence. ³⁰ From the year 2015 to 2019, there was a 31% drop in the CLABSI SIR nationwide. ³¹ However, when an analysis of the data reported to the CDC's NHSN was conducted to assess the potential impact of the COVID-19 pandemic on CLABSIs in acute-care settings, they found that the national SIR for CLABSIs increased significantly by 28% in 2020 and CLABSIs were diagnosed more frequently in acute care settings. ³² The analysis further suggested that at that time (2020), hospitals were faced with managing the emerging COVID-19 pandemic, which may have played a significant role in CLABSI surge. ³² Another CDC analysis published in the *Infection Control and Hospital Epidemiology* in 2022, revealed a higher incidence of CLABSIs in 2021 compared to 2019, which coincided with periods of high COVID-19 hospitalizations. ³³

Insertion Site and Maintenance:

CLABSIs can be prevented through surveillance, choosing low-risk CL, using proper CL insertion techniques, and proper maintenance of the CL. ³⁴ FEM is not recommended as the first choice for non-emergent CVC insertion by national guidelines. ^{34,35} A recently published

randomized trial found that CLABSI rates were lowest for the subclavian site (SUB) and highest for the femoral site (FEM). ^{34,36} Both IJ and FEM sites are associated with greater risk for infection, but dressing disruption (soiled or undressed) is more common at the FEM. ^{34,37} Therefore, it is recommended that the FEM for CVCs insertion be avoided to minimize the risk of CLABSI. ^{34,37} On the other hand, PICCs are more commonly used in inpatient and outpatient settings because they have been reported to reduce the incidence of CLABSI compared with CVCs. ³⁸ A recent retrospective analysis found that when compared to CVCs, PICCs were associated with significantly lower CLABSI rates even though they were in place longer than CVCs. ³⁸ Whereas, PORTs have been proven to be safe and effective for long-term use if they are implanted using standardized techniques and maintained properly. ¹³

Proper insertion precautions such as—hand hygiene, aseptic technique, maximal sterile barriers (mask, cap, gown, sterile gloves, and sterile full body drape), and using chlorhexidine– alcohol are among the CDC's major strategies to prevent CLABSI. ³⁹ Furthermore, taking into account that some CLs have long dwell times, best practices for properly maintaining CLs include, using transparent and semipermeable dressings as well as using chlorhexidineimpregnated sponge dressings for short-term CLs, and minimizing dressing disruption. ³⁴ Other research suggests that covering up lumens, disinfecting access ports before and after use, and also changing dressings on a weekly basis for non-tunneled CVCs can further help prevent CLABSI. ³⁴ It has been well established that following strict precautions for CL insertion and maintenance as well adherence to the steps result in less catheter colonization, decreased CLABSI incidence and mortality, and decreased healthcare costs.³⁴

While dressing covers and protects the catheter site, dressing disruption has been shown to be an obstacle. ⁴⁰ As previously mentioned, dressing disruption is more common at the FEM

site, which is another reason why FEM is not the recommended site for CVC insertion. ^{34,37} A study found that dressing disruption was a common event for patients in the ICU. ⁴⁰ They demonstrated that dressing disruption is significantly associated with skin colonization at catheter removal, and the rate of dressing disruption was higher for the sickest patients. ⁴⁰

New Securement Device:

SecurAcath is a new catheter securement device that uses a small subcutaneous anchor to secure central venous catheters. ^{41,42} It is specifically designed for PICCs and has small, flexible securement feet that are inserted beneath the skin to stabilize the catheter right where it enters the body. ^{43,44} What is unique about SecurAcath is that when dressings are removed and discarded, SecurAcath does not need to be removed at this stage unless there is a device malfunction or infection. ⁴³ Evidence suggests that SecurAcath is effective, easy to insert and maintain, and associated with lower rate of catheter-related risks and complications. ^{43,44} Other benefits include simple dressing technique, decreased allergic reactions to dressings, less cost of weekly dressing changes, more access for in-depth cleansing purposes, and increased attachment to the skin in order to prevent catheter dislodgement and migration of the tip that can possibly lead to thrombosis. ⁴⁴

Current Clinical Evidence:

