

**ESTIMATING STANDARDIZED INFECTION RATIO FOR
SURVEILLANCE OF SURGICAL SITE INFECTION IN PATIENTS
UNDERGOING CRANIOTOMY**

By

Dr. Lakshmi Natarajan

PDCC Thesis

2025



**SREE CHITRA TIRUNAL INSTITUTE FOR
MEDICAL SCIENCES AND TECHNOLOGY
TRIVANDRUM, KERALA**

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SURVEILLANCE OF SURGICAL SITE INFECTION IN PATIENTS
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THESIS SUBMITTED

By

Dr. Lakshmi Natarajan

To

**SREE CHITRA TIRUNAL INSTITUTE FOR
MEDICAL SCIENCES AND TECHNOLOGY
TRIVANDRUM, KERALA**

in partial fulfilment of the requirements for the award of
Post-Doctoral Certificate Course in Hospital Infection Control

Month and Year of Submission: July 2025

Department of Microbiology

Sree Chitra Tirunal Institute for Medical Sciences and Technology

Thiruvananthapuram

2025

DECLARATION BY STUDENT

I, Dr.Lakshmi Natarajan, hereby declare that this project was undertaken by me under the supervision of the faculty, Department of Microbiology, Sree Chitra Tirunal Institute for Medical Sciences and Technology.

Thiruvananthapuram

Dr. Lakshmi Natarajan

Date:

Forwarded :

The candidate, Dr. Lakshmi Natarajan, has completed the project under my guidance.

Thiruvananthapuram

Date:

Dr.Kavita Raja,

Professor – Senior Grade & Head,
Department of Microbiology,
SCTIMST.



श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
Thiruvananthapuram - 695 011, Kerala, India
(An Institute of National Importance under Govt. of India)

Grams : Chitramet, Phone : +91-471-2443152, Fax : +91-471-2550728 / 2446433, E-mail : sct@sctimst.ac.in, Website : www.sctimst.ac.in

CERIFICATE BY THE RESEARCH GUIDE

Name of the Guide : **Prof. Dr. Kavita Raja**

Department : Department of Microbiology

This is to certify that Dr Lakshmi Natarajan ,department of Microbiology of this institute has fulfilled the requirements prescribed for the PDCC-Hospital Infection Control degree of Sree Chitra Tirunal Institute for Medical Sciences and Technology ,Trivandrum. The thesis entitled,

“ESTIMATING STANDARDIZED INFECTION RATIO FOR SURVEILLANCE OF SURGICAL SITE INFECTION IN PATIENTS UNDERGOING CRANIOTOMY” was carried out under my direct supervision .No part of the thesis was submitted to the award of any degree or diploma prior to this date.

Clearance was obtained from the Institutional Ethics Committee for carrying out the study.

Date: 21/7/25

Signature


Prof. Dr. Kavita Raja



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CERIFICATE BY THE RESEARCH CO-GUIDE

Name of the Co-Guide : **Prof. Dr. Krishnakumar .K**

Department : Department of Neurosurgery

This is to certify that Dr Lakshmi Natarajan ,department of Microbiology of this institute has fulfilled the requirements prescribed for the PDCC-Hospital Infection Control degree of Sree Chitra Tirunal Institute for Medical Sciences and Technology ,Trivandrum. The thesis entitled,

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Clearance was obtained from the Institutional Ethics Committee for carrying out the study.

Date: 02/07/2025

Signature

Prof. Dr. Krishnakumar. K



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CERIFICATE BY THE RESEARCH CO-GUIDE

Name of the Co-Guide : **Dr. Dinoop . K. P**

Department : Department of Microbiology

This is to certify that Dr Lakshmi Natarajan ,department of Microbiology of this institute has fulfilled the requirements prescribed for the PDCC-Hospital Infection Control degree of Sree Chitra Tirunal Institute for Medical Sciences and Technology ,Trivandrum.The thesis entitled,

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Date: 02 . 07 . 2 025

Signature

. Dr .Dinoop . K. P



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CERIFICATE BY THE RESEARCH CO-GUIDE

Name of the Co-Guide : **Ms Preena .V**

Department : Department of Nursing division

This is to certify that Dr Lakshmi Natarajan ,department of Microbiology of this institute has fulfilled the requirements prescribed for the PDCC-Hospital Infection Control degree of Sree Chitra Tirunal Institute for Medical Sciences and Technology ,Trivandrum. The thesis entitled,

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Clearance was obtained from the Institutional Ethics Committee for carrying out the study.

Date: 2.7.25

Signature

Ms. Preena .V



श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
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APPROVAL OF THE THESIS

The thesis entitled

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Submitted by

Dr. Lakshmi Natarajan

for the degree of

Post-Doctoral Certificate course in Hospital Infection Control

of

**SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND
TECHNOLOGY, THIRUVANANTHAPURAM**

is evaluated and approved by

(Name and Signature of the Guide)

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Dr. Lakshmi Natarajan

Post-Doctoral Certificate Course Resident,

Department of Microbiology

SCTIMST, Trivandrum, Kerala

CONTENTS

No	LIST OF CONTENTS	PAGE NO
i.	Introduction	1
ii.	Review of Literature	3
iii.	Aims and Objectives of the study	10
iv.	Materials and Methods	11
v.	Results	16
vi.	Discussion	28
vii.	Summary and Conclusions	32
viii.	References	34
ix.	Appendix	
	Abbreviations Proforma Plagiarism check report Ethics committee letter	

LIST OF TABLES

No	LIST OF TABLES	PAGE NO
TABLE 1	RISK ADJUSTMENT FACTORS INCLUDED IN SIR CALCULATION	14
TABLE 2	ASSOCIATION OF SSI WITH RISK FACTORS	23
TABLE 3	TYPE OF SSI AND MICROBIOLOGICAL PROFILE	26

LIST OF FIGURES

No:	LIST OF FIGURES	PAGE NO:
FIGURE 1	GENDERWISE DISTRIBUTION OF SSI CASES	18
FIGURE 2	DISTRIBUTION OF SSI BASED ON DEPTH OF WOUND	19
FIGURE 3	COMPARISON OF SSI AND TYPES OF LESION OPERATED	20
FIGURE 4	COMPARISON OF SSI AND PROCEDURE DURATION	21
FIGURE 5	COMPARISON OF SSI AND ASA SCORE	22
FIGURE 6	MICROBIOLOGICAL PROFILE OF SSI CASES	25
FIGURE 7	MICROBIOLOGICAL PROFILE OF TYPES OF SSI	27

ESTIMATING STANDARDIZED INFECTION RATIO FOR SURVEILLANCE OF SURGICAL SITE INFECTION IN PATIENTS UNDERGOING CRANIOTOMY

INTRODUCTION

Surveillance as defined from a public health perspective is the ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event. It helps in taking initiatives to reduce morbidity and mortality and to improve health. It helps to measure the burden of disease and to determine the risk factors contributing to the condition by analysing the trend of disease and helps in identifying outbreaks. Monitoring helps in early identification of such occurrences and maintain quality control activities(Tanamas et al., 2023). Surgical site infections (SSI) are usually expressed in terms of rate in hospital settings. The risk of developing infections in different patient populations varies, and SSI rates do not reflect this. Standardized infection ratio (SIR) is a method of risk adjustment. Standardization controls the differences between populations. SIR gives the summary measure of a hospital's performance per procedure. In this study, SSI following craniotomy, as per surveillance definition, is estimated using Standardized Infection Ratio (SIR).

