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# SURGICAL SITE INFECTIONS AMONG PATIENTS UNDERWENT CRANIOTOMY IN KHOULA HOSPITAL: RATE, RISK FACTORS, MICROBIOLOGY FEATURES, CLINICAL OUTCOME ( 2009- 2019).

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## ABSTRACT

**Objective**: To assess the overall clinical outcome of SSI post craniotomy in Khoula hospital in Oman between 2009-2019. Also, it provides data regarding the rate, risk factors and microbiology features of SSI post craniotomy in Oman. **Method**: A retrospective descriptive cohort study conducted in Khoula hospital, include all adult craniotomy cases between 2009-2019. Data collected from Al Shifa system using Excel sheet. All SSI are identified by National Healthcare Safety Network (NHSN) and categorized according to Centre of Disease of Prevention (CDC). Data is analyzed by SPSS program version 24. **Result**: Of the 547 patients undergoing craniotomy during the study period, 35 developed SSI. Among the 35 patients who developed SSI. The most frequent causative Gram-positive organisms were Coagulase Negative Staphylococci11.4%), whereas Pseudomonas aeruginosa (8.5%) was the most commonly isolated Gram- negative agent. In the univariate analysis the factors associated with SSI-CRAN were clean-contaminated surgical site ($p$ =0.006), Use of steroid/chemotherapy pre-operation 2 weeks ($p$ =0.023), and presence of implant ($p$ = 0.020). In the multivariate analysis, Clean-Contaminated surgical site and presence of implant were the only factors independently associated with SSI-CRAN. **In summary**, The risk factors and causative agents of SSI-CRAN identified in this study should be considered in the design of preventive strategies aimed to reduce the incidence of this serious complication.

## INTRODUCTION

Surgical site infection (SSI) is an infection that occurs after surgery in the part of body where surgery took place. It can be superficial infection involving only skin or deep infection involving organs.

Craniotomy is a surgical procedures in which part of the skull bone is removed to expose the brain and the central nervous system. SSIs are late complications relative to nosocomial infection post neurological surgery.[1] Despite that, SSIs increase morbidity, mortality, higher hospital cost, re-admission, multiple surgeries and prolonged length of stay after neurological surgery.[2] Overall Incidence of surgical site infections in neurosurgery center ranged 1-8% in cranial cases to 0.5-18% in spine operations.[3].[4].[5] Similarly, the incidence of SSI after craniotomy ranges from 2.2 to 19.8%.[6-8]

Furthermore, factors of SSIs post craniotomy remain variables such as operations for tumor, younger age, hospitalization length, diabetes, discharge to institutional care, larger hospital bed size, Medicaid insurance, and presence of an EVD.[9]

In Middle East, lack of study conducted in craniotomy surgery with SSI. But recent study in Saudi Arabia evaluate predictors infection factors for patient underwent cranioplasty from preserved subcutaneously preserved bone flaps in abdomen. It shows that, the incidence of SSI 15.7% and most predictors factors is skull defect and blood glucose levels.[10]

Surveillance of SSI after craniotomy and microbiology features is not carried out enough locally, because different in patient risk factors, hospital sitting and prevention policies. It will help quality Improvement Program.

## METHODS

### Study design, setting and patients

A retrospective descriptive cohort study was carried out in neurosurgery hospital in Muscat, Oman which serves for majority of governorates in country. All adult patients (> 18 years old) who underwent primary open craniotomy from 1st January 2009 to 31th January 2019 were included. Patients were retrospectively followed up by investigator and assistant investigator is a doctor who had received training in surveillance methodology to ensure the collection of homogeneous and accurate data. Active surveillance was carried out up to 30,90 days post surgery applying a multimodal approach including the following items: electronic review of clinical records, checking of readmissions, checking of emergency visits and review of microbiological and radiological data within the period of surveillance.

At the moment of SSIs diagnosis, based on CDC case definition; more clinical details obtained. Including: type of SSI (superficial, deep and organ-space SSIs) interventions had been done; there were variable from dressing, systemic antibiotics to re-operation and debridement, microbiological data collected and record any event of death.

