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Effect of Local Gentamicin Infiltration on Surgical Site Infection Following Lower Limb Open Reduction and Internal Fixation: A Randomized Double-Blinded Trial

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Abstract

Background: Surgical site infection (SSI) remains a formidable complication in orthopedic surgery, particularly in the presence of implanted biomaterials such as plates and intramedullary nails. While perioperative antimicrobial prophylaxis is standard practice, local antibiotic infiltration may offer additional protection against infection in open reduction and internal fixation procedures.

Objective: To evaluate the additive effect of local gentamicin infiltration on the incidence of surgical site infection following lower limb open reduction and osteosynthesis.

Methods: This prospective, randomized, double-blind, interventional study enrolled 100 patients with indication for open plating or intramedullary nailing of lower limb fractures or deformities. Participants were randomized into two groups of 50 each: Group A (control) received 4 mL of normal saline, and Group B (intervention) received 160 mg gentamicin (4 mL) infiltrated into the surgical wound prior to closure. Both groups received intravenous ceftriaxone prophylaxis intraoperatively and for 72 hours postoperatively. Wounds were drained, and patients were followed for 90 days. Wound assessment for infection was performed on days 3, 7, 10, 14, 28, and at 6 and 12 weeks using the ASEPSIS score.

Results: Ninety-three patients completed 90-day follow-up (7 lost to follow-up). The majority were male (74.2%) and aged 26–35 years (37.6%). Traumatic fracture fixation comprised 83.9% of cases, with femur (47.7%) and tibia (36.6%) as the most common anatomical sites. Plating was the predominant fixation method (50.5%). The overall infection rate was 11.8%, with 17.4% in Group A and 6.4% in Group B; however, the difference was not statistically significant ($p = 0.120$). Significant risk factors for SSI included BMI >25 kg/m^2 ($p = 0.010$), operative duration >3 hours ($p = 0.019$), and perioperative blood transfusion ($p = 0.001$). No association was found with diabetes, hypertension, or ASA class II status. *Staphylococcus aureus* was the most frequently isolated organism.

Conclusion: Local gentamicin infiltration was associated with a lower infection rate compared with placebo, though the difference did not reach statistical significance. Identified modifiable risk factors – obesity, prolonged operative time, and blood transfusion – warrant targeted preventive strategies.

Keywords: Lower limb; Open plating; Intramedullary nailing; Gentamicin; Surgical site infection.

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Introduction

Surgical site infection (SSI) is clinically defined as pain at a surgically created wound accompanied by swelling, erythema, induration, local tenderness, or purulent discharge (Kisibo et al., 2017). In orthopedic and trauma surgery, the presence of foreign materials – such as plates, screws, and intramedullary (IM) nails – predisposes patients to implant-related infections (IRI), which can result in serious adverse outcomes (Itai et al., 2017; Young et al., 2014). The Centers for Disease Control and Prevention (CDC) defines SSI as infection occurring near or at the incision site, or in deeper underlying tissue spaces and organs, within 30 days of the procedure, or up to 90 days in cases involving implants or prostheses (Borchardt & Tzizik, 2018; Public Health England, 2013).

SSI remains a major global challenge in orthopedic practice (Kisibo et al., 2017; Young et al., 2014). Worldwide incidence ranges from 1.4% to 41.9% (Al-Mulhim et al., 2014; Kisibo et al., 2017), with reported rates of 9.16–18% in some African countries and 7.5–16% in Nigeria (Ukpoju et al., 2020). Bacteria, primarily entering through the incision site, are the principal causative agents; established infections may be superficial (involving skin and subcutaneous tissue) or deep (involving fascia, organ spaces, or implant surfaces) (World Health Organization, 2016). Lower limb fractures account for approximately one-third of all fractures and are associated with substantial morbidity and mortality (Kaye & Jick, 2004). In Africa, the rising incidence of fractures has been attributed to increasing motorization, road traffic accidents, and economic mechanization (Pascal et al., 2017). The tibia and femur are the most commonly fractured lower limb bones and are frequent sites for plating and intramedullary nailing in both traumatic fracture fixation and deformity correction (Palle et al., 2019; Pascal et al., 2017).