In terms of patient outcomes and healthcare costs, the importance of Surgical site infections (SSIs) is significant. The need for further surgical intervention to treat SSIs increases this cost owing to extended postoperative hospital stay, prolonged intravenous antibiotic treatment, delayed wound healing and extended inpatient rehabilitation.(Patel et al., 2019) Risk factors analysed for estimating standardized infection ratio are those recommended by Centers for Disease Control and Prevention(CDC) , National Healthcare Safety Network(NHSN). Other common risk

factors for development of infection like length of preoperative hospital stay, type of lesion and location of lesion are also analysed and compared with those without SSI in the present study.

Microbiological profile of SSI in neurosurgery is analysed as it helps in knowing the common microbial profile and antibiogram in the unit. The feasibility and advantages of incorporating a new surveillance method in monitoring hospital acquired infections, which can be compared with other centers across the globe, is also assessed here.

REVIEW OF LITERATURE AND BACKGROUND

Hospital acquired infections (HAI) also referred to as nosocomial infections are infections that are acquired while receiving treatment at a healthcare facility and were not present at the time of admission to the healthcare facility. They contribute to significant morbidity, mortality and financial burden on the patient and the healthcare system. Emergence of antimicrobial resistance is another complication associated with HAIs. CDC broadly categorizes the types of HAI as follows:

1. Central line-associated bloodstream infections (CLABSI)
2. Catheter-associated urinary tract infections (CAUTI)
3. Surgical site infections (SSI)
4. Ventilator-associated pneumonia (VAP)

The third commonly reported nosocomial infection among HAIs is surgical site infection which accounts for 14-16% of all nosocomial infections. Success of SSI surveillance programme includes standardized definition of infection, effective surveillance methods and stratification of SSIs according to risk factors(Smyth and Emmerson, 2000).

Definitions:

Craniotomy is a procedure where a bone flap is removed temporarily to expose the brain and placed back in the original position after the corrective surgical procedure .(Fang et al., 2017)Various indications for craniotomy include intrinsic tumors of brain parenchyma, extrinsic tumors in the structures of the central nervous system in the

skull and meninges, epilepsy, vascular diseases and traumatic injuries.(Jiménez-Martínez et al., 2021a)

SSI-CRAN(craniotomy) was defined according to Centers for Disease Control and Prevention (CDC) criteria, as follows: a) purulent drainage from a surgical incision; b) organism identification by culture from fluid or tissue obtained aseptically; c) incision that dehisces spontaneously or is deliberately opened by a surgeon or physician, localized pain or tenderness, localized inflammation (heat, erythema and swelling), and/or fever ($> 38^{\circ}\text{C}$); and evidence of abscess on images or surgical revision. SSI-CRAN was also classified according to CDC criteria as superficial incisional, deep incisional or organ-space infection.(<https://www.cdc.gov/nhsn/pdfs/pscmanual/9pscscscurrent.pdf>, n.d.)

Surgical site infections are classified based on depth of infection as superficial incisional involving skin and subcutaneous tissue, deep incisional involving fascia and muscle layers and organ space surgical site infections. Manifestations of SSI following craniotomy are superficial incisional scalp infections, deep incisional infections like subgaleal abscess, calvarial osteomyelitis, cranial epidural abscess and organ space infections such as meningitis, cerebral abscess, subdural empyema and ventriculitis. Most of the manifestations of SSI following craniotomy occur within 30 days of surgery. As per Centers for Disease Control, National Health Safety Network (CDC NHSN) recommendations for surveillance of craniotomy, cases are followed up for a duration of 90 days following surgery for the development of surgical site infections.

Epidemiology and risk factors:

In a multicentric study carried out across 10 hospitals in different parts of India by the International Nosocomial Infection Control Consortium(INICC), SSI rates following

different types of surgeries were analysed and it was found that SSI rate following craniotomy was 3.3%(Singh et al., 2015). Incidence of surgical site infections following craniotomy(SSI-CRAN) is between 2.2-19.8% according to various studies across the globe (Jiménez-Martínez et al., 2019). Estimating the burden of SSIs and understanding the risk factors contributing to it can help improve our practices to prevent them .(Patel et al., 2019) Risk of developing SSI following craniotomy may be due to patient factors like, advanced age, diabetes mellitus, malnutrition, preoperative steroid use, preoperative radiation, obesity, a history of recent neurosurgical intervention, intra-operative factors, like the length of surgery(duration more than four hours),emergency surgeries, clean-contaminated and contaminated surgery, location of the brain tumor with infratentorial and intraventricular tumor excision having a higher risk of surgical site infections, post-operative factors like cerebrospinal fluid(CSF) leak , presence of devices in situ and presence of metal plates,.(Kivunja, 2023)It was noted that use of staples for wound closure following craniotomy pose more risk of development of SSI than the use of sutures.(Lee et al., 2025).

Among brain tumours that required craniotomy for resection, more cases of SSI were reported following glioma excision. Posterior cranial fossa tumours requiring excision have more predilection for developing SSI than others. According to Uzuoka et al, the average period before onset of SSI after surgery ranged from 14 to 78 days (median, 49 days). Among the cases undergoing craniotomy for brain tumors those at increased risk for developing SSI are those with history of previous radiotherapy, those who undergo re-explorations , a longer duration of surgery and CSF leaks.(Uzuoka et al., 2017)In a study by Cassir et al risk factors associated with SSI in craniotomy wounds in the post operative period were found to be post operative ICU stay length >7 days,duration of drainage >3 days and cerebrospinal fluid leakage. Another factor that contributed to the

development of SSI was the presence of co-infection in the form of other nosocomial infections like hospital acquired blood stream infection, urinary tract infection and pneumonia where the same organism is isolated from the SSI site and the co-infection site.(Cassir et al., 2015)

External factors that contribute to SSI include operation theatre conditions like high temperature, high humidity, absence of laminar airflow, provided with high efficacy particulate air (HEPA) filters, absence of air handling unit providing a minimum of 15 filtered air changes per hour among which three (20%) must be fresh air, as recommended by CDC NHSN.(Spagnolo et al., 2013)

Causative organisms:

In a study by Jimenez et al the common organisms causing SSIs following craniotomy were *Cutibacterium acnes*, *Staphylococcus epidermidis*, among Gram positive organisms and *Enterobacter cloacae* among Gram negative organisms.(Jiménez-Martínez et al., 2019), whereas in another study by Dashti et al the common organisms isolated were *Staphylococcus aureus* followed by Coagulase negative *Staphylococcus* and Gram negative organisms like *Enterobacter cloacae* and *Pseudomonas* .(Dashti et al., 2008)

Prevention:

Preoperative preparations that prevent the development of SSI are administration of surgical antimicrobial prophylaxis, hair clipping instead of shaving and head shower with 4% chlorhexidine. Intra-operatively, limiting the number of persons in the theatre, reducing the duration of surgery and maintenance of blood glucose level help prevent SSI.(Jiménez-Martínez et al., 2021a)

Reynolds et al studied 406 patients on the infection risk for hair removal by shaving versus depilatory measures. They identified that wound infection rate was ten times more among people where shaving was used as the method of removal, a rate of 5.6 vs 0.6 for depilatory measures. The razor method posed difficulty on approaching difficult to reach, as well as bony areas of the body where depilatory creams can be used. (Seropian and Reynolds, 1971).

