A nomogram for predicting skin necrosis risk after open reduction and internal fixation for tibia fractures

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Abstract
The purpose of our study was to determine the risk factors for skin necrosis after open reduction and internal fixation (ORIF) for tibia fracture and establish a nomogram prediction model. We retrospectively analysed the clinical data of patients who suffered from tibia fractures and had been surgically treated by ORIF in our institution between August 2015 and October 2020. Perioperative information was obtained through the electronic medical record system, univariate and multivariate analyses were performed to determine the risk factors of skin necrosis, and a nomogram model was constructed to predict the risk of skin necrosis. The predictive performance and consistency of the model were evaluated by the Hosmer-Lemeshow (H-L) test and the calibration curve. In total, 444 patients were enrolled in our study. Multivariate analysis results showed that limb swelling, time until the operation, operation time, distance from fracture end to the skin, and soft-tissue injury (Tscherne classification type 3) were independent risk factors for skin necrosis. The AUC value for skin necrosis risk was 0.906 (95% confidence interval 0.88−0.94). The H-L test revealed that the nomogram prediction model had good calibration ability (P = .467). Finally, we found a correlation between skin necrosis and limb swelling, time until the operation, operation time, distance from fracture end to the skin, and soft-tissue injury (Tscherne classification type 3) after ORIF for tibia fracture patients. Our nomogram prediction model might be helpful for clinicians to identify high-risk patients, as interventions could be taken early to reduce the incidence of skin necrosis.

Keywords
nomogram, ORIF, skin necrosis, tibia fracture
Key Messages
- the purpose of our study was to determine the risk factors for skin necrosis after open reduction and internal fixation (ORIF) for tibia fracture and establish a nomogram prediction model
- multivariate analysis results showed that limb swelling, time till operation, operation time, distance from fracture end to the skin, soft-tissue injury (Tscherne classification type 3) were independent risk factors for skin necrosis
- our nomogram prediction model might be helpful for clinicians to identify high-risk patients, intervention could be taken early to reduce the incidence of skin necrosis

1 | INTRODUCTION

Tibial fractures are the most common types of long bone fractures. Injuries causing tibial fractures vary from low-energy, minimal displacement injuries to high-energy injuries associated with severe soft tissues and bone defects. Tibial fractures with severe soft-tissue injuries have been reported as a predictor of poor prognosis. Open reduction and internal fixation (ORIF) is currently the most common surgical method for the treatment of tibial fractures, but complications such as infection, skin necrosis, fracture non-union, etc., are not uncommon after surgery (Figure 1), which could seriously affect the efficacy of surgery. Currently, the reported incidence of these complications after surgical treatments for tibial fractures in the literature reaches as high as 50%-80% of cases.

For skin necrosis after ORIF, free flaps (muscle or fasciocutaneous) have long been considered as the gold standard for such difficult situations. However, not all reconstructive surgeons are able to perform microvascular free-tissue transfer and not all hospitals may be equipped to undertake microsurgical free flap surgery and intensive postoperative flap monitoring. Therefore, determining how to avoid skin necrosis is very important. There are few studies investigating the variables affecting outcome in fractures of the tibia treated by ORIF at present; it is a challenging clinical problem and remains uncertain. Therefore, identifying those tibia fracture patients who might develop skin necrosis after ORIF is critical for implementing an effective intervention therapy to reduce complications and improve prognosis.

The purpose of this study is to determine the risk factors associated with skin necrosis after tibia fracture with ORIF and to establish a nomogram model to predict the incidence.

2 | MATERIALS AND METHODS

This study followed the guidelines of the ‘Declaration of Helsinki’ and was approved by the hospital’s ethics committee. The requirement for informed consent was waived as the data were analysed anonymously and personal identifiers were completely removed.

