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ORIGINAL ARTICLE

Incidence and risk factors for surgical site infection after open reduction and internal fixation of intra-articular fractures of distal femur: A multicentre study

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There remains a lack of data on the epidemiological characteristics of surgical site infection (SSI) following the open reduction and internal fixation (ORIF) of intra-articular fractures of distal femur, and the aim of this study was to solve this key clinical issue. The electronic medical records (EMRs) of patients who underwent ORIF for distal femoral fracture from January 2013 to December 2017 were reviewed to identify those who developed a SSI. Then, we conducted univariate Chi-square analyses and used a multivariate logistic regression analysis model to determine the adjusted risk factors associated with SSI. A total of 724 patients who underwent ORIF of intra-articular fractures of the distal femur were studied retrospectively, and 29 patients had postoperative SSIs. The overall incidence of SSIs was 4.0% (29/724), with deep SSIs being 1.5% (11/724), and superficial SSIs being 2.5% (18/724). *Staphylococcus aureus* was the most common causative pathogen (8, 42.1%), followed by mixed bacterial pathogens (5, 26.3%). Open fracture, obesity, smoking, and diabetes mellitus were identified as the adjusted risk factors associated with SSIs. Although modification of these risk factors may be difficult, patients and families should be counselled regarding their increased risk of SSI because these patients potentially benefit from focused perioperative medical optimisation.

KEYWORDS
distal femoral fracture, ORIF, risk factors, surgical site infection

1 | INTRODUCTION

Fracture of the distal femur is relatively uncommon in traumatic orthopaedics, accounting for 4.0% to 8.7% of all femoral fractures and less than 1% of all fractures in adults.[1,2] However, about 50% of the distal femur fractures involved the articular surface[1], and if not well managed, they would impose a catastrophic consequence on the function of the knee. The gold standard of treatment of these intra-articular fractures was open reduction and internal fixation (ORIF) by metal plates and screws. However, excessive soft tissue dissection during operation further impaired the already damaged soft tissue, possibly resulting in complications related to surgical incision site and bone union.

Surgical site infection (SSI) is one of the most common complications in orthopaedic surgery, and its incidence was reported to vary greatly[3–5] depending on the definitions of infection, fracture locations and sites, surgical patterns, and the study design. SSIs incresed the possibility of abscess formation, osteomyelitis, and bone union problems, which might have long-term negative effects on the mobility of the unjured limbs or articular joints.[6] On the other hand, postoperative SSIs substantially increased the total medical costs because of secondary surgery or antibiotic treatment and prolonged hospitalisation stay by 7 to 14 days.[4,7] Therefore, identification of the associated risk factors and their use in

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the comprehensive assessment of patients' susceptibility to SSIs, thereby screening patients at risk, could be a simple and cost-effective measure to reduce or prevent SSI occurrence.

By far, the epidemiological characteristics of SSIs following ORIF of a distal femur fracture have not been not well studied. SSI incidence after internal fixation of distal femoral fractures was reported to vary greatly, from 0.3% to 11.2%,[3] and the most risk factors that had been identified were not inconclusive. Hoffmann et al[6] evaluated 106 patients who underwent locked plating treatment for distal femoral fractures and found nine SSIs, including eight deep infections and one superficial infection; they also identified open injury and current smoking as associated risk factors. However, other potential risk factors could not be investigated in their study. One major reason for this is that, in a single non-specialised hospital, the minimal number of SSI cases makes it very difficult to allow a significant statistical result to be obtained for one potential risk factor, known as a type II statistical error.

Given this information, we conducted this retrospective multicentre study to assess the SSIs following ORIF of intra-articular fractures of the distal femur. In this study, our objective was, first, to investigate the incidence of SSIs following ORIF of distal femoral fractures and, second, to identify some risk factors associated with SSIs.

