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INCIDENCE AND PREDICTORS OF SURGICAL SITE INFECTION FOLLOWING OPEN REDUCTION AND INTERNAL FIXATION OF LONG BONE FRACTURES

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Abstract
Surgical Site Infections (SSIs) are a major complication following orthopaedic procedures, particularly Open Reduction and Internal Fixation (ORIF) of long bone fractures. This was a study done to measure the incidence of SSIs and also to identify the independent predictors of SSIs in patients who underwent ORIF surgery due to long bone pathologies in a tertiary care hospital. Twelve months with the participation of 200 patients who received ORIF to treat a fracture of the femur, tibia, humerus, or forearm were practiced as a prospective observational study. Demographic, clinical, and intraoperative data were collected. The classification according to the Centers for Disease Control and Prevention (CDC) guidelines was used in categorizing SSIs. Predictors were determined using univariate and multivariate analysis of logistic regression. The general SSI incidence was 14 %, of which 9 % were superficial and 5 % deep infections. The results of univariate analysis revealed that diabetes mellitus, open fractures, anemia, and prolonged surgery are classical risk factors. Both diabetes and open fractures were independent predictors as confirmed by multivariate analysis (adjusted OR 2.98 and 2.72, respectively). The stratified models showed an infection rate as high as 32 % in higher-risk subgroups. Patient outcomes in orthopedic trauma surgery may be improved by interventions such as glycaemic control and enhancement of wound management policies.

Keywords: Surgical Site Infection (SSI), Open Reduction and Internal Fixation (ORIF), Long Bone Fractures, Risk Factors, Orthopaedic Trauma Surgery

Introduction
The Surgical Site Infections (SSIs) are among the most common and problematic complications in orthopaedic surgery, and in most cases, occur after the operation of fracture fixation.[1] These infections develop within 30 days of a surgical procedure or within a year after implants are inserted, and infections can greatly impact how the patient recovers by increasing the morbidity among patients,

extending hospital stays, necessitating multiple surgical procedures, and causing the escalation of healthcare expenditure.[2,3]

Open Reduction and internal fixation (ORIF) surgery in long bone fractures, SSIs not only hinder the bone healing process but also increase the risk of device failure, prolonged osteomyelitis, and amputation of the affected limb, in extreme cases.[4] Post-ORIF growth of SSIs is an important concern area in trauma orthopaedics, and therefore, there is a need to investigate deeply into its prevalence and risk factors. The most commonly broken bones are the long bones, such as the femur, tibia, humerus, and the radius/ulna. These bones are common in traumatic injury and require internal fixation to restore the anatomical alignment and functional recovery.[5] ORIF has continued to be the gold standard in the treatment of long-bone displaced fractures and the ORIF procedure. However, propensity to increase the chances of patients developing infection, particularly in emergency trauma conditions or where handling of the soft tissues is not ideal.[6] The danger is even increased in open fractures where the limit of external protection, the skin, is broken, and external contaminants penetrate the field of surgery.

Poor host-related factors involving poor glycemic control, smoking, malnutrition, and immunosuppression may affect wound healing even in closed fractures and can expose the patient to the risk of developing an infection. The orthopaedic trauma surgery SSIs burden is high.[7] The rates of infection given varied between 1 and more than 20 % depending on several factors may including the type of fracture including the surgical environment, and the comorbidities of the patient.[8] The burden is even greater in low-resource settings when there is little access to sterile conditions, advanced perioperative care, and monitoring in the postoperative period.[9,10]

SSIs play a significant role in patient dissatisfaction, longer time of antibiotic use, the need for implant removal/revision surgeries, as well as the loss of time in terms of functional recovery.[11] Therefore, it is important to prevent events that can lead to such complications by determining the risk factors and stratifying the patients according to the risk of infection prevention and, thus, achieving positive clinical outcomes. Even after carrying out widespread studies in the field of orthopaedic infections, the epidemiology and predictors of SSIs after the ORIF of long-bone fractures are poorly understood in most regional and institutional settings.[12] The majority of the information available covers hip and knee arthroplasty, and trauma-related long bone fixations remain under-represented, with only a few prospective studies.[13] Also, the validated prediction tools of risks of elective surgeries cannot be simply transferred to the world of trauma cases, where the time-to-surgery, polytrauma, or fracture severity might be the key factors that contribute to postoperative infection risk.[14] Regarding developing regional-specific infection control approaches, there is a continued demand for regional-specific data to determine contextual risks and regionally particular approaches.[15]

Aims and Objectives

The objective of this study is to identify patient-specific and procedural determinants associated with postoperative surgical site infections. Additionally, to evaluate independent risk factors that contribute to the development of SSI, including demographic, clinical, and intraoperative variables.