FIGURE 1  A man with a tibia fracture underwent open reduction and internal fixation, and skin necrosis appeared after the operation. (A) X-ray before operation. (B) X-ray after the operation. (C) Skin necrosis
2.1 Patient group

In a retrospective cohort study, we analysed all patients who were treated for tibia fractures in our department between August 2015 and October 2020. Data were collected from the clinical records of patients from the data bank of our hospital. The eligibility criteria were (a) closed tibia fracture, including proximal tibia fractures, tibial shaft fractures, and distal tibia fractures; (b) age ≥18 years; and (c) recipients of surgeries including ORIF. Exclusion criteria included the following: (a) pathological fractures; (b) multiple fractures or multiple traumas; (c) conservative treatment; and (d) lost to follow-up. In the end, there were 444 patients included in the final analysis.

2.2 Treatment method and rehabilitation

All tibia fractures were managed with ORIF by plate and screws. Patients were encouraged to start active range of motion exercises at the knee and the ankle as soon as possible. The majority of patients were encouraged to partially weight bear at 2-3 weeks after surgery. Patients were allowed to fully weight bear when there was no pain at the fracture site and radiological evidence of bone union.

2.3 Evaluation

The electronic medical records and radiographs of each patient were reviewed. Data records were collected including the age, gender, body mass index (BMI), current smoking status, current drinking status, current diabetes mellitus (DM) status, current hypertension status, whether the patient had undergone lower extremity surgery, mechanism of injury (traffic accidents, crush injury, or fall), current thrombus status, operation site (proximal tibia, tibial shaft, and distal tibia), whether to drain, fracture AO Foundation/Orthopaedic Trauma Association (AO/OTA) classification, soft-tissue injury classification (Tscherne classification), limb swelling (compared with the healthy side), preoperative white blood cells (WBC), percentage of neutrophils preoperative, preoperative C-reactive protein (CRP), preoperative haemoglobin (HB), preoperative albumin, the time until the operation, the operation time, the distance from fracture end to the skin in the X-ray, the angle of fracture in the X-ray, the distance from internal fixation to the skin in the X-ray, and the number of internal plates.

The distance from fracture end to the skin in the X-ray is defined as the average distance on the anteroposterior (AP) view and the distance on the lateral view (Figure 2A). The angle fracture in the X-ray is defined as the acute angle formed by the fracture end and the bone shaft (Figure 2B). The distance from internal fixation to the skin in the X-ray is defined as the average distance on the AP view and the distance on the lateral view (Figure 2C). All measurements are carried out by the measurement tools that come with the Picture Archiving and Communication Systems. Each measurement is performed by two orthopaedic physicians independently, and the average value is the final value.

2.4 Statistical analysis

Continuous variables were expressed as the means ± standard deviations, and categorical variables were expressed as percentages. Comparisons between groups were performed using the χ²-test, Fisher’s exact test, and Student’s t-test. Univariate analyses were used to evaluate the associations between different factors and skin necrosis. To determine the independent risk factors, variables achieving a significance of P < .1 were selected for multivariable analyses. Then, based on the regression coefficients of independent variables, we established the nomogram prediction model of skin necrosis. The distinction of dichotomous results was usually evaluated by calculating the area under the curve (AUC) of the receiver operating characteristic (ROC) curve. Generally, a prediction model with an AUC of 0.5-0.75 was considered acceptable, and an AUC >0.75 means that the model shows excellent discrimination. Statistical analyses were carried out using R version 3.6.1 for Windows (R Foundation for Statistical Computing, Vienna, Austria). P values less than .05 (two-sided) were considered statistically significant. The calibration and discrimination of the model were evaluated by the verification group. The calibration degree is evaluated by Hosmer-Lemeshow (H-L) test, the goodness of fit test, and calibration curve. In addition, the calibration curve was used to judge the predictive consistency.

3 RESULTS

From August 2015 to October 2020, 530 consecutive tibia fracture patients who underwent ORIF in our hospital were involved in this study, of whom 86 were excluded: 30 with open fractures, 20 with multiple trauma, 2 with pathological fractures, and 34 who were lost to follow-up. Ultimately, 444 patients meeting the inclusion criteria were enrolled in our study, of whom 50 (11.26%) suffered skin
necrosis after ORIF, while the remaining 394 patients did not (88.74%, non-skin necrosis group; Table 1).