The effect of care bundle implementation on SSI rate was studied by Jimenez et al and was found that SSI CRAN during intervention period was lower than the pre-intervention period (15.3% vs. 3.5%; $p < 0.001$). The steps of care bundle in this study included preoperative shower with 4% chlorhexidine soap, appropriate hair removal, adequate preoperative systemic antibiotic prophylaxis, the administration of 1 g of vancomycin powder into the sub-galeal space before closing, a post-operative dressing of the incision wound using sterile absorbent dressing for 48 hours after the surgery and head-wash with sterile saline. (Jiménez-Martínez et al., 2021b) In a study by Huber et al there was significant reduction in the number of SSIs following identification and correction of certain practices in the pre and post operative period of patients who developed SSI. The interventions which resulted in decrease in SSI are pre operative use of chlorhexidine gluconate shampoo, increased area of pre operative hair removal, coverage of incision with post operative dressing beyond 24 hours and patient education on hand hygiene prior to dressing removal and improved wound hygiene post operatively. (Huber et al., 2016)

Management:

Potentially devastating consequences of SSI –CRAN are the prolonged hospital stay, complex interventions like bone flap removal, long term antibiotic therapy,

development of antibiotic resistance, increased cost of treatment, need for re-surgeries.(Singh et al., 2015)

Management of surgical site infection following craniotomy varies depending on the depth of involvement. Superficial incisional SSIs are treated with specific wound care using silver containing hydro-fiber dressings and antibiotics. In deep incisional and organ space SSIs, surgical re-interventions involving bone flap removal and systemic antibiotics are required.(Jiménez-Martínez et al., 2019) Treatment with parenteral antibiotic is required for a duration of about six weeks, which increases the length of hospital stay and cost of treatment following the procedure. The above mentioned interventions reduce the rate of relapse of infection.(Berghmans et al., 2022)

Surveillance:

Importance of an effective surveillance system for nosocomial infections has been proven by studies from the United States that have shown a reduction in incidence of hospital acquired infections by as much as 30% and surgical site infections by 55%.(Umscheid et al., 2011)

Surgical site infections were identified and presented as SSI rates in most of the healthcare facilities. The National Healthcare Safety Network (NHSN) initiated the transition from surgical site infection (SSI) rates to the Standardized Infection Ratio (SIR) calculated by statistical models that included perioperative factors. Logistic regression is performed to predict expected SSI based on perioperative factors. Observed and predicted SSI numbers are used to calculate SIR.(Fukuda et al., 2013)Method of standardization controls the differences between populations, in terms of their demographics and other characteristics that confound their comparison. The variables analysed for calculating predictive risk of developing

SSI depends on the surgical procedure being studied. In this study six different parameters are analysed as per CDC NHSN SIR calculation guide. SIR is an indirect standardization method that can be used even when event rates are low. Summary measure of a hospital's performance can be determined per procedure using SIR. Interpretation of SIR is easy as it is a ratio of number of infections observed in a particular procedure relative to the number of expected infections. The limitations of SIR as observed by a study in Australia is that while calculating SIR, data aggregation by larger time intervals can be informative as a high level performance indicator in annual reports, but cannot address local performance issues at frequent intervals.(Tanamas et al., 2023)

Some of the objective parameters considered by CDC NHSN for predicting the risk for developing SSI following craniotomy are age, American Society of Anaesthesiologist Score (ASA), duration of procedure, wound class, body mass index and presence of trauma.

AIM:

To calculate the Standardized infection ratio of surgical site infections in patients undergoing craniotomy.

Primary objective:

- To estimate standardized infection ratio (SIR) for surveillance of surgical site infections (SSI) in patients undergoing craniotomy.

Secondary objective

- To analyze microbiological profile of culture positive cases.
- -To compare risk factors between infected and non infected patients

MATERIALS AND METHODS:

STUDY DESIGN:

Prospective observational study

STUDY SETTING:

Department of Neurosurgery and Department of Microbiology

Sree Chitra Tirunal Institute for Medical Sciences and Technology

Thiruvananthapuram

STUDY PERIOD:

November 2024 – January 2025

STUDY POPULATION

Patients >18 years undergoing craniotomy in neurosurgery department.

INCLUSION CRITERIA:

- 1.All patients,>18 years of age who undergo craniotomy and admitted in neurosurgery ward and ICU at Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST) during study period.
- 2.Patients presenting with features of surgical site infection within 3 months from date of surgery during the study period

EXCLUSION CRITERIA:

1. Patients undergoing endoscopic procedures.

2. Patients<18 years.

SAMPLE SIZE: All the patients who fulfil the inclusion criteria during the specified period

SAMPLING TECHNIQUE:

Consecutive cases

DATA COLLECTION TECHNIQUE:

Using a pre tested questionnaire socio-demographic data as well as the surgical data of patients undergoing craniotomy were obtained. Identification and classification of type of surgical site infection was done based on CDC/ NHSN criteria surveillance system. Details regarding surgical site infections were obtained from medical records during subsequent visit.

The data of patients undergoing craniotomy who fit into the inclusion criteria were collected for a duration of three months using the questionnaire. These patients were followed up for the next three months after surgery to look for features of surgical site infections. Those patients who presented to the outpatient department with features of SSI were evaluated by the neurosurgery team and pus swabs and aspirates were collected from superficial and deep SSI cases and subjected to microbiological evaluation. Those with features of deep SSI were admitted and CSF samples were collected for culture.

Samples received in the microbiology lab were subjected to Gram staining and inoculated on to blood agar, Mac Conkey agar and into thioglycollate broth. The growth on the culture plates were processed for identification of organism by VITEK 2

automated system. Antibiotic sensitivity testing and reporting was done according to the Central laboratory standards institute (CLSI) guidelines.

CALCULATION OF SIR:

Standardized infection ratio=Observed SSI/Predicted SSI

SIR will be calculated only if the number of predicted SSI is ≥ 1 , to help enforce a minimum precision criterion.

Observed SSI:

Observed SSI is taken as patients >18 years who have undergone craniotomy during the study period, who presented with wound discharge, dehiscence or features of organ space infection in the outpatient department and evidence of infection proven by microbiological culture.

Calculation of predicted SSI:

Predicted SSI was calculated using the six parameters of age of patient, presence of trauma, BMI, procedure duration, ASA score and surgical wound class. These data were collected from patient's medical records. The data collected were entered in excel sheet. Probability of SSI for each procedure was calculated by the formula given by CDC NHSN SIR guide (2015 baseline , All SSI SIR model for Adults >18 years).