Materials and Methods

It was a prospective observational study that involved the orthopaedic department in a tertiary care teaching hospital, which took 12 months. This study was approved by the Institutional Ethics Committee. Participants were all registered upon signing written informed consent.

The study population was patients aged 18 years and above who received Open Reduction and Internal Fixation (ORIF) and who fractured their long bones (femur, tibia, humerus, radius, ulna). It was open as well as closed fractures, both open fractures, a Gustilo-Anderson category I to IIIA. Patients were to be excluded when they had pathological fractures, open fractures grades IIIB or IIIC, presence of infection of the fracture site, polytraumatic patients in need of intensive care, or lost to follow-up within 30 days of the surgery.

Sample Size and Sampling Technique

A standard formula used in calculating a sample size in prevalence studies was applied to determine a sample size involving an expected SSI of 10%, a 95 % level of confidence, and a 5 % margin of error, resulting in a sample size of 200. A consecutive non-probability sampling approach was adopted with all eligible patients who met the inclusion criteria within the study period, followed by the determination stage until the necessary sampling size was attained.

Data Collection Procedure

The data were captured with a pre-designed case record form. It has gathered data on a demographic basis (age, sex, and BMI), clinical history (diabetes mellitus, smoking status, alcohol use, and anemia), and fractures (type and place, open or closed, and period between the trauma and the surgery). Intraoperative factors recorded included type of implant, length of operation, haemorrhage, and use of antibiotic prophylaxis. The follow-up was performed regularly up to 30 days or one year (implanted cases), and clinical examination was performed; recording of any indication of surgical site infection was done.

Outcome Measures

The most important outcome was the development of Surgical Site Infection (SSI) using the CDC recommendations. Superficial SSI just involved the skin and subcutaneous tissue, but deep SSI involved the fascial or muscle level of the body or the bone. Proved to be clinically diagnosed depending on the symptoms such as redness, discharge, pain, swelling, and confirmed through laboratory tests or microbiological cultures, where possible.

Predictor Variables

Potential predictor factors measured were Patient characteristics (age, sex, BMI, diabetes, anemia, smoking status, nutritional status), fracture characteristics (Open vs Closed fracture, fragment, location), surgery (type of fixation, procedure duration, experience/expertise, time at which surgery is done after injury, intra operative use of drains, blood loss). The reasons for selecting these variables were literature review and clinical relevance.

Statistical Analysis

The analysis of data was executed with the help of IBM SPSS Statistics version 22.0. Demographic and clinical characteristics were summarized using descriptive statistics. The frequency of SSIs was indicated as a percentage. The univariate logistic regression was first used to evaluate associations among risk factors and SSIs. To produce independent predictors, variables that had $p < 0.10$ in univariate analysis were taken up using the multivariate logistic regression. The findings were expressed as odds ratios (OR) with 95% confidence intervals (CI), and a p-value of less than < 0.05 was accepted to be statistically significant.

Result

The study included 200 patients who underwent ORIF in case of long bone fractures. The average age of the population was 39.2 ± 13.6 years, with male dominance (70 %) of the patients. The comorbidities, such as 18 % diabetes mellitus and 28.5 % anemia (haemoglobin less than 11 g/dL), were also present. A total of 30 % of the patients had a smoking history. The two bones that were involved most often were the tibia (40 %) and femur (35 %), followed by the humerus and forearm bones.

Table 1 shows the demographic and clinical characteristics of the study population. The presence of notable comorbidities was noticed, which included diabetes, smoking, and anemia, all of which could increase the risk of SSI.