There were no statistically significant differences between the two groups regarding sex, drinking, hypertension, lower extremity surgery, thrombus, BMI, percentage of neutrophils, CRP, HB, albumin, angle of fracture, drain, and fracture AO/OTA type ($P > .1$; Table 1).

The average age of patients with skin necrosis was 61.90 ± 13.0 years, which was significantly higher than the age of the control group (58.04 ± 15.13 years) ($P = .057$). The ratio of smoking and DM among patients with skin necrosis was 54% (27/50) and 72% (36/50), respectively, which was significantly higher than the non-skin necrosis group of 28.43% (112/394) and 47.46% (187/394), respectively ($P = .089$ and $P = .001$). There was a statistically significant difference in limb swelling between the skin necrosis group and the control group: 56.98 ± 18.84% and 42.32 ± 13.92%, respectively ($P = .001$). In addition, the mechanism of injury of the two groups was significantly different ($P = .051$); traffic accidents were higher in the skin necrosis group (44% vs 30.96%). Compared with the skin necrosis group, the WBC was significantly lower in the non-skin necrosis group ($8.77 ± 3.02$ vs $8.05 ± 2.37$ $\times 10^9$, $P < .051$). The operation sites of the proximal tibia, shaft, and distal tibia were 20%, 26%, and 54%, respectively, in skin necrosis patients, and 29.18%, 34.77% and 36.29%, respectively, in non-skin necrosis patients ($P = .047$). The Tscherne classification for soft-tissue injury classification 0, 1, 2, and 3 was 2%, 8%, 28%, and 62%, respectively, in the skin necrosis group and 5.33%, 27.92%, 50.51%, and 16.24%, respectively, in the non-skin necrosis group ($P < .001$). In the perioperative stage, among patients with skin necrosis, the time until the operation and operation time were $7.14 ± 3.73$ days and $85.45 ± 20.1$ minutes ($P = .001$ and $P = .062$, respectively). In terms of radiological parameters, the distance from fracture end to the skin and the distance from internal fixation to the skin in the skin necrosis group were $10.37 ± 2.97$ and $8.09 ± 2.86$ mm, respectively, which were significantly shorter than those in the non-skin necrosis group ($15.45 ± 5.33$ and $12.16 ± 4.94$ mm, respectively; both $P = .001$). In addition, there was a statistically significant difference in the number of internal plates between the two groups: 1.42 ± 0.73 and 1.23 ± 0.52, respectively ($P = .082$; Table 1).

The results of the univariate analysis showed that there was a significant difference in age, smoking, DM, mechanism of injury, limb swelling, WBC, time until the operation, operation time, the distance from fracture end to the skin, the distance from internal fixation to the skin, the number of internal plates, operation site, and soft-tissue injury classification ($P < .1$). After multivariate logistic regression analysis, limb swelling, the time until the operation, the operation time, the distance from fracture end to the skin, and soft-tissue injury classification 3 were identified as independent risk factors of skin necrosis after ORIF of tibia fracture (Table 2).

