

Incidence of surgical-site infection following open reduction and internal fixation of a distal femur fracture

An observational case–control study

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Abstract

Surgical-site infection (SSI) is a common complication in orthopedic surgery; however, SSI after surgically managed distal femur fractures was not well studied. The aim of this study was to investigate the incidence of SSI and identify some modifiable and nonmodifiable risk factors.

The patients' electronic medical records (EMRs) were reviewed to identify those who sustained a distal femur fracture and treated by open reduction and internal fixation (ORIF) between March 2014 and February 2018. SSI was defined based on the Centers for Disease Control criteria and confirmed according to the descriptions in EMR. Univariate and multivariate logistic regression models were used to determine the independent risk factors associated with SSI.

Totally, EMRs of 665 patients who underwent ORIF of distal femur fractures were reviewed and 24 SSIs were found, indicating the overall incidence of SSI was 3.6%. The rate of deep SSI was 1.2% and superficial SSI was 2.4%. *Staphylococcus aureus* was the most common causative pathogen, either alone (7/15, 46.7%) or as a mixed infection (3/15, 20%), followed by mixed bacterial (4/15, 26.7%) and *S epidermidis* (2/15, 13.3%) and others. Patients with SSI had approximately twice the length of hospital stay as those without SSIs (29.0 vs 16.0 days, $P < .001$). Open fracture, temporary use of external fixation, obesity, smoking, diabetes mellitus, and preoperative reduced albumin level were identified as independent risk factors associated with SSI, and current smoking and preoperative reduced albumin level were the true modifiable factors.

Patients should be encouraged to cease smoking as early as possible and increase the good-quality protein intake to reduce or prevent the occurrence of SSI. An explanation of the nonmodifiable risk factors should be included when patients are counseled about their increased risk of SSI.

Abbreviations: ALB = albumin, ASA = American Society of Anesthesiologists, BMI = body mass index, CDC = Centers for Disease Control, EMRs = electronic medical records, HGB = hemoglobin, LYM = lymphocyte, NEUT = neutrophile granulocyte, ORIF = open reduction and internal fixation, PLT = platelet, RBC = red blood cell, SSI = surgical-site infection, TP = total protein, WBC = white blood cell.

Keywords: distal femur fracture, open reduction and internal fixation, reduced albumin level, risk factors, smoking, surgical-site infection

1. Introduction

Surgical-site infection (SSI) represents a very common complication in orthopedic operations of various types, including internal

fixation of fractures,^[1–3] arthroplasty for intra-articular fracture, severe osteoarthritis, ischemic osteonecrosis or tumor removal,^[4–6] correction and fixation of congenital deformities or degenerative diseases.^[7,8] Depending on the definitions of SSI, type of operation, location of operation and the study design, the SSI incidence was reported to vary widely. Anyhow, orthopedic SSIs prolong the total hospital stays by 7 to 14 days per patient,^[9,10] double readmission rates, and increase healthcare costs by 3 times.^[11] In addition, SSIs, especially following intra-articular fractures, are always associated with joint stiffness, traumatic osteoarthritis, and formation of heterotopic ossification and the resultant functional restrictions.^[11–13]

The primary task of epidemiologic study is to explore and identify the associated risk factors for 1 clinical event. With these risk factors, we could construct the risk prediction model, thereby, screen out patients who are at high risk and will benefit most from the given targeted interventions. From the perspective of cost performance, it is a most simple and cost-effective measure to reduce or prevent SSI. Although numerous studies have assessed risk factors associated with SSI following traumatic orthopedic surgeries, very few of them focused on distal femur fractures. A major reason for this is the rarity of this type of

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fracture, which accounts for only 4.0% of all femoral fractures^[14,15] and <1% of fractures in adults.^[14] Even so, we should not neglect these injuries, because over 50% of them involved the articular surface^[14] and if not well-managed, they would have a destructive consequence on the function of the knee.