Table 1: Baseline Demographic and Clinical Characteristics (n = 200)

Variable	Frequency (n)	Percentage (%)
Male	140	70%
Female	60	30%
Diabetes Mellitus	36	18%
Smoking History	60	30%
Haemoglobin <11 g/dL	57	28.5%

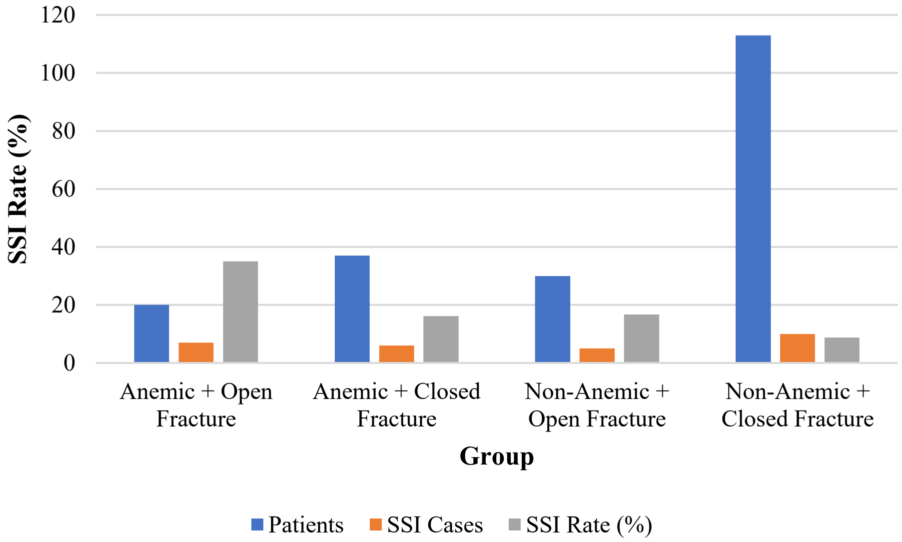

Figure 1: SSI Rate by Haemoglobin Level and Fracture Type

Figure 1 shows how haemoglobin level and type of fracture affect the rate of Surgical Site Infection (SSI). The difficulties are expected to take place or occur in patients with anemia and open fracture, with a 35 % SSI rate which was the highest but non-anemic with closed fracture had the lowest rate of 8.8 %. This highlights the accumulating risk of anemia and open wounds in post-surgical infections.

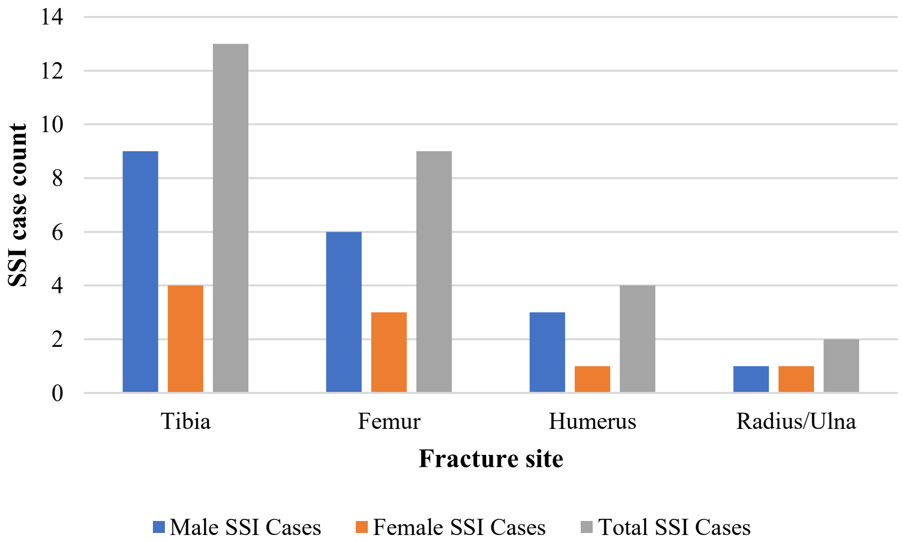

Figure 2: SSI Distribution by Fracture Site and Gender

Figure 2 shows the SSI cases according to fracture sites and gender. The cases per body part were greatest in the Tibia (13: 9 males, 4 females) and then followed by femur (9: 6 males, 3 females). On the Humerus, there were 4 cases (3 men, 1 woman), and the lowest was radius/ulna with 2 cases (1 man, 1 woman).