SSI is the third most common nosocomial infection and a frequent complication following post-traumatic orthopedic operations (Ukpoju et al., 2020; Yanbin et al., 2019). Implants – including IM nails, plates, screws, and wires – maintain reduction and limb alignment; however, hardware infection jeopardizes fracture healing and increases morbidity, hospitalization duration, and healthcare costs (Cook & Sganga, 2015; De Lissovoy et al., 2009; World Health Organization, 2016). In the United States, SSIs contribute to over 400,000 additional hospital days annually, at an estimated cost exceeding $10 billion per year (De Lissovoy et al., 2009). Implant-related infections may necessitate further surgical procedures and intensive care, imposing a significant financial burden on both healthcare systems and patients (Itai et al., 2017; World Health Organization, 2016).

Given these consequences, SSI prevention is a global priority, though it remains complex due to the multitude of risk factors involved. Surgical antibiotic prophylaxis (SAP) – defined as the administration of an effective antimicrobial agent prior to surgical contamination – is a cornerstone of SSI prevention (Obremskey et al., 2020; World Health Organization, 2016). Additional recommended measures include appropriate timing of prophylactic antibiotic administration (approximately 30 minutes before skin incision), use of proper antiseptic agents and techniques for skin preparation, reduction of operating room traffic, and protection of the incision site with sterile dressings (Itai et al., 2017; Obremskey et al., 2020; Young et al., 2014).

Systemic antibiotic administration is standard prophylaxis in orthopedic surgery and has proven effective. Nevertheless, infection rates remain 0.5–5% for total joint replacement and 1–5% for fracture treatment – a clinically significant burden given the severe consequences of infection (Trampuz & Zimmerli, 2006). Consequently, alternative methods of antibiotic delivery have been developed, including antibiotic-impregnated collagen sponges, polymethylmethacrylate beads, antibiotic-coated implants, and topical vancomycin powder (used primarily in spine surgery) (Trampuz & Zimmerli, 2006; Zimmerli, 2014). Local antibiotic delivery permits higher tissue concentrations without risking serious systemic side effects (Itai et al., 2017; Public Health England, 2013; Trampuz & Zimmerli, 2006; Zimmerli, 2014). Antibiotic-coated implants may interrupt the cycle of infection, repeated revision surgeries, and biofilm formation on implant surfaces (Zimmerli, 2014). Prophylactic local antibiotics have gained particular attention in open fracture management and spine surgery (Trampuz & Zimmerli, 2006).

Gentamicin, an aminoglycoside antibiotic, exhibits activity against most Gram-negative bacteria and *Staphylococcus aureus* – the predominant pathogens in postoperative orthopedic infections and open fractures (Trampuz & Zimmerli, 2006; Winkler et al., 2012; Zimmerli, 2014). Although systemically administered gentamicin carries risks of nephrotoxicity and ototoxicity requiring renal monitoring (Trampuz & Zimmerli, 2006), experimental studies have demonstrated that local administration does not adversely affect bone healing, and systemic side effects have not been reported (Trampuz & Zimmerli, 2006; Zimmerli, 2014).

Materials and Methods

Study Design and Setting

This prospective, randomized, double-blind, interventional study was conducted at the National Orthopaedic Hospital, Dala, Kano, Nigeria.

Sample size was calculated using the formula for proportion outcome by YH Chan (Chan, 2003):

$$N = C \times \frac{\pi_1(1-\pi_1) + \pi_2(1-\pi_2)}{(\pi_1 - \pi_2)^2}$$

Where N is the sample size per group; C is the confidence interval constant = 7.9 at 80% power; π_1 is the proportion of patients who develop SSI after lower limb implant surgeries (control group); and π_2 is the proportion of patients who develop SSI after topical gentamicin application (case group).

Zyaie and Saied of Hormozgan University, Iran, found values of 23% incidence of SSI in those who had standard IV antibiotic prophylaxis (control) and 5% in those who had, in addition to IV antibiotic, local gentamicin (Zyaie & Saied, 2008).

With $\pi_1 = 0.23$ and $\pi_2 = 0.05$: $N = 7.9 \times \frac{0.23(1-0.23)+0.05(1-0.05)}{(0.23-0.05)^2} \approx 45$. Accounting for an attrition rate of 10% (4.5 patients), a total sample size of 50 patients per group was adopted. Therefore, 50 patients were recruited in each study group.

