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Predictive factors for pin sites infection in external fixation of open tibia fractures

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ABSTRACT

Objectives: External fixation is a readily available fixation method for some open tibia fracture grades. Pin site infection (PSI) is a common complication that leads to pin loosening and osteomyelitis. Understanding the predictive factor for PSI can reduce the incidence. This study aimed to determine the predictive factors for PSI in the external fixation of open tibia fractures.

Methods: This was a prospective observational study. The biodemographic variables of the patient collected were age, sex, marital status, mechanism of injury, body mass index, number of pins inserted, pre-operative hematocrit, comorbidity, duration of the hospital stay, Gustilo/Andersen grades of open tibia fractures, and bacterial isolates among those with PSI.

Results: Thirty patients who met the inclusion criteria were included in the study with a mean age of 45.9 years ± 17.7 with a male-to-female ratio of 3.3:1. Motor vehicle accidents and motorcycle/motor vehicle accidents were the predominant cause of injury in 56.7% of the patients. The incidence of PSI was 36.7%, with *Staphylococcus aureus* being the most common bacterial isolated at 81.8%. Only grades of open tibia fractures are the predictive factor for PSI (adjusted odds ratio 18.33, 95% confidence interval of 1.609–208.864, $P = 0.019$).

Conclusion: The predictive factor that was statistically significantly associated with PSI in this study was the grades of the open tibia fractures.

Keywords: External fixation, Open tibia fractures, Predictive factors

INTRODUCTION

External fixation of open tibia fractures remains a viable option in the initial or definitive treatment of patients with some Grades II and III Gustilo and Andersen (GA) staging of open fractures.[1] It is a versatile tool in polytraumatized patients when used as part of damage control orthopedics. While it offers several advantages over other fixations methods in treating open tibia fractures, it has its inherent complication; the most common is pin site infection (PSI). The occurrence of PSI increases pain, the economic cost to the patients, the chance of secondary procedure, and the subsequent length of hospital stay and morbidity.[2-6]

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The complication of PSI can lead to pin loosening with a predisposition to osteomyelitis, which may lead to delayed or non-union of the fracture. The propensity to this complication increases with prolonged use of external fixation, particularly as a definitive treatment. Some factors associated with PSI are patient-related, surgical techniques, and post-operative care pin site protocol used after applying an external fixation device.[7-11]

The reported incidence of PSI has been reported to range from 10% to 100% in some studies, depending on the criteria used for its definition.[3,6] However, a study that included long bones of the extremities using mono-lateral frames reported 40.6% of radial fractures, 57.5% for tibia fractures, and 87.5% of femoral fractures, while others reported different incidences.[10-12] The risk factors associated with PSI have been well documented when using monolateral frames for prolonged bone lengthening.[13] However, few studies evaluated this risk in extremities long bone fractures.[12] There is a paucity of data on the predictive factors associated with using uniplanar frames to treat open tibia fractures. Therefore, this study aimed to determine the predictive factors associated with external fixation in open tibia fracture type II and III GA grades.

MATERIALS AND METHODS

This prospective observational study was done from December 2020 to July 2022. The study location was the Federal Medical Center Owo, Ondo State, Nigeria (7.2136° N, 5.5993° E). It is one of the institutions located in the southwestern part of the country that provides a tertiary level of health care. It has three orthopedic surgeons with a 40-bed adult orthopedic ward and 10-bed units for pediatric orthopedic admission. It serves a population of 276,574 (2023 population projection).[14] However, its catchment areas include three neighboring states: Ekiti, Kogi, and Edo.

The inclusion criteria were all adult patients aged 18 and above who presented to the hospital within 8 h of the injury with open tibia fractures and had wound debridement, who presented to the hospital within 1 week of their injury, who had had their initial wound debridement in peripheral centers, and without wound infections and consented to participate in the study.

The exclusion criteria were open tibia fractures with vascular injuries, those with comorbid conditions such as diabetes mellitus, those on steroids, and those with infected open tibia fractures who presented at the outpatient clinic.