Table 1: Risk Adjustment Factors Included in the SIR Calculation: 2015 Baseline, All SSI SIR Model, Adults ≥18 years of age				
Procedure Category	Parameter	Parameter Estimate	Standard Error	P-value
CRAN	Intercept	-4.9159	0.2752	<.0001
	Trauma: Yes	0.5289	0.2059	0.0102
	Trauma: No	REFERENT		
	ASA score: 3/4/5	0.4024	0.1367	0.0032
	ASA score: 1/2	REFERENT		
	Age at time of procedure/10	-0.11	0.0329	0.0008
	Procedure duration/10	0.0194	0.00368	<.0001
	BMI: ≥30	0.2577	0.1117	0.021
	BMI: <30	REFERENT		
	Surgical wound class: Clean	0.58	0.1927	0.0026
	Surgical wound class: Clean-Contaminated/Contaminated/Dirtv	REFERENT		

Parameter estimates describe the relationship between the variable and the risk of SSI. Positive parameter estimates indicate that the risk of SSI increases with increasing values of the variable. Negative parameter estimate indicates that the risk of SSI decreases with increasing values of the variable. The probability of SSI was calculated using logistic regression model by utilizing the relationship between log odds and probability. Log odds for each procedure was determined. Log odds was converted into a probability or risk of infection for each procedure .

Log odds

$$\text{Logit}(\hat{p}) = \alpha + \beta_1 \chi_1 + \beta_2 \chi_2 + \dots + \beta_i \chi_i$$

α =intercept

B=parameter estimate

X=value of risk factor

(Categorical variables=1,if present

0,if not present)

i= No:of predictors

Probability of SSI= $e^{\text{logit}(p)}$

$$1 + e^{\text{logit}(p)}$$

Probability of SSI for all cases were calculated and summed up to get the predicted value.

Statistical analysis:

Descriptive statistics are expressed as frequencies and percentages for categorical variables . Median and interquartile range were used for expressing continuous variables. Multivariate logistic regression analysis was used to calculate the probability of surgical site infections in each case. For univariate analysis, Fischer exact test was used to compare clinical variables between infected and non-infected cases. A p value of <0.05 was taken as statistically significant. .XLSTAT Life Sciences data analysis solution, Addinsoft;version 2022.4.1, SPSS version 25 and Stata 16 were used for statistical analysis.

RESULTS

As per the inclusion criteria, data of 100 patients >18 years who had undergone craniotomy during the period of three months from November 2024-January 2025, were collected.

Among 100 operated cases, 45(45%) were males and 55(55%) were females. The median age was 47.50 with IQR(38-58). Average procedure duration is 5.23 hours (313.95 mins). Most common indication for craniotomy among the study population was tumor resection, 55(55%) followed by vascular abnormalities, 31(31%). Average pre-operative duration of stay for cases was 4.55 days. There were no trauma cases in the study population. Most of the cases were clean cases 88(88%) and 2(2%) were clean contaminated cases. ASA score of 58 cases(58%) were >2, among them 7 cases(12.06%) developed SSI. Among the 100 cases only 14 cases(14%) had BMI>30 and among them, only one case (7.14%) developed SSI.

CALCULATION OF SIR

Standardized infection ratio = $\frac{\text{Observed SSI}}{\text{Predicted SSI}}$

Number of observed SSI during the study period is 9.

Predicted SSI is obtained by taking the sum of probability of SSI in each operated case. For calculating the probability of SSI, the formula used is

$$\frac{e^{\text{logit}(p)}}{1 + e^{\text{logit}(p)}}, \text{ where logit } p \text{ is calculated by the formula:}$$

$$\text{Logit}(\hat{p}) = \alpha + \beta_1 \chi_1 + \beta_2 \chi_2 + \dots + \beta_i \chi_i$$

α =intercept

B=parameter estimate

X=value of risk factor

(Categorical variables=1,if present and 0,if not present)

i=No:of predictors

Assigning values to this formula using intercept and parameter estimates from the table 1 ,as given by CDC NHSN and other variables from data sheet of this study.

$$\text{logit_p} = -4.9159 + (0.5289 * \text{trauma}) + (0.4024 * \text{asascore}) + (-0.11 * \text{age}) + (0.0194 * \text{procdurationinmin}) + (0.257 * \text{bmi}) + (0.58 * \text{wound})$$

Predicted SSI is 1.93.

$$\text{SIR} = 9/1.93$$

$$= 4.65$$

Where as when we take intercept and parameter estimate values from the data generated from this study ,

$$\text{newlogit_p} = -4.595117 + ((0.7689568 * \text{asascore_num}) + (0.3332916 * \text{age}) + (0.0496914 * \text{procdurationinmin}) + (-0.4466391 * \text{bmi_high}) + (-1.243023 * \text{wound}))$$