The gold standard of treatment of distal femur fractures is open reduction and internal fixation (ORIF) by metal plates and screws. However, patients who undergo this surgery will have a relatively high rate of SSIs,^[15,16] most likely due to the soft-tissue damage upon the accident, fracture severity, systematic comorbidities, tissue dissection during operation, wound contamination, and other patient- or surgery-related factors. In the latter study, Hoffmann et al^[16] evaluated 106 patients who underwent locked plating for treatment of distal femoral fractures, and found 9 SSIs, including 8 deep infections and 1 superficial infection; they also identified open injury and current smoking as the associated risk factors. Except for this, we have not found other studies for investigation of risk factors associated with SSI following ORIF of a distal femur fracture.

Given that, we conducted this study, based on our experience to treat distal femur fractures. The main aims of this study were to: determine the incidence of SSIs following ORIF of distal femur fractures; determine whether modifiable and nonmodifiable risk factors were associated with the development of SSIs. A better understanding of the modifiable and nonmodifiable risk factors would aid in counseling patients and contribute to improved practices.

2. Patients and methods

2.1. Inclusion and exclusion criteria

This study was approved by the Institutional Review Board of the 3rd Hospital of Hebei Medical University (no: 2018-012-1). This is an academic hospital, equipped with over 1200-beds in the department of orthopedics and the occupancy rate was 150% in the last 5 years. The number of the orthopedic operations was about 40,000 each year, which allowed evaluation of some uncommon cases. In this study, we set the review period as 4 years, from March 2014 to February 2018. All patients aged 18 or older with acute distal femur fractures (AO/OTA 33) treated by ORIF with screws/plates or only screws were included. The exclusion criteria were as follows: age <18 years, pathologic fractures, metastatic fracture, patients who had implant removal only, patients who underwent surgical treatment of distal femur fracture at an outside hospital or who presented with SSI after being treated at another hospital, and those with incomplete data.

2.2. Variables of interest and definition

Two researchers (YB and BZ), not involved in the patients' care, reviewed the patients' electronic medical records (EMRs), radiographs, and operative reports for data collection. Demographics and preoperative data included: gender, age, height, weight, living places (rural or urban), injury mechanism, affected side, injury type (closed or open), fracture type according to AO/OTA classification system, coexisting injuries, lifestyles (smoking, alcohol consumption), comorbidities (diabetes mellitus, hypertension, and cardiac disease), and chronic steroid use. Surgery-related data included the preoperative stay (days), American Society of Anesthesiologists (ASA) score, anesthesia type (regional, general, or combination), wound classification (I, clean; II, clean-contaminated; III, contaminated; IV, infected-dirty), the solution used to clean and prepare the

skin, attending surgeon, temporary use of external fixation before definitive surgery, prophylactic use of antibiotics, intraoperative blood loss, postoperative use of antibiotics, and postoperative drainage tube use. We also documented the values of biochemistry indexes within preoperative 24 hours, and accordingly divided them into normal, above normal and below normal. These variables included white blood cell (WBC) count, neutrophile granulocyte (NEUT) count, lymphocyte (LYM) count, red blood cell (RBC) count, hemoglobin (HGB) level, platelet (PLT) count, serum total protein (TP) level, and albumin (ALB) value.

Coexisting injuries were defined as trauma to more than 1 system, among musculoskeletal, cardiothoracic, abdominal urogenital, and central nervous systems, and the summed digital (1, 2, 3, etc) was used to indicate the injury severity. Body mass index (BMI, kg/m²) was divided into obesity (≥ 28.0) and nonobesity (< 28.0), based on the reference criteria suited to the Chinese populations. Preoperative stay was defined as the time interval between the injury and the surgery, and was divided into 2 groups: group 1, <7 days and group 2, ≥ 7 days. Injury mechanism was classified as low-energy (fall from standing height) and high-energy (fall from height, traffic incident, mechanical injuries, and others). ASA was grouped into: I, normal healthy patient; II, mild systemic disease; III, severe systemic disease; IV, severe systemic disease that threatens life; V, moribund patient who is not expected to survive without the operation.^[17] The solution to prepare the skin for surgery was defined as soap, followed by alcohol, iodine or others.