Participants

A total of 100 adult patients with clinical indications for open reduction and internal fixation of lower limb fractures or deformities – using either plate osteosynthesis or intramedullary nailing – were enrolled consecutively. Patients were randomized into two groups of 50 each using a computer-generated randomization sequence. Random numbers were generated from one to a hundred corresponding to the number of patients enrolled. Odd numbers were assigned to group A (control group), and even numbers were assigned to group B (intervention group). The patient picked a number from a box of numbers, and the patient's group was known only to an independent co-investigator; neither the operating surgeon nor the patient had knowledge of the group assignment. At the end of the procedure, the perioperative nurse handed over the placebo or the gentamicin to the surgeon for wound infiltration.

Interventions

Prior to wound closure, Group A (control) received 4 mL of sterile normal saline infiltrated into the deep tissues and subcutaneous layer, while Group B (intervention) received 160 mg of gentamicin (reconstituted in 4 mL) infiltrated in an identical manner. The solutions were prepared by an independent pharmacist not involved in patient care or outcome assessment, ensuring allocation concealment. Both the operating surgeon and the patient were blinded to group assignment.

All patients received intravenous ceftriaxone (1 g) as perioperative prophylaxis at induction of anesthesia, with dosing repeated intraoperatively for procedures exceeding 3 hours, and continued for 72 hours postoperatively. Closed suction drains were placed in all wounds and removed according to institutional protocol.

Follow-Up and Outcome Assessment

Patients were followed for 90 days postoperatively. Wounds were inspected for signs of infection on days 3, 7, 10, 14, and 28, and subsequently at 6 and 12 weeks. The primary outcome – surgical site infection – was assessed using the ASEPSIS scoring system (Wilson et al., 1986). Secondary outcomes included identification of risk factors for SSI and microbiological profile of infected wounds.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics, version 26.0 (IBM Corp., Armonk, NY, USA). Categorical variables were compared using the chi-square test or Fisher's exact test as appropriate, and continuous variables using the independent t-test. A p-value <0.05 was considered statistically significant.

Ethical Considerations

The study protocol was approved by the Dala Orthopaedic Hospital Ethical Committee. Written informed consent was obtained from all participants prior to enrollment. The study was conducted in accordance with the Declaration of Helsinki.

Results

Patient Disposition and Follow-Up

Of the 100 patients enrolled, 93 (93%) completed the 90-day follow-up. Seven patients were lost to follow-up: four (8%) from Group A and three (6%) from Group B. The per-protocol analysis thus comprised 46 patients in Group A and 47 in Group B (Figure 1).

Baseline Characteristics

The demographic and clinical characteristics of the two groups were comparable at baseline (Table 1). The mean age was 35.0 ± 12.7 years in Group A and 38.1 ± 13.7 years in Group B (p = 0.266). The majority of patients were aged 26–35 years (37.6% overall). Males predominated, accounting for 74.2% of the study population (male-to-female ratio 3:1), with no significant difference in sex distribution between groups (p = 0.351).

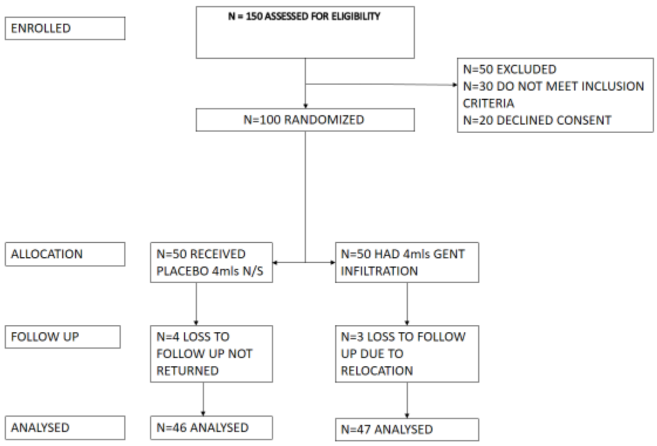

Figure 1: CONSORT flow diagram of patient enrollment, randomization, allocation, follow-up, and analysis.