According to Abalo *et al*., who reported the incidence of PSI in long bone fractures of the femur, tibia, and radius, the reported incidence for external fixation of tibia fractures was 57.5%.[12] We surmise that this will be reduced in this study to 32.5%. Using the sample size calculation for primary outcome as a dichotomous variable in one sample study by Kane.[15]

$$N = P_o q_o \left\{ Z_{1-\alpha/2} + Z_{1-\beta} \frac{\sqrt{p_1 q_1}}{p q_0} \right\}^2 \Big/ P_1 - P_0$$

$q_0 = 1 - p_0$

$q_1 = 1 - p_1$

p_0 = proportion (incidence) of population

p_1 = proportion (incidence) of the study group

N = sample size for the study group

α = probability of type I error (usually 0.05)

β = probability of type II error (usually 0.2)

z = critical Z value for a given α or β

$$N = \frac{0.575 * 0.425\{1.96 + 0.84\sqrt{\ } 0.325 * 0.675 / 0.575 * 0.425\}^2}{(0.325 - 0.575)^2}$$

N = 30. Therefore, the total number of patients recruited into the study was 30 patients.

All potential newly presenting patients at the accident and emergency were sampled using a consecutive sampling technique. All potentially newly presenting patients at the accident and emergency and orthopedic outpatient clinic who met the inclusion criteria had the patients' information sheet given to them and the study protocol explained in a language that was well understood by the patient and was required to endorse the study consent form subsequently.

Patients who presented to the accident and emergency were operated on as soon as possible, while patients who presented through the clinic were admitted at least a day before surgery. All patients had an anesthesiologist's pre-operative evaluation, and the mode of anesthesia was either spinal or general anesthesia administered through a cuffed endotracheal tube. The second author, a senior registrar, was the operating surgeon in most cases, and few involved other senior registrars.

The skin was prepared with chlorhexidine/cetrimide wash, mopped dry, and then cleaned with methylated spirit. After that, the skin was painted with 10% povidone-iodine. The area of the body extending from the affected leg to the ipsilateral iliac crest was included in the skin preparation. Whole body draping was done, exposing the affected leg and foot.

After the wound debridement, the wound was copiously irrigated with normal saline using the rule of 3. Six liters and 9 l of normal saline were used for GA, Grades 2 and 3A, open tibia fractures respectively. The surgeon used a size 11 scalpel blade to make a skin incision for the pin entry site.

Pre-drilling was done with a sharp drill bit of 3.5 mm using a power drill, intermittently stopping and injecting normal saline into the pin track. The exsanguinating tourniquet was not used to minimize thermal necrosis and soft tissue was protected with a drill sleeve. Then, a 5 mm stainless steel Schantz pin was inserted manually using a T-handle till both the near and far cortices were engaged. The principles of near-near and far-far were employed to increase the stability of the construct. All the cases had unilateral external fixation using double tubular bars stacked and clamps. For all cases, pre-operative second-generation cephalosporin (Cefuroxime) 1.5 g was given at induction of anesthesia and continued with 750 mg 12 hourly for 3 days.

Furthermore, a short course of Gentamycin 80 mg 12 hourly for 48 h was added for those with GA type 3A open tibia fracture. All had tetanus immuno-prophylaxis if immunized; otherwise, active immunization was commenced. The pin site was cleaned with normal saline-soaked gauze, and 10% Povidone-iodine dressing was applied to each pin site. The operating surgeon did the first dressing on the 4th post-operative day, and subsequently, the nurses who had been taught the art of dressing change did it every 2 days till discharged from the hospital. The patient was taught how to change the dressing every week, according to W-Dahl *et al*.[16] Recruited patients were also advised to watch out for symptoms of PSI and to call the researcher on the phone promptly if they developed any complications while at home. PSI was classified according to the Checketts–Otterburn classification. Grades 1 to 3 were classified as minor infections, and Grades 4 to 6 were classified as major infections. Bacterial culturing was performed from each infected pin site and the tip of the infected pins at removal.

At removal, the pins were assessed clinically as loose or fixed. A loose pin was defined as a pin that could be removed by hand without instruments. All the patients had a uniform analgesic protocol postoperatively that consisted of parenteral pentazocine 30 mg 6 hourly, acetaminophen 600 mg 6 hourly, and diclofenac sodium 75 mg 12 hourly for 24 h. Subsequently, oral medication of diclofenac potassium 50 mg 12 hourly and acetaminophen 1000 mg was given for 72 h postoperatively. The follow-up period was for 3 months.

The biodemographic variables of the patients collected were age, sex, marital status, body mass index (BMI), mechanism of injury, grades of open fractures, estimated blood loss, pre-operative hematocrit, duration of hospital admission, presence or absence of PSI, number of pins, and white blood cell counts. The primary outcome measure was PSI. Checketts–Otterburn classification was used to grade the PSI. The secondary outcome measure was bacterial cultures of those with PSI.