Predicted SSI=11.00

$$\text{SIR} = 9/11$$

$$= 0.81$$

FIGURE 1:GENDER WISE DISTRIBUTION OF SSI CASES

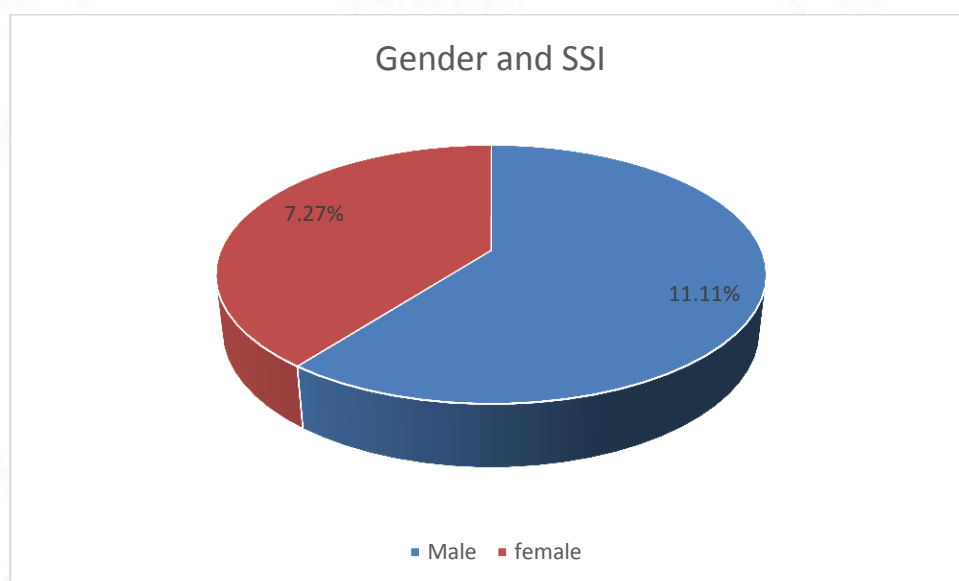


FIGURE 2: DISTRIBUTION OF TYPES OF SSI

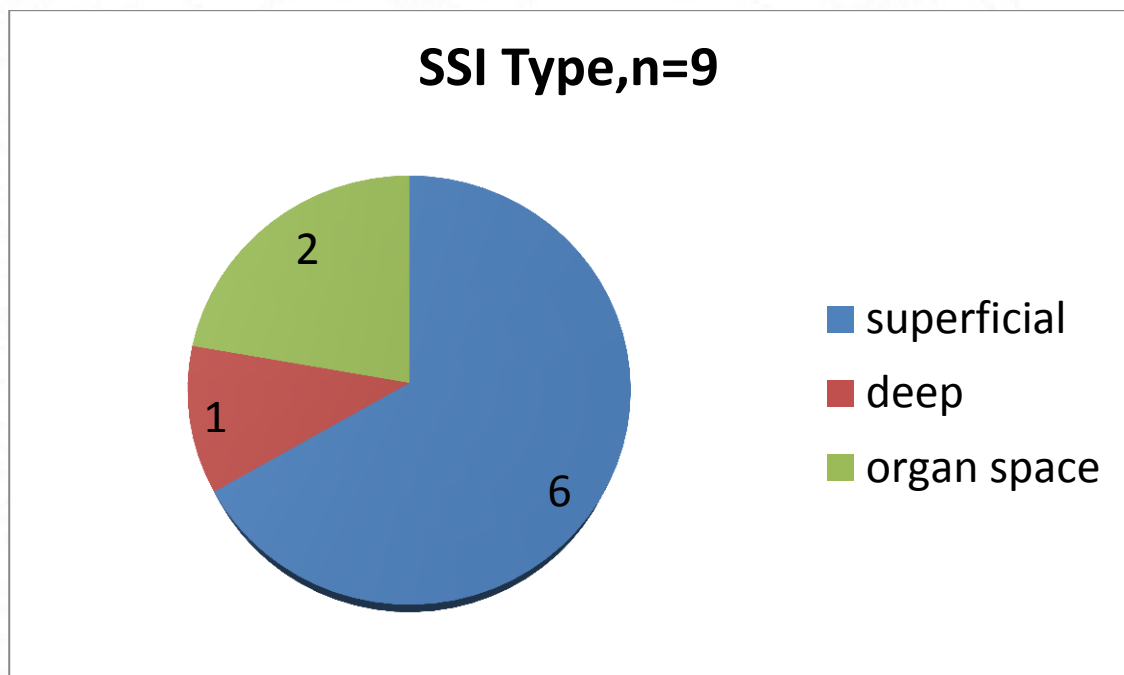
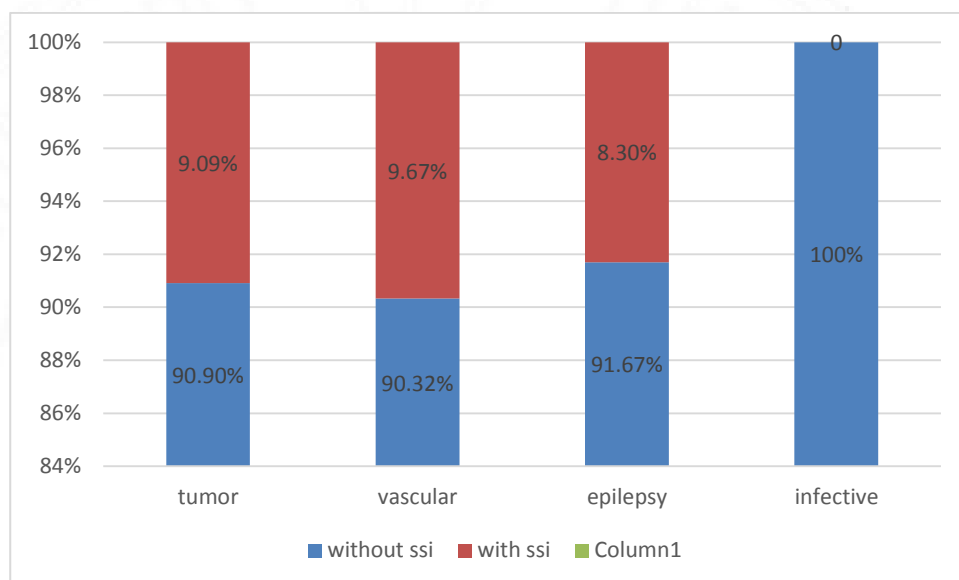
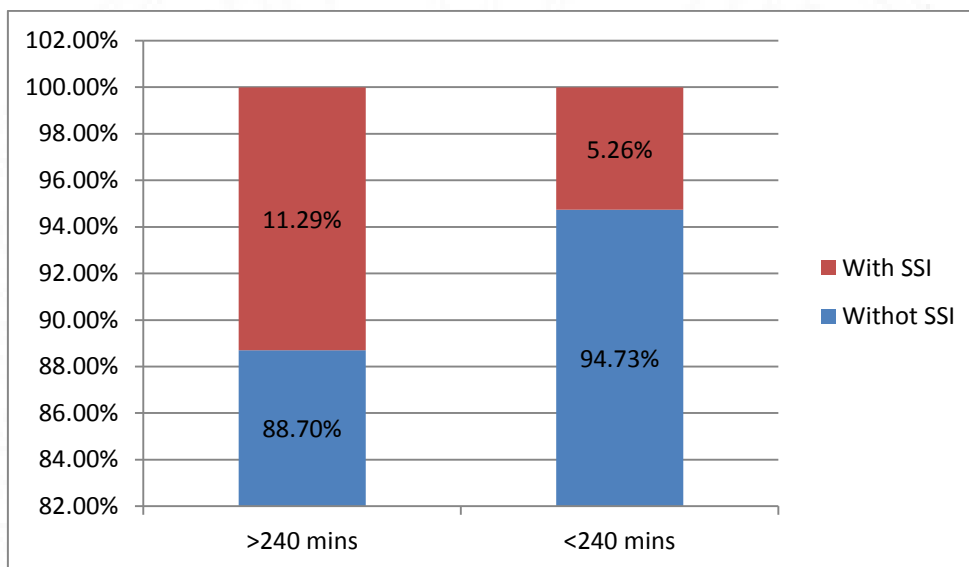


FIGURE 3: COMPARISON OF SSI AND TYPES OF LESION OPERATED



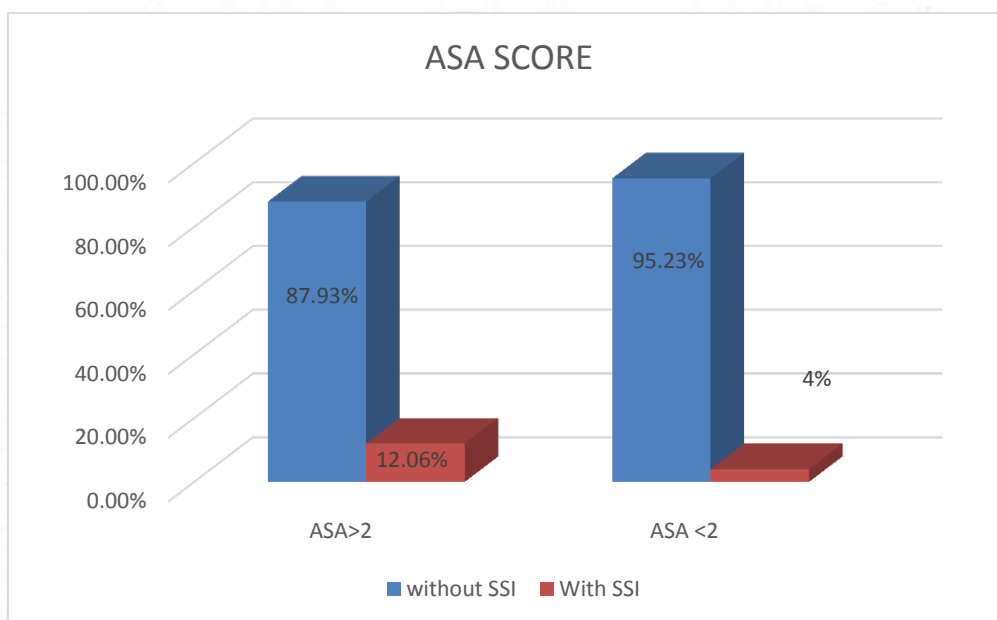
Among the 9 cases that developed SSI, 9.09% (5/55) were tumor resection, 9.67% (3/31) were vascular indications and 8.33%(1/12) were epilepsy cases .