A nomogram was established to predict the risk for skin necrosis based on the multivariate logistic regression analysis (Figure 3). To use the nomogram, the points corresponding to each prediction variable were obtained, and the sum of the points was then calculated as the total score; the predicted risk corresponding to the total score was the probability of skin necrosis. For example, in a tibia fracture patient with Tscherne classification 3, the limb swelling was 80% that of the normal side. The X-rays before surgery showed that the distance from fracture end to the skin was 14 mm, and the patient was treated with ORIF 5 days later. The operation time was 60 minutes. The total score was $44 + 44 + 60 + 45$
| Variable                        | Skin necrosis group (n = 50) | Non-skin necrosis group (n = 394) | t or χ² | P value |
|--------------------------------|-------------------------------|-----------------------------------|---------|---------|
| Sex (male/female)              |                               |                                   | χ² = 0.086 | .77     |
| Male                           | 29 (58%)                      | 237 (60.15%)                     |         |         |
| Female                         | 21 (42%)                      | 157 (39.85%)                     |         |         |
| Age (y)                        | 61.90 ± 13.0                  | 58.04 ± 15.13                    | t = 1.94 | .057*   |
| Smoking                        |                               |                                   | χ² = 2.891 | .089*   |
| Yes                            | 27 (54%)                      | 163 (41.37%)                     |         |         |
| No                             | 23 (46%)                      | 231 (58.63%)                     |         |         |
| Drinking                       |                               |                                   | χ² = 2.433 | .119    |
| Yes                            | 9 (18%)                       | 112 (28.43%)                     |         |         |
| No                             | 41 (82%)                      | 282 (71.57%)                     |         |         |
| DM                             |                               |                                   | χ² = 10.686 | .001*   |
| Yes                            | 36 (72%)                      | 187 (47.46%)                     |         |         |
| No                             | 14 (28%)                      | 207 (52.54%)                     |         |         |
| Hypertension                   |                               |                                   | χ² = 1.61 | .205    |
| Yes                            | 21(42%)                       | 203(51.52%)                      |         |         |
| No                             | 29(58%)                       | 191(48.48%)                      |         |         |
| Lower extremity surgery        |                               |                                   | χ² = 0.15 | .698    |
| Yes                            | 17 (34%)                      | 145 (36.8%)                      |         |         |
| No                             | 33 (66%)                      | 249 (63.2%)                      |         |         |
| Mechanism of injury            |                               |                                   | χ² = 5.967 | .051*   |
| Traffic accidents              | 22 (44%)                      | 122 (30.96%)                     |         |         |
| Crush injury                   | 19 (38%)                      | 138 (35.03%)                     |         |         |
| Fall down                      | 9 (18%)                       | 134 (34.01%)                     |         |         |
| Thrombus                       |                               |                                   | χ² = 1.353 | .245    |
| Yes                            | 14 (28%)                      | 82 (20.81%)                      |         |         |
| No                             | 36 (72%)                      | 312 (79.19%)                     |         |         |
| BMI (kg/m²)                    | 22.43 ± 2.0                   | 22.36 ± 1.69                     | t = 0.25 | .80     |
| Limb swelling (%)              | 56.98 ± 18.84                 | 42.32 ± 13.92                    | t = 5.321 | .001*   |
| WBC (*10⁹)                     | 8.77 ± 3.02                   | 8.05 ± 2.37                      | t = 1.955 | .051*   |
| Percentage of neutrophils (%)  | 71.17 ± 13.46                 | 68.66 ± 11.11                    | t = 1.265 | .211    |
| CRP, mg/L                      | 9.03 ± 8.86                   | 8.99 ± 6.27                      | t = 0.033 | .974    |
| HB, g/L                        | 116.68 ± 22.83                | 114.05 ± 17.07                   | t = 0.786 | .435    |
| Albumin, g/dL                  | 35.48 ± 5.37                  | 36.52 ± 4.67                     | t = 1.458 | .145    |
| Time till operation (d)        | 4.04 ± 2.33                   | 7.14 ± 3.73                      | t = 8.189 | .001*   |
| Operation time (min)           | 91.24 ± 24.18                 | 85.45 ± 20.1                     | t = 1.873 | .062*   |
| Distance from fracture end to the skin (mm) | 10.37 ± 2.97 | 15.45 ± 5.33 | t = 10.165 | .001* |
| Angle of fracture (°)          | 47.42 ± 20.34                 | 49.10 ± 18.07                    | t = 0.608 | .543    |
| Distance from internal fixation to the skin (mm) | 8.09 ± 2.86 | 12.16 ± 4.94 | t = 8.584 | .001* |
| Number of internal plates      | 1.42 ± 0.73                   | 1.23 ± 0.52                      | t = 1.771 | .082*   |

(Continues)
+ 8 = 201, which corresponds to an almost 40% risk of reduction loss.