The data were analyzed using IBM SPSS version 22. The continuous variables were expressed as mean and standard deviation, while Chi-square was used for categorical variables, and the significance level was P < 0.05. The dependent variable, the primary outcome measure, was reverse-coded as 0 for the presence of PSI and 1 for the absence of PSI. Binary logistic regression was used to assess the association between the independent variables of the age group of the patients, mechanism of injury, grades of open tibia fractures, estimated blood loss, number of pins used, and dependent variable, which was PSI. Those variables that were significantly statistically at $P < 0.2$ were used for multivariate logistic regression.

RESULTS

Of the 30 patients with 160 pins, the male-to-female ratio was 3.3:1 with a mean age of 45.9 years ± 17.7 standard deviation with a range of 18–79 years. Two-thirds of the patients were below the age of 45 years [Figure 1]. The total number of pins per patient ranged from 4 to 6. Motor vehicular accidents accounted for 30% of the cause of the injury, followed by motor vehicle/motorcycle accidents at 26.7% [Table 1]. Analysis of age group versus mechanism of injury showed that motorcycle/motor vehicle accidents were the predominant cause of injury in the 26–35 age groups.

PSI occurred in 11 patients, representing an incidence of 36.7%; of this, 8 (26.7%) were male, and 3 (10.0%) were female. The PSI was classified as minor in all cases, with 4 (13.3%) being grade 1 and 7 (23.3%) being Grade 2 of Checketts and Otterman's classification. These were treated with improved pin site dressing and a combination of enhanced pin site dressings and oral antibiotics for Grades 1 and 2, respectively. Three patients (10%) who had 4 Shantz pins inserted with a total of 12 pins had no PSI, 14 patients (46.7%) who had 5 Shantz pins inserted with a total of 70 pins had 30 (42.9%) PSI, and 13 patients who had 6 Shantz pin inserted with a total of 78 pins had 30 PSI (38.5%). This was statistically significant at $P < 0.05$ ($P = 0.001$, Chi-square 10.67). Of the 160 pins inserted, 60 (37.5%) had PSI.

Twenty-three (76.7%) of our patients wore the external fixation as definitive treatment, while only 7 (23.3%) had it for a month before exchange nailing was done. The average wearing time for those who had external fixation as definitive treatment was 10 weeks (8–12 weeks). The patients' mean BMI was 21.6 kg/m^2, ranging from 17.1 to 25.5 kg/m^2. Twenty-seven (90%) of patients had a BMI and had healthy or normal weight, while two patients (6.7%) were overweight, and only one (3.3%) was underweight. Ten patients (33.3%) had PSI among those with normal weight, and only one (3.3%) had PSI among those who were overweight. The difference was not statistically significant.

Among those with hematocrit, <36%, 7 (23.3%), and 4 (13.3%) of those with hematocrit >37% had PSI,

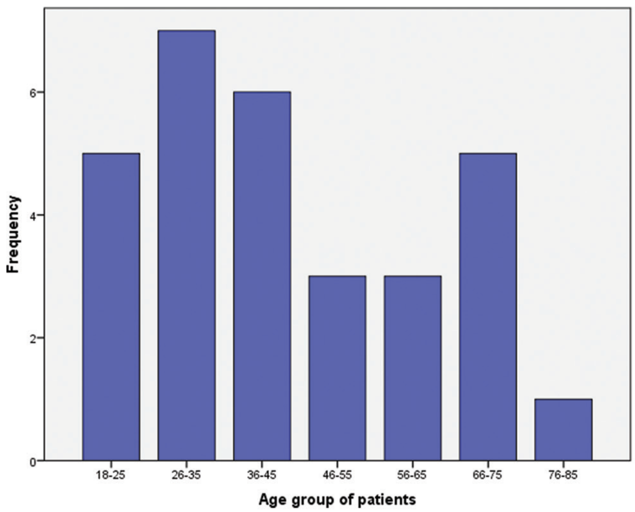

Figure 1: Bar chart of age group of patients in the study.

respectively, but the difference was also not statistically significant.

Of the six patients classified as GA Grade 2, only 1 (3.3%), while among those with GA Grade 3A, 6 (20%) had PSI, respectively, [Table 1] with a statistically significant difference ($P < 0.008$). Further, the analysis showed a statistically significant number of pin infected and grades of open fractures with $P < 0.001$. This showed that the higher the number of pins used, the higher the number of PSI. The incidence of PSI in this is 36.7% (11 out of 30 patients). The *S. aureus* was the predominant micro-organism cultured in 9 (81.8%) of the 11 patients with PSI [Table 2].