In a study published in 2020, researchers investigated the impact of securement devices on the CLABSI rate in patients who had PICCs and found a significant difference in relative risk (RR) among securement devices utilized in the study population. ¹¹ The study results suggested that the use of SecurAcath in a hospital setting is effective in reducing the risk of CLABSI. ¹¹ A

recent randomized trial reported that SecurAcath saves more time during dressing changes when compared with other securement devices such as StatLock. ⁴⁵ A European study also suggested that SecurAcath is a highly effective and cost-effective method for securing medium to longterm PICCs with expected duration longer than 30 days. ⁴⁶ The use of SecurAcath showed a positive impact on—reducing catheter-related complications and the number of PICC replacements, reducing therapy interruption, and cost savings. ⁴⁶ Another article reported the results of three prospective clinical studies conducted in a university hospital regarding the efficacy, safety and cost effectiveness of using anchoring devices such as SecurAcath. ⁴⁷ They found that the implementation of securement device is especially beneficial for vulnerable patients like neonates, children, non-compliant older patients with cognitive difficulties, patients with skin abnormalities, and other patients with high risk of catheter dislodgement. ⁴⁷

Addressing the Burden of CLABSI:

The burden of outcomes associated with hospital acquired CLABSI is high. Increased length of hospital stay, increased cost, and increased morbidity and mortality are among the reasons that make CLABSI an important area of investigation. ^{46–52} Because of the high morbidity and mortality associated with CLABSI, healthcare facilities are required to report CLABSIs to the CDC's NHSN. ⁵³ While proper CL insertion and maintenance practices have been proven to effectively reduce CLABSI incidence, CLABSIs remain a major cause of healthcare-associated morbidity and mortality in the U.S. ¹⁷ Consequently, hospitals are continuously making efforts to reduce CLABSI risks and adverse outcomes through the implementation of evidence-based practice and strategic selection of products for their patients. ^{19,54} At UCSD hospitals in La Jolla and Hillcrest, PICCs are the most frequently used CL and are

placed by the PICC team or interventional radiology (IR) when a longer dwell duration is expected. In emergency situations, the ICU teams insert CVCs primarily in the IJ and/or FEM (high-risk) sites, rarely in the SUB site.

Since May 2021, SecurAcath devices have been used for all PICCs at UCSDH hospitals in La Jolla and Hillcrest. Soon after the introduction of SecurAcath for PICCs, UCSD hospitals observed a decline in CLABSI incidence that was sustained for over 9 months. It was hypothesized that the adoption of SecurAcath had contributed to this decline. Therefore, UCSD hospitals were interested in knowing whether this hypothesis was true or not. Understanding the impact of the SecurAcath on the CLABSI rate is critical for clinicians and hospital, as well as the patients in making informed decisions about their health, raising concerns, and most importantly, to minimize the risk of CLABSI.

Purpose of Study:

The main objective of this study was to assess a temporal association between the introduction of SecurAcath and the observed reduction in CLABSI incidence. More specifically, this study aimed to investigate if the overall decline in CLABSI incidence was associated with a decline in PICC CLABSI using the SecurAcath.

METHODS

Study Design and Setting

This was a retrospective observational cohort study of hospital reported CLABSIs from January 1st, 2020, to July 31st, 2022. The study was conducted at UCSD Medical Center in Hillcrest, and UCSD Jacobs Medical Center and Sulpizio Cardiovascular Center in La Jolla. They operate under University of California San Diego Health (UCSDH) System in San Diego, California, which is a leading academic health system that includes hospitals, clinics, and research facilities. UCSD Medical Center in Hillcrest is a 381-bed facility that provides advanced medical care and surgical procedures across various specialties, with focus on burn, trauma, and HIV services, and UCSD Jacobs Medical Center and Sulpizio Cardiovascular Center in La Jolla are 418-bed facilities specialized in more complex healthcare services (medical and surgical oncology, bone marrow transplants, solid organ transplants, and complex cardiovascular surgeries) and serve more critically ill patients. ⁵⁵

Since the study's primary objective was to investigate if CLABSI incidence decreased after the introduction of SecurAcath, the null hypothesis (Ho) was that the CLABSI rate after introduction of SecurAcath did not differ from the rate prior to its introduction, and the alternative hypothesis (Ha) was that the rate of CLABSI after introduction of SecurAcath decreased compared to the rate of CLABSI prior to the introduction of SecurAcath.