In addition, we drew the ROC curve of predicted probability and calculated the AUC value. The AUC value for skin necrosis risk was 0.906, suggesting that the nomogram prediction model has an excellent discrimination (Figure 4); meanwhile, the 95% confidence interval was 0.88-0.94. The Hosmer-Lemeshow test also showed that the nomogram prediction model had good calibration ability ($P = .467$, Figure 3).

**4 | DISCUSSION**

According to Zelle et al, high-energy tibial fractures are challenging to orthopaedic surgeons. Soft-tissue injuries associated with fractures of the tibia are a predictor of poor prognosis. Skin necrosis is a common complication after ORIF of tibia fracture which leads to internal fixation exposure and even amputation. The advent and refinement of microsurgical techniques have led to a revolution in the treatment of tibia extremity trauma.
Role of soft-tissue reconstruction in necrosis after ORIF is not limited to covering the wound to prevent desiccation and infection. The soft tissues also contribute to the repair of the fracture as they are a source of osteoprogenitor cells, growth factors and, of course, vascular supply.

This study was designed to evaluate patients in a retrospective manner, document tibia fracture patient characteristics that might have an impact on the incidence of skin necrosis as a primary end point, and create a predictive nomogram model of risk factors for skin necrosis associated with orthopaedic fracture surgery. We included predefined standardised criteria and definitions for evaluating our outcome of interest: skin necrosis. We identified soft-tissue injury severity and classification, distance from fracture end to the skin, operation time, time until the operation and limb swelling as independent risk factors in the incidence of surgical site skin necrosis.

Tibia fractures are often accompanied by soft-tissue swelling and are associated with prolonged hospitalisation and soft-tissue complications. Definitive internal osteosynthesis cannot be undertaken until the swelling of the surrounding soft tissues has resolved. It is vitally important for the surgeon to delay surgery until the swelling subsides sufficiently, because wound edge necrosis, skin slough, and postoperative infections can be the consequence of a prematurely performed ORIF. This is especially true in high-energy tibia fractures, where a compromised soft-tissue envelope with extensive oedema, fracture blisters, and ecchymosis may be present. For high-energy tibia fractures, it is not uncommon for the procedure to be delayed for up to 2 weeks while awaiting oedema resolution. In this study, as the limb swelling subsides, the probability of skin necrosis after surgery decreases. Zhang et al stipulated that closed tibial fracture resulted in a significant reduction of functional capillary density, red blood cell velocity, and volumetric blood flow in both extensor digitorum longus muscles and the periosteum. Microvascular diameter, leucocyte adherence, and macromolecular leakage were markedly increased, indicating trauma-induced inflammation and endothelial disintegration. This results in an increased risk of wound infections, wound healing disorders, and compartment syndromes. Elevation and cooling produce a sufficient reduction in swelling, permitting internal osteosynthesis in about 10 days. Schnetzke compared vascular impulse technology (VIT)
with elevation and found that VIT results in a significant reduction in the time (8.2 days) to achieve operability in fractures of the lower limb. In this study, the time until the operation of the control group was 7.14 days, which was longer than in the skin necrosis group (4.04 days). This trauma-induced damage to the microcirculation starts around 1 to 2 hours after trauma, needs time to fully develop and usually reaches a peak after 24 to 72 hours.\textsuperscript{20,21} Waiting for suitable soft-tissue conditions has certain benefits in reducing perioperative complications of internal fixation of fractures.\textsuperscript{22,23} As is the case in Figure 5, there was a severe proximal tibia fracture, severe soft-tissue swelling, and a large number of blisters. With enough waiting time before surgery, recovery will be faster after surgery.