Key Messages

- Surgical site infection (SSI) incidence after open reduction and internal fixation of a distal femur fracture was 4.0%, with deep SSIs of 1.5% and superficial SSIs of 2.5%
- *Staphylococcus aureus* remains the most common causative pathogen (42.1%), followed by mixed bacterial pathogens (26.3%)
- open fracture, obesity, smoking, and diabetes mellitus were identified as the adjusted risk factors associated with the SSI

2 | PATIENTS AND METHODS

2.1 | Inclusion and exclusion criteria

This study was approved by the Institutional Review Board of the three level I centres: the General Hospital of Jizhong Energy Xingtai Mining Group, the Cangzhou Central Hospital, and No.153 Hospital of the Chinese People' Liberation, before it began. All patients who were aged 16 or older with acute intra-articular fractures of distal femur treated by ORIF with metal plates and screws from January 2013 to December 2017 were included in this study. The exclusion criteria were as follows: age less than 16 years old, old fractures (>21 days from initial injury), pathological fractures, and admission for treatment of SSIs at another hospital. Patients with open fractures or with multiple injuries were also included in order to evaluate their influence on SSIs.

2.2 | Variables of interest

Three researchers (the first three authors from three different hospitals) acquired the patients' electronic medical records (EMRs) for data collection. Demographic and preoperative data included: gender, age, height, weight, living places (rural or urban), injury mechanism, injury type (closed or open), fracture type according to Arbeitsgemeinschaftfür Osteosynthesefragen/Orthopaedic Trauma Association (AO/OTA) classification system (type B or C), affected side, coexisting injuries, lifestyles (smoking, alcohol consumption), and morbidities (diabetes mellitus, hypertension, and coronary heart disease). Surgery-related data included American Society of Anesthesiologists (ASA), intraoperative blood loss and the subgroups (≥400 mL; <400 mL), prophylactic use of antibiotic, postoperative use of antibiotic, anaesthesia type (regional, general or combination), incision classification (clean, clean-contaminated, contaminated, infected), and postoperative drainage tube use. We also documented the values of biochemistry indices within preoperative 24 hours and accordingly divided them into normal (a range), above normal, and below normal. These variables included white blood cell (WBC), neutrophile granulocyte (NEUT), lymphocyte (LYM), red blood cell (RBC), haemoglobin (HGB), platelet (PLT), serum total protein (TP), albumin (ALB), and globulin (GLOB).

2.3 | Definition of SSI and the variables

Body mass index (BMI, kg/m^2) was calculated as weight divided by the square of height and was divided into five subgroups: underweight, <18.5; normal, 18.5 to 23.9; overweight, 24 to 27.9; obesity, 28 to 31.9; morbid obesity; 32 and higher, based on the reference criteria suited to the Chinese populations. Preoperative stay was defined as the time interval between the injury and the ORIF and was divided into two groups: 1, <7 days and 2, ≥7 days. Injury mechanism was classified as low-energy (fall from standing height) and high-energy (falls from height, traffic accidents, mechanical injuries, and others).

An SSI was defined with reference to the CDC criteria[11] and was confirmed based on the descriptions in the EMRs. A deep infection was defined as an infection that met any one of the following criteria: infection surpassing the deep fascia, persistent wound discharge or dehiscence, visible abscess or gangrenosis requiring surgical debridement, and implant exchange or removal. Any patient who underwent antibiotic treatment for wound problems (redness, swelling, hot, pain) but did not meet the criteria for deep infection was deemed to have a superficial SSI, irrespective of any microbiology results.

2.4 | Statistical analysis

A Whitney *U* test or *t* test was used to compare continuous variables between SSI and non-SSI groups depending on the equal variance and normality distribution status. Univariate logistic analysis was used to evaluate the relationship between each categorical variable and the risk of SSI. Factors found to be approximately significant ($P < 0.2$) in the univariate analysis were entered into the multivariate logistic regression analysis model to determine adjusted results. A stepwise backward elimination approach was used to exclude confounding covariates from the final models. Covariates were retained in the final model if $P \leq 0.10$. Odd ratio (OR) and 95% confidence interval (95% CI) were used to indicate the correlation magnitude between variables and SSI risk. A *P* value less than 0.05 was considered statistically significant. The Hosmer-Lemeshow test was performed to examine goodness of fit of the final model, and a $P > 0.05$ indicated an acceptable fitness. All statistical analyses were performed by SPSS19.0 (SPSS Inc., Chicago, Illinois). Permission was obtained from the Institutional Review Board.