Outcome Measures

To address the study's research question and test the hypotheses, the standardized infection ratio (SIR) and the CLABSI rate (per 1000 line-days) were calculated. The primary outcome measure was a change in the SIR. A decrease in the SIR, after the adoption of

SecurAcath, indicates a reduction in CLABSI incidence. If the SIR is 1, then the same number of CLABSI cases were observed as predicted, given the baseline data (with the risk adjustments); If the SIR is greater than 1, then more CLABSI cases were observed than predicted, given the baseline data (with the risk adjustments); and if the SIR is less than 1, then fewer CLABSI cases were observed than predicted, given the baseline data (with the risk adjustments); ³⁰

The secondary outcome measure was CLABSI rate (per 1000 line-days). A lower CLABSI rate, after the adoption of SecurAcath, suggests a decrease in the CLABSI events. Chisquare test of independence and Fisher's exact test would further indicate if there is a significant association between the intervention and the presence of SecurAcath.

Intervention

The primary exposure in this study was the adoption of a new anchoring device called SecurAcath, in May 2021 at UCSD hospitals in La Jolla and Hillcrest. The SecurAcath was solely used for PICC insertions after the adoption. To evaluate if the decline in CLABSI incidence was directly linked to the intervention, a comparison group (control), that was not exposed to SecurAcath, was used. Having a control group is important because it would allow us to measure and compare the outcomes of both time periods (exposed vs. unexposed to SecurAcath).

Study Sample

We obtained the list of all CLABSI cases that UCSD hospitals had reported to the CDC's NHSN from January 1st, 2020, to July 31st, 2022. The specific dates were chosen to allow for sufficient comparison of patients with CLABSI, who were exposed to SecurAcath for PICCs,

with patients who were unexposed to SecurAcath for PICCs. A total of 234 patients diagnosed with CLABSI were reported. These patients had one or more eligible central vascular catheters in place more than two calendar days before the onset of CLABSI.

Exclusion Criteria:

To allow for consistency in the reporting of CLABSIs and focusing on infections that are directly associated with the use of CLs, we excluded patients who met any of the following criteria: 1) Mucosal barrier injury laboratory-confirmed bloodstream infections (MBI-LCBIs), which are bloodstream infections that occur in patients who suffer from neutropenia (e.g. with an absolute neutrophil count below 1000 cells/mm³) with conditions like hematopoietic stem cell transplantation, organ transplantation, or certain malignancies; 2) Extracorporeal life support (ECLS or ECMO), which is a life-support technique that provides cardiac and respiratory support to patients with heart or lung failure; 3) ventricular assist device (VAD), which is a device used to support the pumping function of the heart in patients with severe heart failure; 4) Patient self-injection, which occurs when patients misuse their CL by self-injecting illegal drugs into their CLs which is considered CL manipulation and may contaminate the insertion site; 5) Epidermolysis bullosa (EB), which is a group of rare genetic disorders that cause skin to blister; 6) Munchausen syndrome by proxy (MSBP), which is a form of child abuse in which a caregiver induces illness in another person (often a child); 7) Pus at the vascular access site, which more often occurs in patients with an eligible CL and another vascular access device; 8) Infants less than 1 year of age were also excluded. These exclusion criteria were applied based on the CDC's NHSN recommendations because of their indirect association with CLs. ⁵⁶

Data Collection:

After the inclusion and the exclusion criteria, patients' data were collected from the UCSD electronic medical record system also known as EPIC. CLABSIs were defined based on the CDC's NHSN criteria. Using EPIC, manual chart review of each patient with CLABSI was performed thoroughly. The main variables of interest for this study were: CLABSI event date, CL types (PICC, IJ, FEM, SUB, and/or PORT), CL insertion date, the location during the CL insertion (if not available, CL insertion location was marked as present-on-admission (POA)), and CL removal date or hospital discharge date. Other variables were: age, gender (male or female), hospital admission date, LCBI status, hospital location (UCSD hospital in La Jolla or in Hillcrest), hospital unit during the CLABSI event (ICU, ONCU, or neither ICU nor ONCU), pathogen description., and the location during the CL insertion (if not available, CL insertion during the CL insertion (if not available, CL insertion during the CL insertion (ICU, ONCU, or neither ICU nor ONCU), pathogen description., and the location during the CL insertion (if not available, CL insertion location was marked as present-on-admission (POA)).

Comparison Group:

Based on the implementation date of SecurAcath for PICCs (May 2021) and the date patients were diagnosed with CLABSI, the study sample was divided into the pre-intervention (control) group and the intervention group. Both groups included patients with CLABSI, who had at least one eligible central vascular catheter (PICC, PORT, or CVC in IJ, FEM, and/or SUB) in place more than two calendar days before the onset of infection. The only difference between the pre-intervention group and the intervention group was the date (before and after the adoption of SecurAcath for PICCs). The pre-intervention group started from January 1st, 2020, to April 30th, 2021, and the intervention group started from May 1st, 2021, to July 31st, 2022.