2.3. Definition of SSI and the variables

The SSI was defined on basis of Centers for Disease Control (CDC) and Prevention criteria.^[18] Deep SSI was defined as an infection that involved deeper soft tissues within the 1st postoperative year (deep SSI), when an implant was left in place. In the EMRs, the signs or symptoms for SSIs might be described as follows: persistent wound discharge or dehiscence, visible abscess or gangrenosis requiring surgical debridement, and implant exchange or removal. Superficial SSI was defined as an infection that involved only skin and subcutaneous tissues of the incision within 30 days after the operation (superficial SSI), regardless of presence of an implant. SSI that resolved with a single course of oral antibiotics or physiotherapy for wound problems (pain or tenderness, localised swelling, redness, or heat) but did not meet the criteria for deep infection was deemed to be a superficial SSI.

2.4. Statistical analysis

Mann-Whitney *U* test was used to compare total hospital stays between SSI and non-SSI groups. Univariate logistic analysis was used to evaluate the association of each categorical variable with the risk of SSI. Significant ($P < .05$) or near-significant variables ($P < .2$) identified in the univariate analysis were further entered into the multivariate logistic regression model to determine the adjusted results. A stepwise backward elimination method was used to exclude confounding covariates, and variables with a $P < .05$ retained at the final models. Odds ratio (OR) and 95% confidence interval (95% CI) were used to indicate the correlation between variables and SSI risk. The goodness-of-fit of the final multivariate regression model was evaluated by the Hosmer-Lemeshow test, with a $P > .05$ being an acceptable result and larger *P*-value meaning better fitness and reliability. All statistical analyses were performed by SPSS19.0 (IBM, Armonk, NY).

3. Results

During the 4-year observation period, a total of 1037 patients with distal femur fractures were admitted for surgical treatment. After our strict inclusion and exclusion criteria, 372 patients were excluded, leaving 665 patients (665 cases of distal femur fractures) eligible for data extraction and analysis. There were 372 men and 293 females, with the average age of 49.4 ± 15.7 years (range, 18–77 years). There were 57 (8.6%) cases of open fractures, and 67 (10.0%) patients had coinjuries of other systems. Based on the AO/OTA classification system, there were 299 type A, 153 type B and 213 type C fractures of distal femur. Over 70% (73.1, 486/665) of the patients could be operated within 1 week, and the mean preoperative stay was 6.2 ± 5.5 days (range, 0–37 days). The total hospital stay in SSI group was 16.5 days in average (standard deviation, 9.6 days), with 16.0 days in those non-SSI patients and 29.0 days in those SSI patients; and the difference was statistically significant ($P < .001$).

3.1. SSI characteristics

There were 24 cases of SSIs, indicating an accumulated incidence of 3.6% (24/665) (95% CI, 2.2–5.0%). Of them, 19 cases of SSIs were found during patients' initial hospitalization for treatment of distal femur fractures; and the remaining 5 cases were confirmed when patients were readmitted for treatment of SSIs. There were 8 deep and 16 superficial SSIs, indicating the respective incidence being 1.2% (95% CI, 0.4–2.0%) and 2.4% (95% CI, 1.2–3.6%). The earliest diagnosis of SSI was at the 4th day while the latest was at the 142th day postsurgery, with median time of 11.5 days. Swabs from wound of 15 cases of SSIs (6 deep and 9 superficial SSIs) were cultured positive for bacterial species. *Staphylococcus aureus* was the most common causative bacteria, either alone (7, 46.7%) or as a mixed infection (3, 20%), followed by mixed bacterial (4, 26.7%) and *S epidermidis* (2, 13.3%) and others.

3.2. Univariate and multivariate analysis

Table 1 presents the results of univariate analysis for the categorical variables. Obesity, chronic steroid use, diabetes mellitus, open fracture, smoking, wound class, and use of temporary external fixation before definitive fixation were demonstrated to be significantly associated with SSI occurrence, and were to be entered into the multivariate logistic regression model. In addition, some approximately significant variables ($P < .20$) including cardiac disease, history of previous operation at any site, coinjuries ≥ 2 systems, prophylactic use of antibiotics, RBC, HGB, platelet, and ALB were identified, and were entered into the multivariate logistic regression model.

Table 2 presents the results of the multivariate logistic regression analysis. We identified 6 factors that were significantly associated with SSI: open fracture (OR, 5.2; $P < .001$), temporary external fixation (OR, 2.4; $P = .005$), obesity (OR, 3.2; $P = .002$), current smoking (OR, 2.8; $P = .021$), diabetes mellitus (OR, 2.2; $P = .004$), and preoperative reduced ALB (<35 g/L). Of them, smoking and preoperative reduced ALB level were modifiable factors. The final multivariate predictive model of SSI was reliable (Hosmer–Lemeshow test, $X^2 = 3.94$, $P = .656$).