3 | RESULTS

From January 2013 to December 2017, a total of 895 patients with intra-articular fractures of distal femur were admitted for surgical treatment; 157 patients were excluded because of age, fracture cause, incomplete medical data, and others, and 14 patients who died from related complications or system organ failure were also excluded. Finally, 724 patients treated by ORIF with metal plates and screws met the inclusion criteria and were included for data analysis. There were 406 males and 318 females, with an average age of 47.5 ± 15 years (range, 16-74 years); there were 378 cases involving the left side and 346 cases involving the right side; there were 68 (9.4%) open fractures. According to the AO/OTA classification system, there were 293 cases of type B and 431 cases of type C fractures. The mean preoperative stay (between initial and operation) was 5.5 ± 6 days (range, 0-19 days), and over 80% of the patients were operated within 1 week. The mean total hospital stay for the initial treatment of the fracture was 15.4 ± 11.5 days (range, 4-115 days).

3.1 | SSI characteristics

During patients' hospitalisation stay for treatment of fractures, there were 22 SSIs, including 7 deep SSIs and 15 superficial SSIs; after discharge, seven patients were admitted again for treatment of SSIs, including 4 deep and 3 superficial SSIs. Therefore, the overall incidence of SSI was 4.0% (29/724), with deep SSIs being 1.5% (11/724) and superficial SSIs being 2.5% (18/724). The earliest diagnosis of SSI was at the third day, while the latest was at the 127th day after surgery, with median time of 8 days. Swabs from the wounds of 11 cases of deep SSIs and 9 superficial SSIs were cultured for bacterial species, and the results showed that *Staphylococcus aureus* (methicillin-resistant *S. aureus* in 2 cases) was the most common causative pathogen (8, 42.1%), followed by mixed bacterial (5, 26.3%), *Staphylococcus epidermidis* (3, 15.8%), *Pseudomonas aeruginosa* (1, 5.3%), and others.

3.2 | Univariate and multivariate analysis

Table 1 presents a comparison of the results of several continuous variables between both groups. There was no significant difference with regards to age between the patients of SSI and non-SSI groups (46.0 vs 47.6 years). Patients with SSI appeared to wait a longer time before the surgery, but the difference was not significant ($P = 0.062$). In addition, intraoperative blood loss was not significantly different. The operation duration was 137 minutes on average for those with SSI, significantly longer than for those without SSI ($P = 0.009$). There was a significant difference in hospital stay between both groups (15.0 vs 24.6 days) ($P < 0.001$).

Table 2 shows that injury type, BMI, smoking, incision cleanliness, and diabetes mellitus were found to be significantly associated with SSI occurrence, and then, they were entered into the multivariate logistic regression model. In addition, other factors, including coronary heart disease, history of previous operation at any site, concurrent injuries, ASA, LYM, RBC, and ALB that tested as approximately significant in the univariate analyses, were also entered into the multivariate analysis models.

Table 3 presents the results of the multivariate logistic regression analysis. Open fracture, obesity, smoking, and diabetes mellitus were identified as the adjusted risk factors associated with SSIs. The results of the Hosmer-Lemeshow test demonstrated adequate fitness ($X^2 = 4.316$, $P = 0.552$).

4 | DISCUSSION

Knowledge of epidemiological characteristics of SSI following orthopaedic surgery is the primary task for efforts to

TABLE 1 Comparison of continuous variables between patients with and without SSI

Variables	Patient without SSI (mean ± SD, range) (*n* = 695)	Patient with SSI (mean ± SD, range) (*n* = 29)	*P*
Age (years)	47.6 ± 18.5 (16-74)	46.0 ± 16.0 (19-64)	0.164
Preoperative stay (d)	5.5 ± 4.2 (0-17)	6.2 ± 3.5 (0-19)	0.062
Intraoperative blood loss (mL)	240 ± 155 (40-2200)	242 ± 152 (50-2200)	0.648
Operation duration (min)	125 ± 62 (55-320)	137 ± 66 (60-360)	0.009
Hospital stay (d)	15.0 ± 12.8 (5-62)	24.6 ± 21.5 (10-115)	<0.001

Abbreviation: SSI, surgical site infection.