Incidence of Surgical Site Infection

Among 200 patients, 28 of them got surgical site infections, which presents a total incidence of 14%. Superficial SSIs occurred in 9 % (n=18) of cases, whereas deep SSIs occurred in 5 % (n=10). The majority of infections (78.6 %) were detected during the first 14 days of the surgery process, which reveals the high-risk post-operative time range to monitor infections. The other six infections occurred later, implying delayed recovery or inapparent infection. Table 2 indicates the time of development of Surgical Site Infection (SSI) after an operation. The most frequent infections were 8-14 days after the surgery (50%), followed by 28.6 % of cases during the first 7 days, and 21.4 % of cases after 2 weeks, thus representing the extremity of relevance of early postoperative monitoring.

Table 2: Timing of SSI Presentation (n = 28)

Time After Surgery	Number of SSIs	Percentage (%)
0–7 days	8	28.6%
8–14 days	14	50%
>14 days	6	21.4%

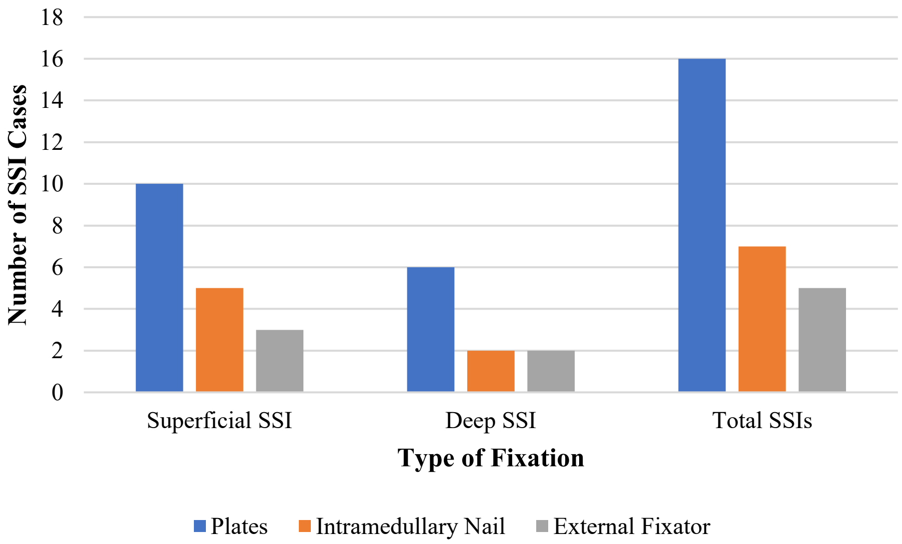

Figure 3: SSI Type by Type of Fixation Used

Figure 3 shows the cases of SSI according to fixation type and infection depths. The Plate fixation recorded the highest rates of SSIs. 10 superficial SSIs, 6 deep SSIs, and a total superficial SSIs were 16. Superficial and deep SSIs of a total of 5 and 2 were seen in intramedullary nails, and 3, 2, and 5 superficial, deep, and deep SSIs were seen in external fixators.

Univariate Analysis of Predictors

The univariate logistic regression showed four factors which significantly contributed to the risk of SSI, namely, diabetes mellitus (OR 3.45, p=0.003), open fractures (OR 2.96, p=0.009), lower haemoglobin (<11 g/dL; OR 2.48, p=0.025), and surgery lasting more than 2 hours (OR 2.15, p=0.049). These findings indicate that the predisposing factors of the development of postsurgical infection can be both systemic health impacts and intraoperative ones. Table 3 presents univariate analysis data, determining diabetes, open fracture, low haemoglobin, and long surgery as major risk factors of surgical site infection related to high odds ratios and statistically significant results.