FIGURE 4:COMPARISON OF SSI WITH PROCEDURE DURATION



Among the 9 cases that developed SSI, 5.26% (2/38) were in cases where the surgery took less than 240 mins and 11.29% (7/62) were in cases where the surgery took more than 240 mins.

FIGURE 5: COMPARISON OF SSI AND ASA SCORE



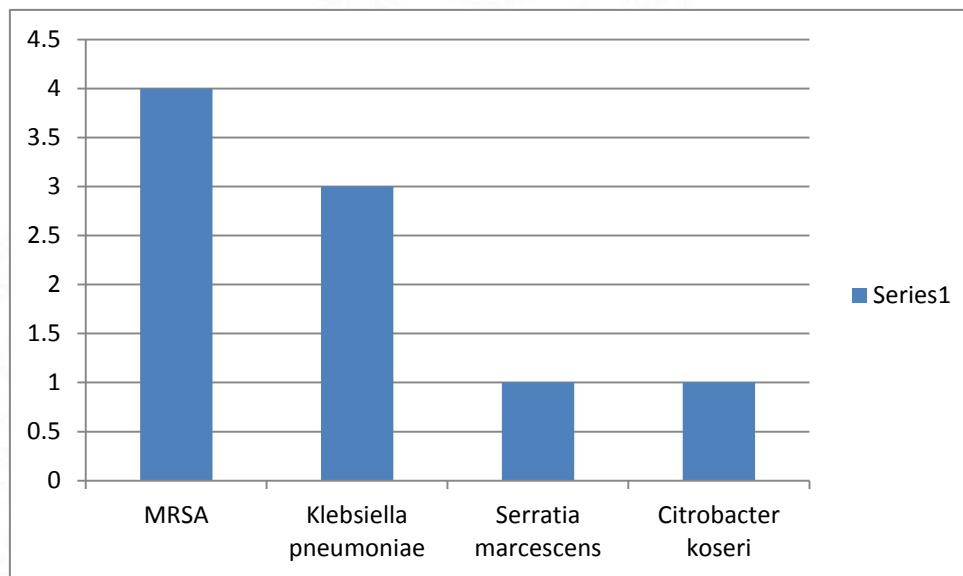
Among the 9 cases that developed SSI, 12.06% (7/58) were cases with ASA score more than 2 and 4% (2/42) were cases with ASA score less than 2.

TABLE 3:ASSOCIATION OF SSI WITH RISK FACTORS

Variable		Without SSI n=91 (%)	With SSI n=9 (%)	p value
Gender	Male	40(88.89%)	5(11.11%)	0.78
	Female	51(92.72%)	4(7.27%)	
Age group	>/=47	45(90%)	5(10%)	0.72
	<47	46(92%)	4(8%)	
Type of lesion	Tumor	50(90.90%)	5(9.09%)	1.0
	Vascular	28(90.32%)	3(9.67%)	
	Epilepsy	11(91.67%)	1(8.33%)	
	Infective	2(100%)	0(0%)	
Pre operative stay in days	>4.5 days	34(89.47%)	4(10.52%)	0.67
	<4.5 days	57(91.93%)	5(8.06%)	
ASA score	>2	51(87.93%)	7(12.06%)	0.20
	<2	40(95.23%)	2(4.76 %)	
Procedure duration in minutes	>240	55(88.70%)	7(11.29%)	0.30
	<240	36(94.73%)	2(5.26%)	
BMI	>30	13(92.85%)	1(7.14%)	0.79
	<30	78(90.69%)	8(9.30%)	

Gender, age group, type of lesion ,pre operative stay in hospital , ASA score ,procedure duration in minutes and BMI were the variables which were analysed for finding the association with Surgical site infection in the above table. As none of the exposure variables were found to be statistically significant ,odds ratio for the same is not provided. Low sample size may be the reason for statistical insignificance.

FIGURE6: MICROBIOLOGICAL PROFLE OF SSI CASES

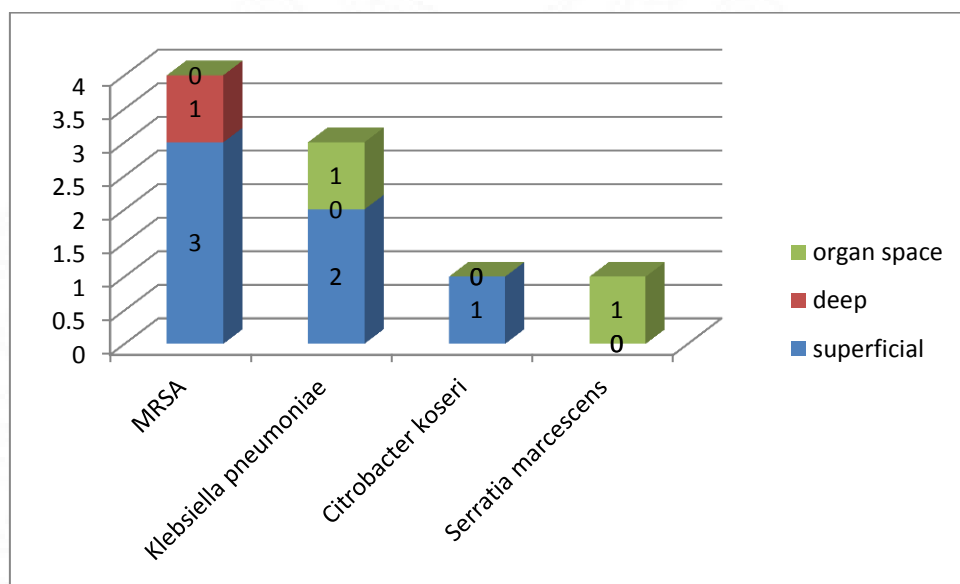


Most commonly isolated organism among the SSI cases in the study group was methicillin resistant *Staphylococcus aureus*(MRSA),4 (44.46%) followed by *Klebsiella pneumoniae*,3 (33.33%) and 1(11.11%) each of *Serratia marcescens* and *Citrobacter koseri* .

TABLE 2:TYPE OF SSI AND MICROBIOLOGICAL PROFILE

ORGANISM	SUPERFICIAL SSI	DEEP SSI	ORGAN SPACE
MRSA	3(50%)	1(100%)	0
<i>Klebsiella pneumoniae</i>	2(33.33%)	0	1(50%)
<i>Citrobacter koseri</i>	1(16.67%)	0	0
<i>Serratia marcescens</i>	0	0	1(50%)
TOTAL	6	1	2

FIGURE7:MICROBIOLOGICAL PROFILE OF TYPES OF SSI



Among the 6 superficial SSI cases, 3(50%) were caused by MRSA, 2(33.33%) were caused by *Klebsiella pneumoniae* and 1(16.67%) by *Citrobacter koseri*. 2 cases of deep space SSI were caused by *Klebsiella pneumoniae* and *Serratia marcescens*, 1 case each(50%). Only one case of deep SSI with bone involvement was reported and that was caused by MRSA.