Table 1: Baseline Demographic and Clinical Characteristics

Characteristic	Group A (n=46)	Group B (n=47)	Total (n=93)	*p*
Age (years), mean ± SD	35.0±12.7	38.1±13.7	36.6±13.2	0.266
Age category, n (%)				
18–25	10 (21.7)	9 (19.1)	19 (20.4)	
26–35	19 (41.3)	16 (34.0)	35 (37.6)	
36–45	9 (19.6)	11 (23.4)	20 (21.5)	0.266
46–55	4 (8.7)	4 (8.5)	8 (8.6)	
56–65	3 (6.5)	6 (12.8)	9 (9.7)	
>65	1 (2.2)	1 (2.1)	2 (2.2)	
Sex, n (%)				
Male	34 (73.9)	35 (74.5)	69 (74.2)	0.351
Female	12 (26.1)	12 (25.5)	24 (25.8)	
Indication for surgery, n (%)				
Traumatic fracture fixation	39 (84.8)	39 (83.0)	78 (83.9)	1.000
Deformity correction	7 (15.2)	8 (17.0)	15 (16.1)	
Anatomic location, n (%)				
Femur	22 (47.8)	22 (46.8)	44 (47.3)	
Tibia	18 (39.1)	16 (34.0)	34 (36.6)	0.451
Ankle	5 (10.9)	4 (8.5)	9 (9.7)	
Hip	1 (2.2)	5 (10.6)	6 (6.5)	

Table 1 continued

Characteristic	Group A (n=46)	Group B (n=47)	Total (n=93)	p
Diagnosis, n (%)				
Fracture	31 (67.4)	23 (48.9)	54 (58.1)	
Fracture-dislocation	3 (6.5)	3 (6.4)	6 (6.5)	
Mal-union	4 (8.7)	9 (19.1)	13 (14.0)	0.176
Nonunion	5 (10.9)	11 (23.4)	16 (17.2)	
Deformity	3 (6.5)	1 (2.1)	4 (4.3)	
Mode of skeletal stabilization, n (%)				
Intramedullary nail	23 (50.0)	23 (48.9)	46 (49.5)	0.408
Plate and screw	23 (50.0)	24 (51.1)	47 (50.5)	

Primary Outcome: Surgical Site Infection

The overall SSI rate was 11.8% (11/93). In Group A (control), 8 patients (17.4%) developed SSI compared with 3 patients (6.4%) in Group B (gentamicin) (Table 2). Although the infection rate was lower in the gentamicin group, this difference did not reach statistical significance (χ^2 = 2.42; p = 0.120). The absolute risk reduction was 11.0%, and the number needed to treat (NNT) was 9.1.

Table 2: Primary Outcome: Wound Infection Rate by Study Group

Wound outcome	Group A (n=46)	Group B (n=47)	Total (n=93)	p
Infected	8 (17.4)	3 (6.4)	11 (11.8)	0.120
Not infected	38 (82.6)	44 (93.6)	82 (88.2)	

Risk Factors for Surgical Site Infection

Univariate analysis identified three factors significantly associated with SSI (Table 3): body mass index (BMI) $>$25 kg/m^2 (p = 0.010), operative duration $>$3 hours (p = 0.019), and perioperative blood transfusion (p = 0.001). Neither patient age (p = 0.709) nor comorbid conditions such as diabetes or hypertension (p = 0.323) showed a significant association with wound infection. The mode of skeletal stabilization (IM nail vs. plate and screw) was also not significantly related to SSI (p = 0.749).

Table 3: Risk Factors for Surgical Site Infection

Risk factor	Infected (n=11)	Not infected (n=82)	*p*
Age category			
18–25 years	1 (9.1)	18 (22.0)	0.709
26–35 years	4 (36.4)	31 (37.8)	
36–45 years	3 (27.3)	17 (20.7)	
46–55 years	2 (18.2)	6 (7.3)	
56–65 years	1 (9.1)	8 (9.8)	
>65 years	0 (0)	2 (2.4)	
Comorbidity			
None	7 (63.6)	66 (80.5)	0.323
Diabetes mellitus	1 (9.1)	3 (3.7)	
Hypertension/heart disease	2 (18.2)	9 (11.0)	
Diabetes + hypertension	1 (9.1)	3 (3.7)	
Other	0 (0)	1 (1.2)	
BMI category (kg/m^2)			
<18.5 (underweight)	2 (18.2)	52 (63.4)	**0.010***
18.5–24.9 (normal)	2 (18.2)	11 (13.4)	
25–29.9 (overweight)	5 (45.4)	13 (15.9)	
≥30 (obese)	2 (18.2)	6 (7.3)	
Duration of surgery			
<2 hours	1 (9.1)	11 (13.4)	**0.019***
2–3 hours	3 (27.3)	52 (63.4)	
>3 hours	7 (63.6)	19 (23.2)	
Perioperative blood transfusion			
Yes	7 (63.6)	12 (14.6)	**0.001***
No	4 (36.4)	70 (85.4)	
Mode of stabilization			
Intramedullary nail	4 (36.4)	38 (46.3)	0.749
Plate and screw	7 (63.6)	44 (53.7)	