Table 3: Univariate Logistic Regression Analysis

Predictor Variable	OR	95% CI	p-value
Diabetes Mellitus	3.45	1.51–7.88	0.003
Open Fracture	2.96	1.31–6.67	0.009
Haemoglobin <11 g/dL	2.48	1.12–5.49	0.025
Surgery >2 hrs	2.15	1.00–4.65	0.049

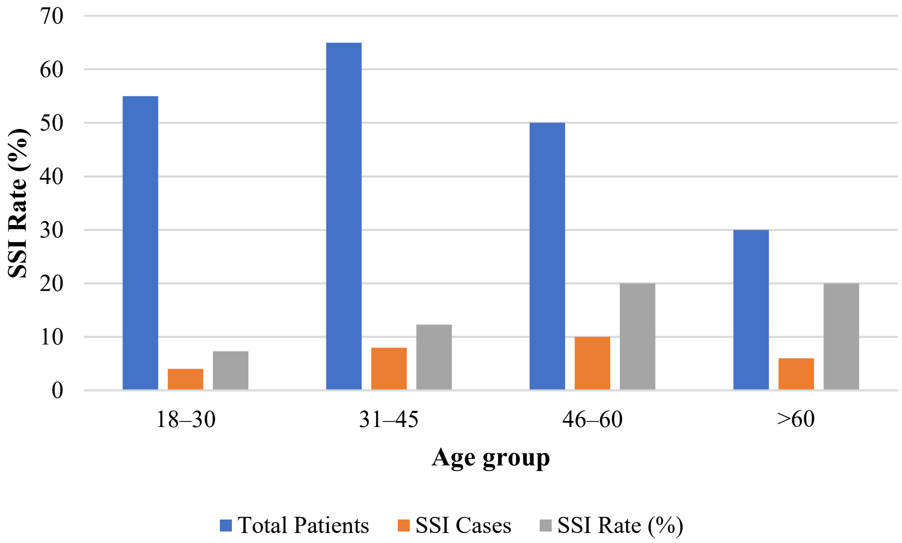

Figure 4: SSI Rates by Age Group

Figure 4 shows the Surgical Site Infection (SSI) incidence across different age groups. The SSI rate increases with advancing age, with the highest infection rates (20%) observed in patients aged 46–60 and above 60 years, indicating age as a potential risk factor for postoperative infections.

Multivariate Regression Analysis

Multivariate analysis showed that diabetes mellitus (adjusted OR 2.98, p=0.020) and open fractures (adjusted OR 2.72, p=0.036) might be considered significant independent predictors of SSI. Variables like anemia and the increased length of the surgery, being of significance during unadjusted analysis, did not emerge to be significant in adjusted analysis. Table 4 contains the result of multivariate logistic regression analysis indicating that diabetes mellitus and open fractures were found as independent predictors of surgical site infection whereas low haemoglobin and long surgery were no longer significant predictors.

Table 4: Multivariate Logistic Regression Analysis

Predictor Variable	Adjusted OR	95% CI	p-value
Diabetes Mellitus	2.98	1.19–7.49	0.020
Open Fracture	2.72	1.07–6.94	0.036
Haemoglobin <11 g/dL	1.89	0.76–4.71	0.170
Surgery >2 hrs	1.68	0.73–3.86	0.222

Subgroup or Stratified Analyses

The highest SSI rate (28.5 %) was indicated by stratified analysis, which was observed in patients having both diabetes and open fractures. The rate of infection was high (32%) among diabetic patients who had to pass through more than two hours of procedures. On the other hand, the infection rates were low among patients who did not have diabetes or open wounds compared at 8.8%. Table 5 shows higher SSI rates when risk factors are superimposed, and the highest numbers were for diabetes and when lengthy surgery was involved. The lowest infection rate was in those who did not have diabetes or open fractures, showing the compounding effect of numerous risk factors.