Statistical Analyses

1. Standardized Infection Ratio (SIR):

To test the primary outcome measure of this study, SIR was calculated by dividing the number of observed CLABSIs by the number of predicted CLABSIs:

SIR = Number of observed infections / Number of predicted infections

The observed infections were the number of CLABSI cases during the pre-intervention or the intervention period, and the predicted infections were calculated using CDC's NHSN 2015 national HAI aggregate data (which is adjusted for each healthcare facility). ³⁰ The SIR was calculated only if the number of predicted CLABSIs were equal to or greater than one. This was taken into account to avoid calculation of statistically imprecise SIR that typically has extreme values. ³⁰ SIRs were calculated to compare the intervention group (exposed to the SecurAcath) with the pre-intervention group (unexposed to the SecurAcath).

Washout Period (WO):

A washout period (WO) was then introduced for the first two months of the intervention period (May 1st, 2021, to June 30th, 2021). This was introduced to avoid diluting the effect of the PICC securement device, minimize the confounding factors that may distort the results, establish a more robust relationship, allow for a more accurate assessment of the intervention's impact, avoid misclassification, and account for problems that might have occurred as staff became accustomed to using SecurAcath. By implementing a WO, any residual effects from prior interventions can be minimized, ensuring that the observed reduction in CLABSI is attributed to the adoption of SecurAcath device rather than the influence of previous interventions. Thus, SIRs were also calculated to compare the intervention period (July 1st, 2021, to July 31st, 2022), that excluded events occurring during the 2-months WO (May 1st, 2021, to June 30th, 2021) with the pre-intervention (January 1st, 2020, to April 30th, 2021).

By calculating SIRs to compare the intervention with the pre-intervention (including and excluding the 2-months WO), we can evaluate if the WO presents a significant impact on the intervention group. Comparing SIRs with and without the WO would allow us to determine whether it is appropriate and necessary to consider the WO when calculating CLABSI rate (per 1000 line-days), and Pearson's chi-square test of independence and Fisher's exact test. It would also help us ensure that the observed effects are attributable to the intervention being studied for final discussions and interpretations.

2. CLABSI Rate (Per 1000 Line-days):

Given that not all CL types pose the same risk of CLABSI, and that the presence of multiple lines increases this risk, we controlled for CL types (i.e., single vs multiple use) and by the dwell time for each CL type during the pre-intervention and the intervention periods. This would help us understand the risk of infection associated with single and multiple CL. We took this approach because CDC's NHSN typically does not differentiate single from multiple CL use when calculating CLABSI rates (per 1000 line-days). This means that regardless of how many CL the patients have at the time of CLABSI diagnosis, NHSN still considers that each CLABSI event is attributed to one CL.

Next, the demographics and the characteristics of the study sample were summarized using descriptive statistics. Frequencies and percentages were calculated for categorical

variables, and the median and interquartile range (IQR) were calculated for continuous variables. Then, CLABSI rate (per 1000 line-days) for the pre-intervention and the intervention groups were calculated for CLABSIs with single and multiple CLs: PICC, IJ, FEM, SUB, and PORT. The rate ratio (RR) was also calculated to indicate an increase or decrease in the rate for the intervention group. CLABSI rate (per 1000 line-days) was calculated by dividing the number of CLABSI cases by the number of line-days and multiplying the result by 1000:

CLABSI Rate = (Number of CLABSIs / Total number of central line-days) x 1000

The total number of central line-days were calculated for PICC, IJ, FEM, SUB, and PORT for each patient with CLABSI. This was done by subtracting the date of CL insertion from the date of CL removal. ⁵⁶ If a patient had been admitted to the hospital with a CL presenton-admission (POA), the day of first CL access began the line-days count; And, if a patient did not have a CL removal date, the day of hospital discharge was considered the last day of CL access for counting line-days.

Association between CL Types and Intervention:

We were also interested in comparing the distribution during the pre-intervention and the intervention periods in the presence of single and multiple CLs. In order to do that, we calculated Pearson's chi-square test of independence with 1 degree of freedom, and Fisher's exact test (if more than 20% of table cells had expected frequencies < 5). ⁵⁷ This was performed by using 2x2 contingency tables with rows representing the pre-intervention (control) group and the

intervention group, and columns representing single and multiple CLs: PICC, IJ, FEM, SUB, and PORT.