4. Discussion

By far, there remains scarce of data on epidemiologic characteristics of SSI following an operated distal femur fracture. With 665

Table 1

Univariate analysis of variables potentially associated with surgical-site infection (SSI).

Variables	Number (%) of patients without SSI (n=641)	Number (%) of patients with SSI (n=24)	P
Gender (males)	357 (55.7)	15 (62.5)	.510
Age, yr			.669
18–45	323 (50.4)	10 (41.7)	
45–64	263 (41.0)	12 (50.0)	
≥65	55 (8.6)	2 (8.3)	
Living place (rural)	373 (58.2)	13 (54.2)	.695*
Obesity (BMI ≥ 28.0)	127 (19.8)	9 (37.5)	.035*
Diabetes mellitus	58 (9.0)	7 (29.2)	.001*
Hypertension	141 (22.0)	6 (25.0)	.728
Cardiac disease	37 (5.8)	3 (12.5)	.174
Chronic steroid use	29 (4.5)	4 (16.7)	.007*
History of previous operation at any site	93 (14.5)	6 (25.0)	.156*
Smoking	138 (21.5)	10 (41.7)	.020*
Alcohol consumption	252 (39.3)	11 (45.8)	.521*
Open fracture	51 (8.0)	6 (25.0)	.003*
Mechanism (high energy)	497 (77.5)	20 (83.3)	.503
Side (left)	326 (50.9)	14 (58.3)	.472
Fracture type			.880
AO type A	287 (44.8)	12 (50.0)	
AO type B	148 (23.1)	5 (20.8)	
AO type C	206 (32.1)	7 (29.2)	
Coinjuries (≥2 system)	63 (9.8)	4 (16.7)	.085
Preoperative stay (≥7 d)	171 (26.7)	8 (33.3)	.470
Surgeon level (chief)	532 (83.0)	19 (79.2)	.625
Wound class			.001*
I–II	596 (93.0)	18 (75)	
III–IV	45 (7.0)	6 (25)	
ASA class			.275
I–II	557 (86.9)	19 (79.2)	
III–IV	84 (13.1)	5 (20.8)	
Anesthesia			.621
General	193 (30.1)	5 (20.8)	
Local anesthesia	402 (62.7)	17 (70.8)	
Combined anesthesia	46 (7.2)	2 (8.3)	
Solution to prepare the skin			.497
Alcohol	292 (45.6)	8 (33.3)	
Iodine	328 (51.2)	15 (62.5)	
Others	21 (3.3)	1 (4.2)	
Temporary external fixation use	89 (13.9)	7 (29.2)	.036*
Prophylactic antibiotics use	621 (96.9)	22 (91.7)	.186
Postoperative antibiotics use	592 (92.4)	21 (87.5)	.384
Drainage use	478 (74.6)	18 (75.0)	.962
Intraoperative blood loss (≥400 mL)	202 (31.5)	7 (29.2)	
Surgical duration			.995
<90 min	102 (15.9)	4 (16.7)	
90–150 min	459 (71.6)	17 (70.8)	
>150	80 (12.5)	3 (12.5)	
WBC (10 ⁹ /L)			.228
References (4–10)	504 (78.6)	17 (70.8)	
<4	52 (8.1)	1 (4.2)	
>10	85 (13.3)	6 (25.0)	
NEUT (10 ⁹ /L)			.576
References (1.8–6.3)	487 (76.0)	16 (66.7)	
<1.8	41 (6.4)	2 (8.3)	
>6.3	113 (17.6)	6 (25)	
LYM (10 ⁹ /L)			.373
References (1.1–3.2)	528 (82.4)	19 (79.2)	
<1.8	27 (4.2)	0	
>3.2	86 (13.4)	5 (20.8)	
RBC (10 ¹² /L)			.157
References [†]	532 (83.0)	17 (70.8)	
<Lower limit	76 (11.9)	6 (25.0)	
>Upper limit	33 (5.1)	1 (4.2)	
HGB			.185
References [‡]	540 (84.2)	17 (70.8)	
<Lower limit	64 (10.0)	5 (20.8)	
>Upper limit	37 (5.8)	2 (8.3)	
Plt			.142
References (100–300 × 10 ⁹ /L)	584 (91.1)	19 (79.2)	
<Lower limit	22 (3.4)	2 (8.3)	
>Upper limit	35 (5.5)	3 (12.5)	
TP (<60 g/L)	104 (16.2)	6 (25.0)	.256
ALB (<35 g/L)	117 (18.3)	8 (33.3)	.063