TABLE 2 Univariate analysis of variables of interest

Variables	Number (%) of patients without SSI ($n = 695$)	Number (%) of patients with SSI ($n = 29$)	*P*
Gender (males)	389 (56.0)	17 (58.6)	0.778
Age			0.806
18-45	348 (50.1)	13 (44.8)	
45-59	252 (36.3)	11 (37.9)	
60+	95 (13.7)	5 (17.2)	
Living place (rural)	401 (57.7)	17 (58.6)	0.921
Obesity (BMI ≥ 28.0)	197 (28.3)	17 (58.6)	<0.001*
Diabetes mellitus	62 (8.9)	7 (24.1)	0.006*
Hypertension	121 (17.4)	5 (17.2)	0.981
Coronary heart disease (CHD)	32 (4.6)	3 (10.3)	0.158
History of previous operation at any site	104 (15.0)	7 (24.1)	0.179
Smoking	124 (17.8)	11 (37.9)	0.006*
Alcohol consumption	276 (39.7)	12 (41.4)	0.857
Open fracture	61 (8.8)	7 (24.1)	0.005*
Mechanism (high energy)	528 (76.0)	22 (75.9)	0.989
Side (left)	364 (52.4)	14 (48.3)	0.665
Fracture type			0.516
AO type B	282 (40.5)	11 (34.5)	
AO type C	414 (59.5)	18 (65.5)	
Concurrent injuries (≥1 site)	89 (12.8)	7 (24.1)	0.078
Preoperative stay (<7 days)	559 (80.4)	24 (82.8)	0.757
Surgeon level (chief physician)	577 (83)	23 (79.3)	0.603
Incision cleanliness			0.004*
I-II	649 (93.4)	23 (79.3)	
III-IV	46 (6.6)	6 (20.7)	
ASA			0.147
I-II	576 (82.9)	21 (72.4)	
III-V	119 (17.1)	8 (27.6)	
Anaesthesia type			0.446
General	178 (25.6)	10 (34.5)	
Local anaesthesia	463 (66.6)	18 (62.1)	
Combined anaesthesia	54 (7.8)	1 (3.4)	
Prophylactic antibiotics use	656 (94.4)	22 (75.9)	<0.001*
Postoperative antibiotics use	497 (71.5)	20 (69)	0.766
Drainage use	469 (67.5)	17 (58.6)	0.320
Intraoperative blood loss ≥400 mL	204 (29.4)	8 (27.6)	0.838
Surgical duration	()	()	0.826
<120 minutes	314 (45.2)	12 (41.4)	
120-180 minutes	272 (39.1)	13 (44.8)	
>180	109 (15.7)	4 (13.8)	
WBC (10^9/L)			0.814
References (4-10)	547 (78.7)	24 (82.8)	
<4	42 (6.0)	1 (3.4)	
>10	106 (15.3)	4 (13.8)	
NEUT (10^9/L)			0.613
References (1.8-6.3)	483 (69.5)	18 (62.1)	
<1.8	37 (5.3)	2 (6.9)	
>6.3	175 (25.2)	9 (31.0)	
LYM (10^9/L)			0.173
References (1.1-3.2)	574 (82.6)	20 (69)	
<1.8	67 (9.6)	5 (17.2)	
>3.2	54 (7.8)	4 (13.8)	
RBC (10^{12}/L)			0.094
References	546 (78.6)	19 (65.5)	
<Lower limit	132 (19)	10 (34.5)	
>Upper limit	17 (2.4)	0	
HGB			0.572
References	592 (85.2)	23 (79.3)	
<Lower limit	76 (10.9)	5 (17.2)	
>Upper limit	27 (3.9)	1 (3.4)	
Plt			0.648
References	578 (83.2)	23 (79.3)	
<Lower limit	25 (3.6)	2 (6.9)	
>Upper limit	92 (13.2)	4 (13.8)	
TP (<65 g/L)	88 (12.7)	4 (13.8)	0.858
ALB (<40 g/L)	136 (19.6)	9 (31.0)	0.131
GLOB (<20 g/L)	133 (19.1)	4 (13.8)	0.472