Comparison of CLABSI Rate (Per 1000 Line-days) by Type of CL:

To further examine other potential factors that could be associated with the overall drop in CLABSIs that was sustained for 9 months, both study periods were combined, and the study sample was analyzed as one group (January 1st, 2020, to July 31st, 2022). Each single CL type (PICC, IJ, FEM, SUB, and PORT) was calculated and then compared to all other single CL types during the entire study period. This was done by calculating CLABSI rate (per 1000 line-days) for each single CL type and then comparing it to CLABSI rate (per 1000 line-days) for all other single CL types combined. The rate ratio (RR) was also calculated to indicate an increase or decrease in the rate for the single CL group. The same process was performed for multiple CLs.

Hypothesis Testing:

Null hypothesis: the CLABSI rate after introduction of SecurAcath did not differ from the rate prior to its introduction. An alpha of 0.05 as level of statistical significance was used to test the hypothesis. R-programming on RStudio software was used to conduct the statistical analyses.

RESULTS

Study Sample:

A total of 106 patients with CLABSIs were included in this study. No statistically significant differences in patient characteristics were observed between the pre-intervention group and the intervention group. The pre-intervention group included 57 patients with CLABSI. Of those, 35 (61%) were males and 22 (39%) were females with the average age 58 (IQR = 47-67). The intervention group included 49 patients with CLABSI. Of those, 27 (55%) were males and 22 (45%) were females with the average age 61 (IQR = 42-66) (Table 1).

More than half of CLABSI cases in the pre-intervention group, 41 (72%), and the intervention group, 35 (71%), were diagnosed at UCSD hospital in La Jolla. Whereas, UCSD hospital in Hillcrest had 16 (28%) CLABSI cases during the pre-intervention period and 14 (29%) during the intervention period. The ICU had the highest CLABSI number of cases during the pre-intervention period compared to the oncology units (ONCU) and non-ICU/non-ONCU, 27 (47%), 16 (28%), and 14 (25%) respectively. However, non-ICU/non-ONCU had more CLABSI diagnoses during the intervention period 21 (43%), compared to ICU 15 (31%) and ONCU 13 (27%) (Table 1).

Table 1. Demographics of Sample Population

Variable		Pre-intervention (01/01/20 - 04/30/21)	Intervention (05/01/21 - 07/31/22)	P-value
Patier	nts with CLABSI—n	57	49	
Age—	-median (IQR)	58 (47-67)	61 (42-66)	0.7435
Age C	Category—n (%)			
-	19-29	4 (7)	4 (8)	0.8310
-	30-39	6 (11)	7 (14)	0.5720
-	40-49	7 (12)	5 (10)	0.7529
-	50-59	16 (28)	8 (16)	0.1590
-	60-69	12 (21)	17 (35)	0.1250
-	70-79	8 (14)	7 (14)	0.9681
-	80-89	4 (7)	1 (2)	0.2736
Gender—n (%)				
-	Male	35 (61)	27 (55)	0.5100
-	Female	22 (39)	22(45)	0.5196
Site—	-n (%)			
-	La Jolla	41 (72)	35 (71)	0.0520
-	Hillcrest	16 (28)	14 (29)	0.9538
Locat	ion—n (%)			
-	ICU	27 (47)	15 (31)	0.0837
-	ONCU	16 (28)	13 (27)	0.8646
-	Non-ICU/Non-ONCU	14 (25)	21 (43)	0.0503

*Abbreviations: IQR: interquartile range, ICU: intensive care unit, ONCU: oncology unit.

SIR for Pre-intervention Vs. Intervention Groups:

When CLABSI SIRs were calculated and compared for the pre-intervention period and the intervention period, (Pre = 0.54, Intervention = 0.46, P-value = 0.3827), no statistically significant change was observed (Table 2). The same was true for calculating and comparing SIRs of the pre-intervention and the intervention periods, excluding events during the 2-months WO, (Pre = 0.54, Intervention = 0.49, P-value = 0.6051). (Table 2).