*Statistically significant at p <0.05.

Microbiological Profile

Among the 11 patients with SSI, wound cultures were positive in 9 patients; 2 yielded no growth. *Staphylococcus aureus* was the predominant pathogen, isolated in 6 of 11 culture cases (54.5% of all SSIs; 66.7% of culture-positive SSIs). *Pseudomonas* species and *Klebsiella* species were isolated in 2 (18.2%) and 1 (9.1%) cases, respectively (Table 4).

Table 4: Microbiological Isolates from Infected Wounds

Organism	Group A (n=8)	Group B (n=3)	Total (n=11)	% of SSIs
Staphylococcus aureus	4 (36.3)	2 (18.2)	6 (54.6)	54.5
Pseudomonas species	2 (18.2)	0 (0)	2 (18.2)	18.2
Klebsiella species	1 (9.1)	0 (0)	1 (9.1)	9.1
No growth	1 (9.1)	1 (9.1)	2 (18.2)	18.2

Values are n (%).

Discussion

Surgical site infection remains one of the most challenging complications in orthopedic surgery, particularly in the context of internal fixation where implanted hardware creates a nidus for bacterial colonization and biofilm formation (Winkler et al., 2012; Zimmerli, 2014). This prospective, randomized, double-blind trial evaluated whether local infiltration of gentamicin into the surgical wound prior to closure provides additional protection against SSI beyond standard systemic prophylaxis in patients undergoing open reduction and internal fixation of lower limb fractures and deformities. Our findings demonstrate a lower infection rate in the gentamicin group (6.4%) compared with the placebo group (17.4%), representing an absolute risk reduction of 11.0%; however, this difference did not achieve statistical significance ($p = 0.120$).

Efficacy of Local Gentamicin Infiltration

The observed reduction in SSI incidence with local gentamicin, though not statistically significant, is clinically meaningful and consistent with the biologic rationale for local antibiotic delivery. By achieving high tissue concentrations at the operative site without corresponding systemic levels, local infiltration targets the most common pathogens while minimizing the risk of systemic toxicity (Chiang et al., 2014; Osmon et al., 2013). Previous studies have similarly reported variable efficacy of local antibiotic prophylaxis in orthopedic surgery. A systematic review by Chiang et al. found that local vancomycin powder significantly reduced SSI in spine surgery (Chiang et al., 2014), while evidence for gentamicin infiltration in long-bone fixation remains less robust (Chiang et al., 2014). The lack of statistical significance in our study may be attributed to the modest sample size, which provided limited power to detect a difference of this magnitude. Post-hoc power analysis suggests that approximately 180 patients per group would be required to achieve 80% power to detect an 11% absolute risk reduction at $\alpha = 0.05$. This underscores the need for larger, multicenter trials to definitively establish the efficacy of this intervention.

Risk Factors for Surgical Site Infection

Our analysis identified three independent risk factors significantly associated with SSI: elevated BMI, prolonged operative duration, and perioperative blood transfusion. Each of these factors is well-established in the literature and carries important clinical implications.

Body mass index. Overweight and obese patients (BMI ≥ 25 kg/m^2) accounted for 63.6% of all SSIs in our cohort, and the association was highly significant ($p = 0.010$). Obesity impairs wound healing through multiple mechanisms, including compromised microvascular perfusion, increased tension on wound edges, and altered immune function (Dowsey & Choong, 2009; Sørensen, 2012). The subcutaneous adipose layer in obese patients also presents a larger potential space for hematoma and seroma formation, creating an ideal environment for bacterial proliferation (Kabata et al., 2015). These findings reinforce the importance of meticulous surgical technique, adequate dead-space closure, and extended wound surveillance in overweight patients. Only 18.2% of patients who were underweight developed SSI despite having a greater number of participants (58.1%).