DISCUSSION

This is a hospital based prospective observational study conducted in departments of neurosurgery and microbiology for a duration of three months, between November 2024 and January 2025.

Surgical site infection after craniotomy (SSI-CRAN) is a serious complication which increases the morbidity and increase the length of hospital stay and cost of treatment for the patients. SSI rate of the study population is 9%, which is similar to the overall SSI-CRAN rate in most of the studies, 2.2-19.8%. (Jiménez-Martínez et al., 2019) Among the 9 SSI cases 2 cases had history of previous craniotomy. Their indication for present surgery was recurrence of tumor and one among them had history of radiotherapy which increases the risk for SSI following craniotomy.

The aim of this study is to find the standardized infection ratio of SSI-CRAN. It was found to be 4.65 using the formula and parameter estimate values given by CDC NHSN SIR guide 2015, All SSI SIR model for adults >18 years, SSI-CRAN model, which is more than 1, that means the number of infections is more than the predicted numbers. When the same formula is used with parameter estimates and intercept from the data of this study population SIR value becomes 0.81 which is less than the SIR value calculated using CDC NHSN criteria. SIR is very unique to the study population as it compares the number of observed infections to the predicted risk of infection for this population based on a formula which takes into account a set of parameters affecting the development of SSI following surgery in each category. The six factors which were analyzed for calculating the predicted SSI were those given in CDC NHSN, SIR guide. They are age of the patient, American Society of Anaesthesiologist Score (ASA), duration of procedure, Body mass index (BMI), presence

of trauma and surgical wound class. The parameter estimate used for each of this parameter in calculating SIR as given by CDC NHSN is based on the population characteristics of a different place. Another unique feature of the population studied here is that none of the operated cases of craniotomy had this history of trauma. Very less number of contaminated and clean contaminated wounds were observed in the study population. The cases with BMI >30 in our population was low and all these factors affected the parameter estimate value. In our study these factors were not found to be significant risk factors which may be due to the small sample size. In a study by Huber et al at Johns Hopkins medical center, the SIR SSI-CRAN for one year was 1.99 which was almost twice the predicted number. (Huber et al., 2016)

International Nosocomial Infection Control Consortium (INICC) is a network of researchers committed to investigate healthcare associated infections (HAIs) in low and middle income countries. Adhering to the standards of CDC NHSN the data on HAI are collected from Middle East, Latin America, Asia and Eastern Europe. In such a study from hospitals of Middle East conducted between 2014 to 2023, SSI-CRAN rate was 3% Vs 2.1% of CDC NHSN datasets. (Rosenthal et al., 2024) Whereas in an INICC study conducted across six cities in India, SSI-CRAN rate was 3.9% with 95% CI (3.2-4.7). (Singh et al., 2015)

The median age of patients >18 years who have undergone craniotomy in this study population is 47.50 (IQR: 38-58) and median age of those who have developed SSI is 48. This finding is similar as in the study by Patel et al where the median age of those who underwent craniotomy was 47.5. (Patel et al., 2019) Another study by Buchanan et al also had similar findings. (Buchanan et al., 2018)

Most of the SSI cases in this study were having superficial infection 6(66.67%) , followed by organ space infection 2(22.22%) which was not in line with the findings of study by Jimenez et al and Adapa et al where organ space infections were more,67(17.6%) and 27(31%) respectively and superficial infections were only 8(8.8%) and 10(11.5%) respectively.(Jiménez-Martínez et al., 2019)(Adapa et al., 2024)All cases of superficial SSIs in this study were managed by local cleaning and dressing as well as oral antibiotic therapy.The case with deep SSI involving bone required bone flap removal.The two cases with organ space SSI presented with features of meningitis.They were managed with intravenous antibiotics.Among the two cases one case had scalp wound infection later progressed to features of meningitis .That case was presented after 8 days of surgery and required extensive wound debridement and dressing along with intravenous antibiotic therapy.Causative organism was multidrug resistant *Serratia marcescens* sensitive to tigecycline and fosfomycin.Initially treated with intravenous tigecycline and later with Ceftazidime avibactam and Aztreonam .The second case of organ space SSI had features of meningitis in the immediate post operative period.*Klebsiella pneumoniae* was isolated from cerebrospinal fluid.The *Klebsiella pneumoniae* isolated was Amp C producing strain.The case was treated with intravenous Meropenem.None of the SSI case in the study population expired.

The most common indication for craniotomy in this study was tumor resection, followed by vascular indications . Among the cases operated for tumor 5(9.09%) developed SSI and 3(9.67%) of operated cases for vascular pathology developed SSI and 1 case(8.33%) among those operated for management of epilepsy developed SSI.This is similar to the findings of the study by Abu Hamed et al where 11.11% of vascular cases developed SSI compared to 6.45% of SSI developed among operated

cases of tumor resection.(Abu Hamdeh et al., 2014)In this study there are two cases operated for infective causes(cerebellar abscess) and both of them did not develop SSI.

Number of surgeries exceeding four hours operating time was 62(62%) and among them 7 cases(11.29%) developed SSI whereas 38 cases(38%) of craniotomy were completed in less than 4 hours , among which 2 cases (5.26%) developed SSI..The findings of a study done by Patel et al is consistent with the findings of this study.(Patel et al., 2019)

Microbiological profile of SSI cases in this study shows that most number of cases were caused by Gram positive organisms(Methicillin resistant *Staphylococcus aureus*) 4(44.44%) followed by *Klebsiella pneumoniae* 3(33.33%) and 1 (11.11%)case each of *Citrobacter koseri* and *Serratia marcescens* .This finding is concurrent with the findings of other studies where common pathogen involved in SSI after craniotomy were Gram postive organisms,but it differs from this study in terms of species and drug resistance pattern.The MRSA cases isolated from other studies were much less as compared to this study.Most commonly isolated Gram positive organisms in other studies are *Staphylococcus epidermidis* and *Cutebacterium acne*.Among the Gram negative organisms the most common isolate from other studies are *Enterobacter cloacae* whereas in this study commonly isolated organism is *Klebsiella pneumoniae*.(Jiménez-Martínez et al., 2019)All the Gram positive organisms isolated from the SSI cases in this study were Methicillin resistant *Staphylococcus aureus* (MRSA),none of the isolates were coagulase negative *Staphylococcus* or Methicillin sensitive *Staphylococcus aureus* which shows the predominance of MRSA colonizers and the emphasises the need for screening for MRSA prior to craniotomy.

SUMMARY AND CONCLUSION

Surgical site infections among 100 operated cases of craniotomy during a period of three months was studied. Estimation of the infection was done by standardized infection ratio. This is in contrast to the regular practice of using SSI rates in surveillance studies.