Table 5: Stratified Analysis of Infection Rates by Risk Profile

Subgroup	SSI Incidence	Total Patients	Percentage (%)
Diabetes + Open Fracture	10	35	28.5%
Diabetes without Open Fracture	6	28	21.4%
No Diabetes, No Open Fracture	12	137	8.8%
Diabetes + Surgery >2 hrs	8	25	32%

Discussion

The study revealed that the general incidence of surgical site infection of Open Reduction and Internal Fixation (ORIF) of long bone fractures is 14 %, of which 9 % were superficial and 5 % were deep infections. It is important to mention that 78.6 % of the infections were detected within 14 days after the operation, which highlights the fact that it is a critical period when a patient needs to be closely monitored. Tibial and femoral fractures were the most frequent sites of infection, and a higher percentage of SSIs were observed in men compared to women in all analysed locations (Figure 1). Four risk factors of SSI, which were confirmed by the univariate analysis, were diabetes mellitus (OR 3.45, p=0.003), open fractures (OR 2.96, p=0.009), low haemoglobin (<11 g/dL; OR 2.48, p=0.025), and surgery duration of >2 hours (OR 2.15, p=0.049). But the multivariate analysis revealed that diabetes (adjusted OR 2.98, p=0.020) and open fractures (adjusted OR 2.72, p=0.036) were the only factors that remained independent predictors (Table 6). These results indicate that many perioperative factors do increase the risk of infection; however, the most important ones include metabolic dysfunction and weakened barriers of soft tissues. Plain levels also supported this trend as stratified analyses consolidated them. The incidence of SSI in patients with open fractures and diabetes was 28.5% whereas the incidence in the presence of diabetes and surgery lasting >2 hours was 32% which shows an aggregating effect of sequential risk factors (Table 7). On the contrary, non-diabetic patients with non-open wounds were effectively less infected (8.8%), showing the protective effect of metabolic stability and well-intact soft tissue enclosures.

These results are significant to orthopedic trauma care. At the initial level, they emphasize the importance of optimizing diabetic patients before surgery since uncontrolled blood glucose is a risk factor, which may be altered, with proven implications on the postoperative outcomes. Second, careful treatment of open fractures, such as appropriate and early debridement and timing of antibiotic protection, is the main focus in preventing infections. The rate at which the operation takes a very long time and the low level of haemoglobin, though, are not independently significant, also indicating the adequacy of smooth intraoperative processes and correction of anemia during preoperative screening.

The 14 % surgical site infection rate, which was reported in this study, is consistent with the generally accepted rate of 1 to 20 % in trauma cases involving patients who were orthopedically operated on.[16] Other studies made in the past have reported similar findings, indicating that diabetes and open fractures are major risk factors for infection.[17] The impact of long-term operations and low levels of haemoglobin has also been emphasized in earlier studies, with more emphasis being laid on the influence of pre-existing immunosuppressive conditions. Trauma cases are usually processed on an emergency basis with unavoidable risk factors rather than standard surgical settings and well-optimized patients. This study provides an important addition to the evidence base of trauma-specific studies, and this study offers regional evidence of a tertiary hospital setting, which has limited description in the international SSI reporting.

Although this study indicates great insights into the incidence and predictors of SSIs developed after ORIF of long bone fractures, it also shows great grounds for areas that need to be explored. Future research can also be aimed at the investigation of the microbiological profile of pathogens involved in SSIs to have a better understanding of how the choice of prophylactic antibiotics and their duration should be made. Moreover, there should be further follow-ups of long-term outcome consequences after 30-276 days, and especially with the case of deep infections using implants, to determine their influence on the healing of the fractured bone and functional restoration. Another possible predictive factor—the nutritional status, and, in particular, the level of serum albumin, and the experience of the surgical team, should be considered, as well. Besides, conducted on randomized controlled trials, other potential evidence-based guidance approaches to preventing infection may include testing particular intervention strategies, including perioperative glycemic control regimes or staged fixation protocols in patients at high risk of the development of fractures. Lastly, integration and validation of tools or scoring systems of predictive modeling or infection risk based on the population characteristics of orthopedic trauma patients may allow real-time, patient risk-specific stratification and realize more patient-specific surgical care paths.

Conclusion

The risk factors for SSIs (noted 78.6 % within 14 days after surgery) are the early phase after surgery, diabetes mellitus, the presence of open fractures, contamination of the wound, and prolonged duration of surgery. To minimize the risk of SSIs, preoperative glycemic optimization, careful management of open wounds, and protocolized programs of early postoperative wound checkup must be put in priority. Another area of concern noted by the study is the need to keep probing into the other modifiable risk factors, such as nutritional status and intraoperative practices.

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