ALB = albumin, ASA = American Society of Anesthesiologists, BMI = body mass index, HGB = hemoglobin, LYM = lymphocyte, NEUT = neutrophil granulocyte, Plt = platelet, RBC = red blood cell, TP = total protein, WBC = white blood cell.

* Significant variable.

[†] Reference range: female, 3.5–5.0/10¹²; males, 4.0–5.5/10¹².

[‡] Reference range: females, 110–150 g/L; males, 120–160 g/L.

Table 2**Significant risk factors associated with surgical-site infection after adjustment of confounding variables.**

Variable	Multivariable logistic regression model	
	Adjusted OR (95% CI)	P
Open fracture	5.2 (2.1–9.0)	<.001
Temporary external fixation	2.4 (1.2–6.2)	.005
Obesity (BMI \geq 28.0 kg/m ²)	3.2 (1.7–7.4)	.002
Smoking	2.8 (1.1–6.5)	.021
Diabetes mellitus	2.2 (1.3–4.2)	.004
Preoperative ALB <35 g/L	1.9 (1.0–5.8)	.037

ALB=albumin, BMI=body mass index, CI=confidence interval, OR=odds ratio.

fractures included, this study demonstrated the overall incidence of SSI following ORIF of a distal femur fracture was 3.6% (deep, 1.2%; superficial, 2.4%); the modifiable risk factors were smoking and preoperative reduced ALB level and the nonmodifiable ones were open fracture, temporary external fixation, obesity (BMI \geq 28.0) and diabetes mellitus, respectively. *Staphylococcus aureus* was the most common causative bacterium for SSI, closely followed by mixed bacterial infections. We found patients with SSI had approximately twice the mean length of hospital stay as those without SSIs (29.0 vs 16.0 days, $P < .001$).

The incidence of SSI following orthopedic surgery varied, depending on the definition criteria of SSI, study design, and treatment modalities. We found a 3.6% incidence of SSI after ORIF of a distal femur fracture, which was in range with data reported by the National Nosocomial Infections Surveillance for orthopedic patients^[19] and other studies for evaluating traumatic fractures of tibial plateau,^[20] ankle,^[21] or calcaneus.^[22] Regarding distal femur fracture, there was lack of similarly well-studied data; instead, most researchers gave only passing mention to the SSI incidence. For example, Downs et al^[23] and Jain et al^[24] reported the incidence of SSI after surgical distal femur fractures was 0.1–11.2%, in their book or article. Hoffmann et al^[16] also found 9 SSIs in 106 patients of distal femur fractures treated by locked plates and screws, indicating an incidence of 8.5%, which was more than twice as ours.

Open fracture and diabetes have also been identified as strong nonmodifiable risk factors associated with SSI, consistent with most studies.^[20,21,25] Undoubtedly, the high-energy mechanism and the resultant serious soft-tissue damage and poor blood supply contribute to a greater risk of SSI. Although contaminated or dirty wound is known to represent a well-established risk factor for SSI in various surgical fields, in this study, it was not a significant result in the multivariate model. We hypothesize that the effect of wound contamination or dirtiness was covered by the stronger risk factors, such as open fracture, because both variables have much overlapping effect on SSI. We used the medical history section of patients' EMR to identify the diabetic status, but did not account for the level of glycemic control. Gulcelik et al^[26] also suggested elevated HbA1c level was an important index factor in patients with diabetes, for predicting SSI or even death. Despite the crude binary classification, diabetes was identified as a strong risk factor for SS; however, we might underestimate the impact of poor glycemic level on SSI development, because not all diabetes patients had a higher HbA1c level.