Since the 2-months WO period did not present a significant impact on the intervention group, we did not account for it when calculating CLABSI rates (per 1000 line-days) for the preintervention group vs. the intervention group and the overall CL comparisons, as well as Pearson's chi-square test of independence and Fisher's exact test. Table 2. SIR for Pre-intervention and Intervention Periods with 2-months WO Exclusion and Inclusion

	Pre-intervention (01/01/20 - 04/30/21)	Intervention (05/01/21 - 07/31/22) Including WO	Intervention (07/01/21 - 07/31/22) Excluding WO
Observed CLABSI	57	49	46
Predicted CLABSI	104.98	107.04	93.936
SIR	0.54	0.46	0.49
RR of SIRs		0.84	0.90
P-value		0.3827	0.6051
95% CI		(0.57, 1.24)	(0.61, 1.33)

*Abbreviations: SIR: standardized infection ratio, WO: washout period, CLABSI: central lineassociated bloodstream infection, RR: relative ratio, CI: confidence interval.

CLABSI Rate (per 1000 line-days):

The majority of CLABSIs with single CLs in both intervention groups occurred in patients with PICCs, the most frequently used CL (24 CLABSIs for 41,829 PICC line-days or 0.57 events per 1,000 line-days in the pre-intervention group, compared with 26 CLABSI for 43,391 PICC line-days or 0.60 events per 1000 line-days in the intervention group). No one in the pre-intervention group had SUB, but only 1 CLABSI case in the intervention group had SUB. More patients in the pre-intervention group had IJs than the intervention group (Pre = 14; Intervention = 5). The majority of CLABSIs with multiple CLs in the pre-intervention group had multiple PICC and IJ, and multiple PICC and FEM, compared to the intervention group in which more CLABSI cases had multiple PICC and IJ. (Table 3)

No significant differences were found when CLABSI rates (per 1000 line-days) were calculated for the pre-intervention group and the intervention group single and multiple CLs, including for PICCs. While single IJ (RR = 0.44, P-value = 0.1076) and single FEM (RR = 0.68, P-value = 0.6417) showed rate ratio <1, the decreased risk for the intervention group was not statistically significant. The same was true for multiple CLs: PICC and IJ (RR = 0.79, P-value = 0.7670), and IJ and FEM (RR = 0.36, P-value = 0.3830) (Table 3).

When comparing single CLs CLABSIs over time, a chi-square test revealed that PICCs were not significantly lower after the intervention. In contrast, single IJ CLABSIs were significantly higher before the SecurAcath intervention compared to after the intervention ($X^2 = 4.22$, P-value = 0.0398) (Table 4).

When the pre-intervention group and the intervention group were combined, the CLABSI rate of single IJ (1.7/1000 line-days) was significantly higher than all other single CLs during the entire study period with the rate ratio >1 which indicates an increased risk for single IJs (RR =

2.98, P-value = 0.0002). The CLABSI rate for multiple CLs PICC and PORT (0.09/1000 linedays) was significantly lower than all other multiple CLs during the entire study period with the rate ratio <1.00, which indicates a decreased risk (RR = 0.16, P-value = 0.0264). (Table 5).

	Pre-intervention (01/01/20 - 04/30/21)			Intervention (05/01/21 - 07/31/22)			RR	P- value
		n = 57			n = 49			
	CLABSI No.	Line- Days	CLABSI Rate	CLABSI No.	Line- Days	CLABSI Rate		
Single CL								
PICC	24	41829	0.57	26	43391	0.60	1.05	0.8802
IJ	14	6162	2.27	5	5017	1.00	0.44	0.1076
FEM	4	2378	1.68	3	2603	1.15	0.68	0.6417
SUB	0	1254	0	1	1537	0.65	-	-
PORT	5	14147	0.35	7	14778	0.47	1.34	0.6326
Total	47	65770	0.71	42	67326	0.62	0.87	0.5245
Multiple CL								
PICC + IJ	4	9510	0.42	3	9119	0.33	0.79	0.7670
PICC + SUB	1	1013	0.99	0	788	0	-	-
PICC + PORT	0	5530	0	1	5718	0.18	-	-
IJ + FEM	4	2694	1.48	1	1900	0.53	0.36	0.3830
IJ + SUB	0	413	0.00	1	302	3.31	-	-
IJ + PORT	1	979	1.02	1	815	1.23	1.21	0.9086
Total	10	20139	0.50	7	18642	0.38	0.76	0.5833

Table 3. CLABSI Rate (per 1000 line-days)

*Abbreviations: RR: rate ratio; CL: central line; PICC: peripherally inserted central catheters; IJ: internal jugular; FEM: femoral; SUB: subclavian; PORT: port-a-cath.