Ethical standards related to anonymity and data confidentiality (access to records, data encryption, and archiving of information) were observed throughout the research process. Patients' confidential information was protected, and the study was approved by the ethical committee

**Main outcome, variables, and data source**

The main outcome analyzed was the development of a SSI-CRAN within 90 days post-surgery. The clinical characteristics of patients who developed SSI-CRAN were obtained. The secondary outcome were to describe risk factors of SSI post craniotomy and provide microbiology features of causative pathogens. Basic demographic data were recorded, along with the following information on patient comorbidities especially diabetes mellitus, taking steroids 2 weeks prior to operation and surgical procedure: information on surgical procedures, including ASA and elective/emergency surgery, reason for surgery, administration of antibiotic prophylaxis according to hospital guidelines, duration of surgery, use of metal plates/drains; characteristics of infection (SSI-CRAN classification and microorganisms identified); and in-hospital outcome data (pre and post-surgery in-hospital stay).

**Definitions**

SSI-CRAN 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 tender- ness, localized inflammation (heat, erythema and swelling), and/or fever (> 38 °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.[11]

Intravenous antibiotic prophylaxis was considered adequate when the following three factors were all met: antibiotic administration according to local protocol, completion of the infusion within 60 min of the surgical incision, and perioperative antibiotic re-administered if indicated.

**Microbiological studies**

In most patients with suspected SSI-CRAN, microbiological samples from wounds and/or CSF fluid or abscesses were taken for culture. Blood cultures were also taken when indicated by the attending physician. Antibiotic susceptibility was determined using the microdilution method following Clinical Laboratory Standard Institute (CLSI) guidelines. The antimicrobial susceptibility of isolates was interpreted according to current CLSI criteria.

Exclusion criteria: patients ages <18 yrs. old, who underwent Tran-sphenoidal approaches, cranioplasty, brain biopsy and with Burr- hole evacuation. Any patient Lost follow up or operated in another hospital have been excluded. SSI defined and categorized according CDC case definition.

**Statistical analysis**

Quantitative variables are reported as medians and median. Categorical variables are reported as absolute numbers and percentages. To detect significant differences between groups, p-value <-0.05 used. Factors associated with SSI-CRAN were evaluated by bivariate and multivariate analysis. Results of multivariate analyses were reported as odds ratios (OR) and 95% confidence intervals (CI). The statistical analysis was performed with version 24.0 of the SPSS software package (SPSS, Chicago, IL). Statistical significance was established at $\alpha = 0.05$, and all reported p-values are two-tailed.

**RESULT**

Total 2867 craniotomy cases conducted during study periods, but based on inclusion criteria total 547 were followed up. The overall SSI-CRAN rate at the end of follow-up was 6.4% (n = 35). Baseline clinical characteristics are summarized in Table1. There were 332 male patients (60.7%) and mean age was 44.9 years (standard deviation [SD] = 16.7). Majority of cases were elective 62.5% and ASA classification 2. The main causes for surgical intervention were neoplasm (n =288, 52.7%), followed with trauma (n = 122, 22.3%). Median total hospital stay was 16 days.

**Table 1: Base line demographic and clinical characteristics of patients with open craniotomy.**

| | Number of Cases (%) |
|---|---|
| **Gender:**<br>**Male**<br>**Female** | <br>332 (**60.7**)<br>215 (39.3) |
| **Mean age, years (SD)** | **44.9** (16.7) |
| **Diabetes Mellitus (DM)** | 117 (**21.4**) |
| **ASA:**<br>**1**<br>**2**<br>**3**<br>**4**<br>**5** | <br>85 (15.5)<br>224 (**41.0**)<br>151 (27.6)<br>78 (14.3)<br>9 (1.6) |
| **Criteria of surgery:**<br>**Elective**<br>**Emergency** | <br>342 **(62.5)**<br>205 (37.5) |
| **Indication of surgery:**<br>**Aneurysm**<br>**AVM**<br>**Brain abscess**<br>**ICH**<br>**Microvascular disease**<br>**Neoplasm**<br>**Trauma**<br>**Others (Brucellosis, trigeminal neuralgia)** | <br>35 (6.4)<br>15 (2.7)<br>3 (0.5)<br>80 (14.6)<br>2 (0.4)<br>288 **(52.7)**<br>122 **(22.3)**<br>2 (0.4) |
| **Antibiotic prophylaxis:**<br>**Adequate**<br>**Not- adequate**<br>**Non given** | <br>415 **(77.9)**<br>64 (18.3)<br>21 (3.8) |
| **Surgical site:**<br>**Clean**<br>**Clean-contaminated** | <br>500 **(91.4)**<br>47 (8.6) |
| **Total hospital stays days, median (25,75 Percentiles)** | **16** (11, 27) |
| **Presence of implant** | 392 **(71.7)** |

Rate of craniotomy SSI noted to be high in 2012-2013.Median days for occurrence of SSI was 12 days. Indeed, out of 35 episodes of SSI-CRAN. Superficial SSI-CRAN was highest type of SSI-CRAN 68.6%. However, 37.1 % of SSI-CRAN required re-exploration of wound.