Abbreviations: AO, Arbeitsgemeinschaftfür Osteosynthesefragen; ASA, American Society of Anesthesiologists; ALB, albumin; BMI, body mass index; GLOB, globulin; HGB, haemoglobin, reference range: females, 110-150 g/L; males, 120-160 g/L; NEUT, neutrophile; LYM, lymphocyte; Plt, platelet; RBC, red blood cell, reference range: females, 3.5-5.0/10^{12}; males, 4.0-5.5/10^{12}; SSI, surgical site infection; TP, total protein; WBC, white blood cell.
*Significant variable.

TABLE 3 Multivariate analysis of factors associated with SSI after ORIF of a distal femur fracture

Variables	Exp (B)	95% CI (lower limit)	95% CI (upper limit)	*P*
Open injury	4.62	2.02	11.48	<0.001
Obesity	2.56	1.15	8.24	0.021
Smoking	3.04	1.44	4.63	0.009
Diabetes mellitus	2.17	1.08	5.62	0.037

Abbreviations: CI, confidence interval; ORIF, open reduction and internal fixation; SSI, surgical site infection.

reduce or prevent this complication. However, there was scarce data on the SSIs following ORIF of a distal femur fracture. In this study, over 700 patients from three level 1 trauma centres during a long period (5 years) were included for evaluation. The results showed that the overall incidence of SSI after ORIF of a distal femur fracture was 4.0%, with the incidence of deep SSIs being 1.5% and superficial SSIs being 2.5%; after adjustment for confounding variables, open fracture, obesity (BMI ≥ 28.0), smoking, and diabetes mellitus were identified to be significantly associated with SSIs. We also found that *S. aureus* was the most common causative bacterium for SSI, closely followed by mixed bacterial; patients with an SSI had a significantly longer hospitalisation stay than those without an SSI (24.6 vs 15.0 days).

The incidence of SSI following orthopaedic surgery varied greatly, partially depending on the definition criteria of SSIs. Based on Centers for Disease Control (CDC) criteria, SSI is defined as an infection that occurs within 1 year if an implant was placed.[8] In this study, CDC criteria for the definition of SSI was referred to, but not completely copied, for use, and SSIs were confirmed by our researchers by reviewing the patients' EMRs during their hospitalisation stay for the treatment of initial fractures or the secondary SSIs. Because of the short monitoring period for SSI (maximum, 165 days), there was a certain possibility that patients who underwent ORIF of distal femur fractures in our three centres received treatment of secondary SSIs in other centres. On the other hand, patients with some superficial SSIs like a skin abscess, which could be easily resolved by local wound therapy or oral antibiotics, would not be admitted to hospital to seek medical care. Therefore, the incidence of SSI following ORIF of a distal femur fracture was underestimated.

Open fracture is a well-established risk factor associated with SSIs following orthopaedic surgeries in literature.[9] Undoubtedly, the high-energy mechanism and the resultant serious soft tissue damage, poor blood supply, and significant wound contamination contribute to a greater risk of SSI. In this study, the incidence of SSI following open fracture was 10.3%, about 3-fold that (3.4%) of closed fractures ($P = 0.005$), which is well within the reported literature.[6,10] In a retrospective cohort of 39 patients with open fracture of distal femur treated by locking plates, 7 patients (incidence, 18%) developed SSIs, and it was also found that poor prognosis was directly related to the SSI.[6] Therefore, in the presence of open fractures, surgeons should consult a heightened risk profile; early intravenous administration of antibiotics and adequate debridement should be compulsory.