Clinically, the extent of soft-tissue damage significantly determines the process of bone healing, the guidance of fracture management, and patient prognosis.\textsuperscript{24,25} The severity of soft-tissue injury plays an important role in the treatment of fracture, especially those that occur in areas with poor integumentary coverage, such as the proximal, diaphyseal, and distal portions of the tibia.\textsuperscript{26,27} Therefore, determining the severity of the initial soft-tissue injury is currently one of the most important factors in selecting the initial treatment. Various classifications have been proposed to try to standardise the measurement of the extent of the integumentary injury.\textsuperscript{28} Oestern and Tscherne classification, which was published in the early 1980s, is the most commonly used piece of literature to describe soft-tissue injury for closed fractures. This classification system rates the severity of blunt soft-tissue injury on a scale from 0 to 3 (0 indicating little or no injury; 3 indicating the most serious injuries, including compartment syndrome and vascular lesions). A previous study\textsuperscript{19} showed its ability to serve as a concise and reliable communication tool in a research capacity. In a similar fashion, the Tscherne system serves as an effective guide for predicting treatment and prognosis.\textsuperscript{29,30} The relationship between the severity of injuries according to this system and long-term outcomes has been assessed. However, we are not aware of any studies that have evaluated the relationship between the soft-tissue injury type and skin necrosis. Physiologic changes that occur at the microvascular and cellular levels will define the zone of injury.\textsuperscript{20,31} In our study, the higher the grade of soft-tissue damage, the greater the probability of skin necrosis, which has a certain connection with the physiologic changes.

The prolonged operation time will increase the probability of postoperative complications. Long-term surgical operations will increase the probability of deep soft tissues being exposed to bacteria, which might cause postoperative skin infections and skin necrosis. In addition, a long operation time means a long tourniquet time. Prolonged soft-tissue ischaemia will cause tissue oedema and ischaemia-reperfusion injury, which could lead to a

![Figure 5](image_url)  
(A) X-ray before operation. (B) Severe soft-tissue swelling and a large number of blisters. (C) X-ray after the operation. (D) Good skin condition after operation. ORIF, open reduction and internal fixation.
series of physiological changes. Al-Mudhaffar et al. retrospectively reviewed 33 calcaneal fracture patients who were treated with ORIF and identified that a tourniquet time in excess of 1.5 hours is a risk factor for postoperative wound complications. Jun Su found that tourniquet time in excess of 1.5 hours is a risk factor for postoperative complications. Jun Su found that trochanteric soft-tissue thickness was likely to be the most dominant parameter over body height and body weight, signifying that a slimmer elderly person, taller or shorter, with less trochanteric soft-tissue thickness, should be advised to take preventive measures against hip fracture following a sideways fall. Thus, as in the findings of Levine’s study, soft-tissue thickness is a protective factor for the occurrence of hip fractures in the elderly. As in our study, with tibia fracture, if the thickness of the soft tissue is considerable, the possibility of postoperative skin necrosis will be reduced. The soft-tissue thickness in the skin necrosis group was 10.37 ± 2.97 mm, whereas in the non-skin necrosis group was 15.45 ± 5.33 mm. Therefore, skin necrosis should be taken into account for patients with thin tibial soft tissue or severe fracture displacement after internal fixation.

There were several limitations in our study. First, this was a retrospective study, and selection bias was unavoidable. Second, we did not collect information on open fracture, perioperative antibiotic use, and cases of intramedullary nail treatment. Third, the data in this article came from a single centre and the amount of data was limited. Therefore, in the following work, we need to conduct a prospective multicentre study to obtain a larger sample size and apply the constructed nomogram algorithm for internal verification.

5 Conclusion

We found a correlation between skin necrosis and limb swelling, time until the operation, operation time, distance from fracture end to the skin, and soft-tissue injury (Tscherne classification type 3) after ORIF for tibia fractures patients. Our nomogram prediction model might be helpful for clinicians to identify high-risk patients, as interventions could be taken early to reduce the incidence of skin necrosis.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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