Univariate analysis of risk factors found that: clean-contaminated surgical site (p = 0.006]), use steroid/chemotherapy pre-operation 2 weeks (p= 0.023) and Present of implant (p= 0.020) to be significantly associated with SSI CRAN. As shown in table 2.

**Table 2: Bivariate and multivariate analysis of risk factors for developing SSI-CRAN.**

| **Overall( n=35)** | **Bivariate** | **Multivariate** | | |
|---|---|---|---|---|
| **Risk factors** | **p-value** | **OD** | **95% CI** | **p-value** |
| **Gender**<br>**Male**<br>**Female** | 0.475 | | | |
| **DM** | 0.524 | | | |
| **Indication of surgery** | 0.309 | | | |
| **Surgical site:**<br>**Clean**<br>**Clean-Contaminated** | **0.006** | **2.7** | 1.109-6.66 | **0.028** |
| **Criteria of surgery:**<br>**Elective**<br>**Emergency** | **0.589** | | | |
| **Use steroid/chemotherapy pre-operation 2 weeks** | **0.023** | 0.5 | 0.25-1.155 | 0.11 |
| **Pre-op antimicrobial** | 1.000 | | | |
| **Antibiotic prophylaxis:** | 0.708 | | | |

| | | | | |
|---|---|---|---|---|
| **Appropriate**<br>**Inappropriate**<br>**Non given** | | | | |
| **Presence of implant** | **0.020** | 3.00 | 1.036-8.714 | **0.042** |
| **ASA**<br>**> 2** | 0.867 | | | |

However, with Multivariate analysis using Logistic Regression: compare clean group to contamination 2.7 was more risk for SSI (p value= 0.028). Also, compare absent of implant to present of implant had 3 times likely to get SSI. (p value=0.042).

Another important aspect of the study was to identify the most common pathogens, their incidence and their distribution as detected in the CSF and wound swab. The etiology variable was found sporadic cases with multiple pathogens. Overall, Coagulase Negative Staph (n=4, 11.4%) commonly found in gram-positive microorganisms. Whereas Pseudomonas aeruginosa (n =3, 8.5%) was the most prevalent gam-negative microorganism. 4 cases with Coagulase negative Staphylococcus were only one case was with EVD and 3 cases associated with meningitis. The 30 and 90-days mortality were 17.14% and 22.9% respectively.

**DISCUSSION**

This study of a large cohort of hospitalized patients undergoing a craniotomy at neurosurgery hospital in Oman found that, the overall SSI-CRAN rate was 6.4%. This percentage is similar in previous study (a rate of 6.8%).[12] However, this rate found lesser than those reported in other studies (rate was 15.3%).[13] In line with other study, the most frequently isolated causative agents were Gram-positive cocci.[13] Superficial SSI-CRAN was the most prevalent surgical site infection, compare to previous studies where organ-space SSI-CRAN was the most prevalent surgical site infection.[13],[8],[14] Despite that, mortality at 30 and 90 days was higher than in previous study (was 2.2%).[13]

Regarding risk factors, we did not find any relationship between age, gender, emergency procedures, antibiotic prophylaxis, surgical site. Likewise, and in agreement with other studies.[13],[14]

We found that the only independent risk factors for SSI-CRAN was, using of steroids or chemotherapy preoperative. Which is well known risk factors in study by Lieber et al.[15]

The **strengths** of this study are the large number of patients included and procedure using an internationally accepted definition of surgical site infection and a well-defined follow-up period according to the guidelines.

However, there are certain limitations that should be acknowledged. For example, the study was conducted at a single center, and our findings need to be validated by other studies. Nevertheless, this is retrospective study and found some missing data from the record of the patients. Presence of confounding factors can also effect data accuracy.

**CONCLUSION**

547 cases of craniotomy were included in the study. We report an incidence of 6.4% of SSI in this study. The 30 and 90-days mortality were 17.14% and 22.9% respectively. Among all risk factors included in this study, type of craniotomy wound and present of implantation were significantly associated with infection. We recommend, Enhanced adherence to strict aseptic techniques in the placement of implant (EVD), will probably lead to reduction in SSI rates. Presence of active surveillance for elective craniotomy infection is recommended to monitor trends. Standardizing postoperative wound management by might be helpful to reduce SSI rate.

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