It is believed that diabetes mellitus and potential for poor glycaemic control plays an important role in the development of SSI following surgeries,[11,12] which was consistent with our finding that diabetes mellitus increased SSI risk by 2.2 times (95% CI, 1.1-5.6). Gulcelik et al[13] also showed that elevated HbA1c level was an important index factor in patients with diabetes mellitus for predicting SSI occurrence or even death. To improve the outcome for these patients, we would recommend early medical input in this patient group to optimise glycaemic control.

Smoking has a significant negative effect on wound union, and the mechanism is related to reduced tissue perfusion and oxygenation, impaired inflammatory response, and oxidative bactericidal mechanisms.[14,15] In the present study, the OR of SSI was three times higher in current smokers that of non-smokers, which is in line with prior studies of orthopaedic surgery.[3,16,17] In a meta-analysis of 140 cohort studies including 479 150 surgical patients, authors found that the pooled adjusted OR for SSI was 1.79 (1.57-2.04) in smokers compared with non-smokers.[18] In addition, the subgroup analysis of four randomised controlled trials showed that smoking cessation intervention was associated with a reduced risk of SSI (57%).[18] Another meta-analysis of 25 studies showed that smokers who quit more than 3 to 4 weeks before surgery had reduced risk of wound-healing complications by 31% and respiratory complications by 23% compared with current smokers. In our clinical practice, patients will be proactively informed of the harm of smoking on wound union and the benefits of immediate smoking cessation on their admission to our centre, and they are encouraged to cease smoking as early as possible before the surgery.

Obesity is of particular importance to orthopaedics surgeons as various studies have described an association between obesity and numerous postoperative complications, including SSIs, sepsis, pulmonary or urethral infections, and even mortality.[19–22] A meta-analysis of 20 original studies showed that obese patients had increased 1.9 times the risk of SSIs following orthopaedic surgeries.[23] In this study, we obtained the consistent finding that obese patients had a 7.9% risk of SSI compared with 2.4% in the non-obese group ($P < 0.001$), and the adjusted OR was 2.56 (95% CI, 1.15-8.24). On one hand, obesity often resulted in prolonged surgical duration and aggravated local tissue trauma, most likely secondary to increased soft tissue dissection, excessive tissue distraction, and difficulty with implant positioning.[21,24,25] On the other hand, adipocytokines and adipose tissues take an active part in inflammation and immune response,[26,27] which predisposes obese patients to infection. Particular attention should be paid by surgeons to the dose of the prophylactic antibiotics. In obese patients, antibiotic serum level may be less adequate because prophylactic antibiotics are always not dose-adjusted to weight.[28] Therefore, adjustment of the dose of prophylactic antibiotics to weight is necessary in obese patients with traumatic injuries, especially a complex injury requiring extended surgical time.

The major advantages of this study included multicentre design, large sample size of patients, and adjustment for numerous related variables. The limitation of this study was the retrospective nature and the method of data collection. Reliance solely upon EMRs and picture archiving and communication systems (PACS) may weaken the reliability of the data. Although this was a large cohort of patients, this study did not permit us to investigate the significance of some infrequent cases like glucocorticoid use. It may be that this is a type II error and that our sample size was simply not large enough.

In conclusion, the incidence of SSI following ORIF of a distal femur fracture was 4.0%. Open fracture, current smoking, obesity, and diabetes mellitus were identified to be significantly associated with the increased risk of SSI. Although modification of these risk factors may be difficult, patients and families should be counselled regarding their increased risk of SSI because these patients potentially benefit from focused perioperative medical optimisation.

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CONFLICTS OF INTEREST

The authors have no conflicts of interest to report.

Author contributions

Q.Q. designed the study; K.L., J.Z., and J.C. searched the electronic medical record; C.Y. and H.L. analysed and interpreted the data; H.W. and X.Y. searched the relevant literature; K.L. and J.Z. wrote the manuscript; and Q.Q. approved the final version of the manuscript.

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