Predictive factors for PSI in external fixation of open tibia fractures

Binary logistic regression showed that BMI and grade of tibia open fractures were associated with PSI at $P < 0.2$. However, in the multiple logistic regressions, those having Grade 3A of the GA had 18.33 time odd of PSI compared to those with Grade 2 (adjusted odds ratio 18.33, 95% confidence interval 1.609–208.864, $P = 0.019$).

DISCUSSION

The tibia is often the most frequently involved in open injuries due to the predominantly subcutaneous anteromedial border. The use of external fixation comes in handy. It has gained popularity either as a stop-gap measure when it is used in polytraumatized as damage control measures to prevent the occurrence of a second hit phenomenon or when it is used as a definitive treatment for open tibia fractures.[1] However, with its increasing use comes the concern for PSI, which can become a grave concern for the surgeon, especially when it leads to pin loosening and chronic osteomyelitis.[1,8-11] Most studies on external fixation and its complications dwelt mostly on the incidence of PSI and often involved a heterogeneous population where other long bones are included in the studied population.[3-5,17,18] A few reported incidences of PSI in specific body regions following external fixation.[19] Our study is one of the few that focused on risk factors associated with the use of external fixation in open tibia fractures, for there is a paucity of data regarding it in the literature.[12] However, their study was on a heterogeneous population

Table 1: The biodemographic variables and pin site infection.

Variables	PSI Present (%)	PSI Absent (%)	*P*-value
Age groups in years			
18–25	3 (10)	2 (6.7)	0.063
26–35	1 (3.3)	6 (20)	
36–45	0 (0)	6 (20)	
46–55	2 (6.7)	1 (3.3)	
56–65	1 (3.3)	2 (6.7)	
66–75	4 (13.3)	1 (3.3)	
76–85	0 (0)	1 (3.3)	
BMI in kg/m^2			
<18.5	0 (0)	1 (3.3)	0.693
18.5–24.9	10 (33.3)	17 (56.7)	
25.0–29.9	1 (3.3)	1 (3.3)	
Number of pins inserted			
4	0 (0)	3 (10)	0.370
5	6 (20)	8 (26.7)	
6	5 (16.7)	8 (26.7)	
Comorbidity (Hypertension)			
Yes	3 (10)	2 (6.7)	0.236
No	8 (26.7)	17 (56.7)	
Hematocrit in %			
<36	7 (23.3)	10 (33.3)	0.558
>36	4 (13.3)	9 (30.0)	
GA grade of open fractures			
GA2	1 (3.3)	5 (16.7)	**0.008**
GA3A	18 (60.0)	6 (20.0)	
Duration of hospital stay in days			
≤17	6 (20)	8 (26.7)	0.510
≥18	5 (16.7)	11 (36.7)	
GA grade of open tibia fractures	Number infected pins		
GA2	20	6	**0.001**
GA3A	40	88	

PSI: Pin sites infections, BMI: Body mass index, GA: Gustilo-Andersen, The bold values was to highlight the value that was significant

Table 2: Organisms cultured among the 11 patients with pin site infection.

Organism isolated	Frequencies (%)
Staphylococcus aureus	9 (81.8)
Staphylococcus epidermidis	1 (9.1)
Pseudomonas aeruginosa	1 (9.1)

that involves other long bones in the body. In this study, the mean age of the patient was 45.7 years, which is similar to the findings by Parameswaran *et al.*[8] but contrasted with the findings by Chua from Singapore[20] and Mwafulirwa *et al.* in Malawi.[21] This may be due to demographic differences in the studied population. Furthermore, our study showed that open fractures of the tibia that need external fixation are most common in the 2nd to fourth decades of life. This compares favorably with previous studies by Weber *et al*.[22] and Elniel and Giannaoudis.[1] These are actively mobile populations and are predominantly male, as shown by the findings in this study. Motor vehicle accidents and collisions between motor vehicle and motorcycle accidents accounted for more than half of the cause of the injuries in this study. The use of motorcycles for commuting has been on the increase in most sub-Saharan African countries due to the unmet transportation needs of the community. The riders are often under pressure to make a certain amount of money daily, which results in disregarding traffic rules that predispose them to accidents.[22,23]