The risk factors for development of SSI and their microbiological profile was analyzed. Age, procedure duration, body mass index, presence of trauma, wound class, American association of anaesthesiologists score of patient were the risk factors studied as per CDC guidelines for SSI in craniotomy. None of these risk factors had statistically significant association in causing SSI in the study population. This observation may be because of small sample size or short study duration. On analysing the microbiological profile of the SSI cases it was observed that number of infections caused by Methicillin resistant *Staphylococcus aureus* was more, followed by *Klebsiella pneumoniae*. SIR of SSI-CRAN in this study population is 4.65 using the intercept and parameter estimate values recommended by CDC SIR guide. The SIR value calculated using the intercept and parameter estimate values from this study population data, is 0.81, which shows that the infection numbers are less than predicted number for this study population. However, in our study these factors were not found to be significant risk factors which may be due to the small sample size. Hence it is suggested that SIR that is specific for a particular hospital may be generated using a large sample size while using this parameter as an estimate in surveillance studies.

Standardized infection ratio of surgical site infection is a true reflection of the infection control practices in a healthcare facility. Calculation of SIR includes the comparison of number of SSIs in operated cases with the predicted number of infections for the same

population in study based on their risk factors. Hence any number of infections more than the predicted value can be taken as due to breach in aseptic practices in pre or post operative period.



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LIST OF ABBREVIATIONS

SSI: Surgical site infection

ASA: American Society of Anaesthesiologists

CDC; Centers for disease Control and Prevention

NHSN: National Healthcare Safety Network

CSF: Cerebrospinal Fluid

PROFORMA

Case no:

Surgical Procedure:

Date of admission:

Date of Surgery:

History of trauma:

ASA Score:

Age in years:

Procedure duration in minutes:

BMI:

Wound class:

Whether Re-exploration required:

Re admission:

SSI:

Date:

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Thesis submitted in partial fulfilment of the rules and regulations for Post-doctoral Certificate course Sree Chitra Tirunal
Institute for Medical Sciences and Technology By Dr. Lakshmi Natarajan Post-doctoral Certificate course in Hospital
Infection Control Month and Year of Submission: July 2025 Department of Microbiology Sree Chitra Tirunal Institute for
Medical Sciences and Technology Thiruvananthapuram 2025 DECLARATION I, Dr. Lakshmi Natarajan, hereby declare that
this project was undertaken by me under the supervision of the faculty, Department of Microbiology, Sree Chitra Tirunal
Institute for Medical Sciences and Technology. Thiruvananthapuram Dr. Lakshmi Natarajan Date: 25-6-2025 Forwarded :
The candidate, Dr. Lakshmi Natarajan, has completed the project under my guidance. Thiruvananthapuram Date: 25-6-
2025 Dr. Kavita Raja, Professor – Senior Grade & Head, Department of Microbiology, SCTIMST. ACKNOWLEDGEMENT I
take this opportunity to express my sincere gratitude to Dr. Kavita Raja, Sr. Professor of Microbiology and
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and caregivers who willingly participated in this study. Dr. Lakshmi Natarajan Post-Doctoral Certificate Course Resident,
Department of Microbiology SCTIMST, Trivandrum, Kerala INDEX

i. Introduction 1 ii. Review of Literature 3 iii. Aims and Objectives of the study 11 iv.
Materials and Methods 13 v. Results 28 vi. Discussion 59 vii. Conclusions

13

69 viii. References 71 ix. Appendix 76 a. Abbreviations b. Proforma . Ethics committee letter d. Plagiarism check report
LIST OF TABLES: Formatted: Font color: Text 1 TABLE 1 RISK ADJUSTMENT FACTORS INCLUDED IN SIR CALCULATION
Formatted: Font color: Text 1 TABLE 2 TYPE OF SSI AND Formatted: Font color: Text 1 MICROBIOLOGICAL PROFILE
Formatted: Font color: Text 1 TABLE 3 ASSOCIATION OF RISK FACTORS Formatted: Font color: Text 1 WITH SSI



श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
Thiruvananthapuram - 695 011, Kerala, India
(An Institute of National Importance under Govt. of India)

Grams : Chitramet, Phone : +91-471-2443152, Fax : +91-471-2550728 / 2446433, E-mail : sct@sctimst.ac.in, Website : www.sctimst.ac.in

Institutional Ethics Committee

CDSO Registration No: ECR/189/Inst/KL/2013/RR-24
DHR Registration No: EC/NEW/INST/2022/2775

SCT/IEC/2370/MARCH-2025

15.05.2025

Dr. Lakshmi Natarajan
Resident
Department of Microbiology
SCTIMST, Thiruvananthapuram

Dear Dr. Lakshmi Natarajan,

The Institutional Ethics Committee held on 15th March, 2025, reviewed and discussed your application to conduct the study titled "ESTIMATING STANDARDIZED INFECTION RATIO FOR SURVEILLANCE OF SURGICAL SITE INFECTION IN PATIENTS UNDERGOING CRANIOTOMY" (IEC/2370).

Principal Investigator	Dr. Lakshmi Natarajan, Resident, Department of Microbiology, SCTIMST
Co-Principal Investigator(s)	Dr. Kavita Raja, Professor, Department of Microbiology, SCTIMST Dr. Krishnakumar K. Professor, Department of Neurosurgery, SCTIMST Dr. Dinooop KP, Associated Professor, Department of Microbiology, SCTIMST Ms. Preena V, Nursing Officer – C, Nursing Superintendent Office, SCTIMST
Duration of the study	3 months

The following members of the Ethics Committee were present at the meeting held on 15th March, 2025

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Dr. Kusuma Kumary P	MD in Paediatrics	Female	Clinician (Chairperson)	No
2.	Dr. Manoj Murhekar	MD (Preventive & Social Medicine)	Male	Social Scientist	No
3.	Dr. Pradeep S	MBBS, MDI	Male	Basic Medical Scientist	No
4.	Dr. Rejnish Kumar	MBBS, MD, DNB	Male	Clinician	No
5.	Dr. Indu PV	MBBS, DPM, MPhil, PhD	Female	Clinician	No
6.	Adv. Priya Kaimal	LLM, MBL	Female	Legal Expert	No
7.	Adv. N Anand	BAL, L LB	Male	Legal Expert	No
8.	Smt. Rekha Radhakrishnan	M A (Eng.); B. Ed	Female	Lay person	No
9.	Dr. Narayanan Namboodiri. K K	MBBS, MD, DM	Male	Clinician	Yes
10.	Dr. Biju Soman	MBBS, MD, DPH, MSc, DLSHTM	Male	Basic Medical Scientist	Yes
11.	Dr. Srinivas G	PhD	Male	Basic Medical Scientist (Member Secretary)	Yes

The following documents were reviewed:

Original submission

1. Covering letter addressed to the Chairperson, IEC, SCTIMST dated 03.01.2025
2. Proforma
3. Consent Form in English and Malayalam
4. Participant Information Form in English and Malayalam
5. Checklist Form
6. IEC Application Form
7. Declaration Form
8. Study proposal
9. CV of PI and Co-PIs

Revised submission

1. Covering letter addressed to the Chairperson, IEC, SCTIMST dated 29.04.2025
2. CV of Co-PI
3. Consent Form in Malayalam
4. Study proposal

IEC Decision

The IEC approved the conduct of the study in the present form.

Remarks:

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,



Dr. G. Srinivas
Member Secretary, IEC

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE (IEC)
SCTIMST, THIRUVANANTHAPURAM