	Pre-intervention (01/01/20 - 04/30/21) n = 57	Intervention (05/01/21 - 07/31/22) n = 49	X ²	P-value
Single CL	n = 47	n = 42		
PICC	24	26	1.06	0.3035
No PICC	23	16		
IJ	14	5	4.22	0.0398
No IJ	33	37		
FEM	4	3	-	1
No FEM	43	39		
SUB	0	1	-	0.4719
No SUB	47	41		
PORT	5	7	0.69	0.4058
No PORT	42	35		
Multiple CL	n = 10	n = 7		
PICC + IJ	4	3	-	1
No PICC + IJ	6	4		

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Table 4. Comparison of CL Types During Pre-intervention and Intervention Periods Using $2x^2$ Contingency Tables (Chi-square Test with 1 degree of freedom and Fisher's Exact Test if at least one expected value is < 5)

*Abbreviations: X²: chi-square test; CL: central line; PICC: peripherally inserted central catheters; IJ: internal jugular; FEM: femoral; SUB: subclavian; PORT: port-a-cath.

PICC + SUB

IJ + FEM

IJ + SUB

No IJ + FEM

No IJ + SUB

No IJ + PORT

IJ + PORT

No PICC + SUB PICC + PORT

No PICC + PORT

1

9

0

10

4

6

0

10

1

Overall (01/01/20 - 07/31/22) n = 106						RR	P- value	
Single CL	Overall CLABSI No.	Overall CL Days	CLABSI Rate	Single Line Compari- son CLABSI No.	Single Line Compari- son CL Days	Single Line CLABS Rate	I	
PICC	50	85220	0.59	39	47876	0.81	0.73	0.1278
IJ	19	11179	1.70	70	121917	0.57	2.98	0.0002
FEM	7	4981	1.41	82	128115	0.64	2.20	0.0680
SUB	1	2791	0.36	88	130305	0.68	0.53	0.5922
PORT	12	28925	0.41	77	104171	0.74	0.55	0.0515
Total	89	133096	0.67	356	532384	0.67	1.00	0.9906
Multiple CL	Overall CLABSI No	Overall CL Days	CLABSI Rate	Multiple Lines Compari- son CLABSI No.	Multiple Lines Compari- son CL Days	Multiple Lines CLABSI Rate		
PICC + IJ	7	18629	0.38	10	20152	0.50	0.76	0.5849
PICC + SUB	1	1801	0.56	16	36980	0.43	1.30	0.7400
PICC + PORT	1	11248	0.09	16	27533	0.58	0.16	0.0264
IJ + FEM	5	4594	1.09	12	34187	0.35	3.11	0.0531
IJ + SUB	1	715	1.40	16	38066	0.42	3.33	0.3097
IJ + PORT	2	1794	1.11	15	36987	0.41	2.71	0.2257
Total	17	38781	0.44	85	193905	0.44	1.00	0.9769

Table 5. Overall Single and Multiple CL Comparison Using CLABSI Rate (per 1000 line-days)

*Abbreviations: RR: rate ratio, CL: central line, PICC: peripherally inserted central catheters, IJ: internal jugular, FEM: femoral, SUB: subclavian, PORT: port-a-cath.

DISCUSSION

Our study showed a decrease in CLABSI SIR from the pre-intervention period to the intervention period (Pre = 0.54, Intervention = 0.46); however, this difference was not statistically significant. Analysis of CLABSI events by anatomical site revealed that the CLABSI rates (per 1000 line-days) for PICC, IJ, FEM, SUB, and PORT lines did not change after introducing SecurAcath. Interestingly, CLABSI events associated with single IJ were significantly higher compared to all single CLs. When comparing all combined multiple CLs, the CLABSI rate was lowest among patients who had a PICC and a PORT CL.

The findings suggest that the introduction of SecurAcath was not associated with an overall decline in CLABSI incidence in UCSD hospitals La Jolla and Hillcrest. When comparing CLABSI rates (per 1000 line-days) over time by CL type, single vs multiple line use, single IJs (high-risk lines) were significantly associated with a higher CLABSI rate. Whereas, combined use of PICC and PORT (low-risk lines) was associated with lower CLABSI rates (per 1000 linedays). This suggests that accessing a single high-risk CL increases the opportunity for skin bacteria to enter the bloodstream either due to improper aseptic technique or because of a nonintact dressing and then to cause a CLABSI. In contrast to the NHSN methodology, we accounted for the dwell time of each CL which resulted in nearly doubled line-days when multiple CLs were used. This led to lower CLABSI rates in patients with multiple CL, which seemed to contrast with the common concept that multiple lines increase the risk of infection. Therefore, we could not compare CLABSIs rates in patients with single versus multiple lines. The study also found that the pre-intervention group had a high number of CLABSIs in the ICU, which coincided with the initial phase of the COVID-19 pandemic: e.g., patients admitted to the ICUs for respiratory failure due to acute COVID-19 pneumonia or patients with acute severe

diseases that needed urgent attention (cancer, organ failure, solid organ transplant) and did not have an indwelling central line present upon admission.