The incidence of PSI in this study was 36.7%. This was higher than those reported by Shah *et al*. from Pakistan[10] but lower than those reported by Abalo *et al*.[12] in Togo and Mohammed *et al.* in Kenya.[7] In our environment, where the health-care expenses are usually funded out-of-pocket, 80–90% of external fixation is used as definitive treatment, which is converted to above knee weight-bearing cast once there is callus bridging of the fractures bone fragment on the radiograph. The population in the study from Pakistan was similar to ours, while those from Togo were heterogeneous and involved other long bones. In addition, the study from Togo included some patients with closed fractures. The discrepancies in PSI rates might be due to different definitions used in various studies. Second, in some studies, PSI was considered per patient and individual pin in others, and third, the technique of application of pins, pin site dressing protocol, patient demographics, and study duration. In our study, PSI was considered per patient. PSI occurs from an interplay of host factors, surgical techniques, mechanism of injury, type of pin care protocol, and pin design. The systematic review by Fridberg *et al*. on host factors and risk of PSI in external fixation showed that there was no significant association between the age of the patients, BMI, smoking, and comorbidity such as diabetes mellitus.[24] However, Finkler *et al*. found a significantly increased rate of PSI in patients with higher glycosylated hemoglobin.[25] However, in this study, we excluded diabetic patients due to a slight increase in infection. In our study, the only factor that significantly increased PSI was the grade of open fractures. Those with 3A had 18.33 odds of having PSI than those with Grade 2. This is usually due to the mechanism of injury because high-energy injuries are more frequently associated with more severe grades of soft-tissue injuries, which may increase the predisposition to infection at the pin-bone interface. However, this should be interpreted with caution due to the wide confidence interval, which may imply that there is little knowledge of the effect of the grade of open fractures on the occurrence of PSI. An increase in the sample will decrease the standard error and confidence interval, thereby increasing the effect size. One of the modifiable factors targeted at reducing PSI is using various pin designs in different studies. A recent systematic review on the role of coating and materials of external fixator pins on the rates of pin tract infection revealed no statistically significant difference in the use of hydroxyapatite (HA) coated pin, stainless-steel pin, silver coated pin and stainless steel, and use of titanium pin compared to HA-coated pin. However, HA-coated pins had superior bone anchorage. In this study, only stainless-steel pins were used.[26]

Further, the analysis showed no case of pin loosening, nor was there development of chronic osteomyelitis. This was in tandem with findings by Shah *et al*.,[11] this may be because we had only minor grades of PSI using the Checkett and Ottermann's classification.

The most commonly isolated organism with PSI in various studies remains *S. aureus*.[4,7,14] This was similar to the findings in this study but contrasted with recent findings in a study from India where *Acinetobacter baumannii*, followed by *Pseudomonas aeruginosa* and *Citrobacter koseri,* were the most predominant isolates with different bacterial susceptibility patterns.[3] This may be due to different patient demographics and environment.

Limitation

This was a prospective observational study with no benefit of randomization to allocate the risks for the outcome of interest by chance. Second, this was a single-center study with a limited sample size. Third, the follow-up of the patients was for 3 months, which may exclude those that develop PSIs, especially those for which an external fixator was used as the definitive treatment of their fractures.

CONCLUSION

The incidence of PSI in this study compares favorably with others from developed countries. The only predictive factor significantly associated with its occurrence was the grade of open fractures of the tibia. Therefore, we recommend that attention should focus on this grade of injury to reduce the incidence of PSIs.

Recommendation

In future studies, we recommend a multi-center study with a large sample size, which may reveal other predictive factors for PSI in open tibia fractures.

AUTHORS' CONTRIBUTIONS

AAO conceived and designed the study, analyzed and interpreted data, and wrote the initial and final draft of the article. GEJ was involved in the design and data collection. All authors have critically reviewed and approved the final draft and are responsible for the manuscript's content and similarity index.

ETHICAL APPROVAL

This prospective observational study received the approval of the Health Research Ethics Committee of Federal Medical Center, Owo, Ondo State, Nigeria on August 21, 2020 (FMC/OW/380/VOL.XCIV/77).

USE OF ARTIFICIAL INTELLIGENCE (AI)-ASSISTED TECHNOLOGY FOR MANUSCRIPT PREPARATION

The authors confirm that there was no use of Artificial Intelligence (AI)-Assisted Technology for assisting in the writing or editing of the manuscript and no images were manipulated using the AI.

DECLARATION OF PATIENT CONSENT

The authors certify that they have obtained all appropriate patients consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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CONFLICTS OF INTEREST

There are no conflicting relationships or activities.

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