Temporary external fixation and obesity (BMI > 28.0 kg/m²) were nonmodifiable in emergent or elective trauma surgeries. On one hand, it is almost impossible to adjust or modify our patients' BMI in several or a dozen days before the surgery. On the other hand, obesity might also be a mixed factor that contributed to the

increased risk of SSI. Besides its direct negative effect on SSIs, obesity was reported to be significantly associated with multiple surgery-related variables or morbidities, such as postoperative venous thromboembolism, increased intraoperative blood loss, longer surgical time, diabetes, or cardiac diseases,^[27–29] which were also important contributors for development of SSI. The fact that use of temporary external fixation was associated with increased SSI risk did not implicate the external fixation itself, but more likely indicated the soft-tissue damage or soft-tissue problems. In other words, if Gustilo–Anderson classification for severity of soft tissues/bone as 1 variable is entered into the multivariate regression model, the results might be very likely different. Accordingly, we believe both risk factors reflect patient medical conditions or trauma severity, rather than factors amenable to intervention.

Smoking and preoperative reduced ALB were identified as the modifiable risk factors, which was consistent with most previous findings.^[30–33] The mechanism that smoking increases the risk of SSI is related to reduced tissue perfusion and oxygenation and impaired inflammatory response.^[30,31] Otherwise, temporary smoking cessation before the surgery could significantly reduce the risk of SSI. In a subgroup meta-analysis of 4 randomized controlled trials, authors found smoking cessation intervention was associated with 57% reduced risk of SSI.^[32] Another meta-analysis of 25 studies showed smokers who quit smoking several weeks before surgery had reduced risk of wound-healing complications by 31% and respiratory complications by 23%, compared to current smokers. In our clinical practices, patients will be proactively informed of the harm of smoking on wound healing and the benefits from immediate smoking cessation upon their admission to our center; smokers are encouraged to cease smoking as early as possible before the surgery. In a meta-analysis of 13 studies including over 112,000 orthopedic patients, Yuwen et al^[33] found perioperative serum ALB < 35 g/L was associated with 2.5-fold increased risk of SSI. Buteera^[34] advised preoperative supplementation to increase ALB levels before elective surgery, and ALB > 30 g/L was demonstrated to promote adequate healing.

There are several limitations that should be mentioned in this study. The 1st was the retrospective nature. We were not able to evaluate the impact of some important variables on SSI, such as the flow of operating room personnel and visitors and air cleanliness of the operating room, which had been reported to be associated with bacterial colonization and loading.^[35] We were not able to analyze some of the identified variables, such as daily amount of cigarettes and the days for use of temporary external fixation before the definitive fixation. The 2nd was merely relying on the EMR to collect data, which may weaken the reliability of data. The 3rd limitation involved the single-center design. Our orthopedic center represents a tertiary referral center, providing the highest treatment level for traumatic fractures in Hebei province with a catchment population over 75 million. Therefore, patients admitted frequently presented with more severe or refractory fractures, which likely resulted in a selection bias. Third, the postoperative 1-year for surveillance of SSI was not mandatory. We assumed a patient who was not diagnosed with an infection during hospitalization stay and did not return specifically for treatment of SSIs in the next 12 months did not have a SSI. As such, some patients with slight superficial SSI which resolved by physical therapy or oral antibiotics might not to be readmitted for treatment. Therefore, some patients suffering from subacute SSI might have been missed.

In conclusion, we found the incidence of SSI following ORIF of a distal femur fracture was 3.6%. Six independent risk factors

were identified, including open fracture, temporary use of external fixation, current smoking, obesity, diabetes mellitus, and preoperative ALB level <35 g/L. Of them, current smoking and preoperative reduced ALB level were the true modifiable factors, and patients should be encouraged to cease smoking as early as possible and to increase the good-quality protein intake to reduce or prevent the SSI occurrence. An explanation of the nonmodifiable risk factors should be included when patients are counseled about their increased risk of SSI.

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Author contributions

Bing Zhang designed the study; Xiong Zhang and Ye Tian abstracted and documented the data; Yanbin Bai and Dehu Tian analyzed and interpreted the data; Yanbin Bai and Xiong Zhang wrote the manuscript and Bing Zhang approved the final version of the manuscript.

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