Strengths and Limitations:

This study addresses an important and relevant topic since CLABSIs are associated with significant morbidity and mortality, making this an important area of investigation. One major strength of this study is the assessment of CL types, single vs multiple use, and the dwell time for each CL type during the pre-intervention period and the intervention period. This comprehensive and thorough approach led to a rigorous assessment of CLABSI rate by CL type and the level of risk each CL poses when single or multiple. The study also utilized a retrospective cohort design which is faster and less costly compared to prospective cohort studies.

While this study has several strengths, it also has some limitations. The sample size was rather small which limits the statistical power and the generalizability of the findings. The study also counted two same site CLs with no other lines as a single CL. For example, if a patient with CLABSI had two PICCs, the patient was counted as having one PICC. For multiple lines, CL days were counted as a combination of those days. In other words, if a patient had a PICC from June 1st to 10th) and an IJ from June 1st to 5th, line-days were counted as 15. This overcounting of line-days underestimates the risk of multiple CLs and does not allow the comparison between the single and multiple CL rates. Another limitation is that the study relied on the data entered by healthcare workers in the electronic medical record, which may be subject to incomplete or missing information, potential biases, and a reliance on previously-collected data. The timing of the study was during the COVID-19 pandemic, and therefore we could not control for the potential effects that the pandemic had on the selection of patients; however, patient

characteristics did not differ between the two study periods suggesting that this did not impact our findings. The study was conducted at UCSD hospitals in La Jolla and Hillcrest only, which may also limit the generalizability of the findings because CLABSI rates and the impact of SecurAcath device may vary across different hospitals, patient populations, and geographical locations. Therefore, the results may not be representative of other healthcare facilities. The study also relies on CLABSIs reported to the CDC's NHSN by the hospitals staff which may be subject to underreporting or misclassification biases, potentially affecting the accuracy and reliability of the results. In terms of the time, the study's timeframe spans only two and a half years, which may not capture the long-term impact of SecurAcath device on CLABSI rates. Lastly, the study did not control for potential confounding variables that could influence the results such as changes in infection control practices, staff education, or other interventions during the study period.

CONCLUSION

This study contributes to the understanding of CLABSI rates and potential impact of a new securement device for PICCs. The study provides healthcare workers at UCSD Health with additional information on the risks associated with different CL types. This information may help medical providers to make informed decisions when selecting the type of venous access based on the potential risk and benefits associated with each option. Although in the ICU setting, staff insert CVCs in high-risk sites such as FEM and IJ for emergent access, acute dialysis, or heart failure support, however, the longer these lines stay in, the higher the risk of CLABSI for the patients. Alternatively, once the patient is stable but in need of CL for a longer period, the healthcare provider can remove high-risk lines and insert low risk CLs (PICC and Port) to mitigate the patient's risk of CLABSI. This will potentially minimize the risk of dressing disruption which will inevitably lead to bacterial or fungal migration from the skin into the catheter and may cause a bloodstream infection.

This study also concludes that it is necessary for UCSD clinical staff to collaborate with their infection prevention and control department to further implement new strategies aimed at reducing CLABSI. This may include adopting new practices for single high-risk lines, implementing training programs, and establishing new protocols for monitoring and surveillance. Such practices may enhance patient safety and reduce morbidity and mortality, length of stay, and ultimately healthcare costs associated with CLABSIs in the long-term.

Recommendations for next steps include incorporating peripheral intravenous (IV) catheter associated bloodstream infection surveillance, and a better methodology to account for the utilization of multiple versus single central lines. We think that more detailed standardized and risk-adjusted surveillance of bloodstream infections inclusive of all CL types may be helpful

to target more impactful interventions. It will strengthen the evidence found in this study to further identify best practices to prevent CLABSI and improve patient outcomes. Future research could also repeat this study by expanding it to other healthcare facilities to assess other benefits associated with SecurAcath such as: easy dressing technique, less allergic reactions to dressings, less cost of weekly dressing changes, and better attachment to the skin.

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