Operative duration. Procedures exceeding 3 hours were strongly associated with SSI ($p = 0.019$), with 63.6% of infected patients falling into this category. Prolonged operative time correlates with increased bacterial inoculum, greater tissue desiccation, and higher doses of anesthetic agents that may impair immune function (Proctor et al., 2010). Additionally, extended duration often reflects surgical complexity, which itself is a recognized risk factor (Cheng et al., 2017). Our data support the established recommendation that operative efficiency should be optimized without compromising surgical quality, and that prolonged cases warrant enhanced prophylactic measures.

Perioperative blood transfusion. This was the strongest predictor of SSI in our study ($p = 0.001$), with 63.6% of infected patients receiving transfusion compared with only 14.6% of uninfected patients. Allogeneic blood transfusion is known to induce immunomodulation through transfusion-related immunosuppression (TRIM), which impairs both cellular and humoral immune responses (Blumberg & Heal, 1994; Vamvakas & Blajchman, 2007). Furthermore, transfusion often reflects significant intraoperative blood loss and tissue trauma, compounding the risk of infection. These findings align with growing evidence supporting restrictive transfusion strategies and the use of autologous blood salvage techniques in orthopedic surgery (Bierbaum et al., 1999; Carson et al., 2016).

Microbiological Profile

Staphylococcus aureus was the predominant pathogen, isolated in 54.5% of culture-positive infections. This is consistent with global patterns of orthopedic SSI, where coagulase-negative staphylococci and *S. aureus* predominate (Moran et al., 2007; Trampuz et al., 2007). The predominance of gram-positive organisms supports the rationale for using gentamicin, which retains activity against staphylococci, although its spectrum is primarily directed against gram-negative bacilli (Edmiston et al., 2017). The isolation of *Pseudomonas* and *Klebsiella* in three cases highlights the polymicrobial nature of some infections and the importance of culture-directed therapy when SSI occurs.

Comparison with Existing Literature

Our overall SSI rate of 11.8% is consistent with reported rates from similar settings in sub-Saharan Africa, where rates range from 9% to 18% (Akinleye et al., 2019; Ogirima & Dahiru, 2006). This is higher than rates reported from high-resource settings (de Boer et al., 1999), reflecting differences in infrastructure, patient comorbidity profiles, and case complexity. The comparable baseline characteristics between our groups and the double-blind design strengthen the internal validity of our findings, though the single-center nature and modest sample size limit generalizability.

Strengths and Limitations

This study has several strengths. The prospective, randomized, double-blind design minimizes bias and confounding. The use of a standardized prophylactic regimen (ceftriaxone) and a validated outcome measure (ASEPSIS score) enhances comparability and reproducibility (Wilson et al., 1986). The 90-day follow-up period is appropriate for implant-related infections (Zyaie & Saied, 2008).

However, limitations must be acknowledged. The sample size of 100 patients, reduced to 93 in the per-protocol analysis, provided insufficient statistical power to detect a clinically meaningful difference. Seven patients were lost to follow-up, which may introduce attrition bias, although the proportion was balanced between groups. We did not perform multivariate logistic regression to adjust for confounders, given the small number of outcome events. Additionally, the study was conducted at a single institution, potentially limiting external validity.

Clinical Implications

Despite the lack of statistical significance, the observed 63% relative reduction in SSI with local gentamicin infiltration, combined with its low cost, wide availability, and favorable safety profile, supports consideration of this adjunctive measure in resource-limited settings where SSI rates are high (Chan, 2003; Chiang et al., 2014). Surgeons should remain vigilant regarding modifiable risk factors – particularly obesity, operative efficiency, and blood conservation strategies – to further reduce infection rates (Metsemakers et al., 2018; Vamvakas & Blajchman, 2007). Future research should focus on adequately powered multicenter trials, ideally with stratification by risk category, to clarify the role of local gentamicin in contemporary orthopedic practice.

Conclusion

Local gentamicin infiltration at wound closure was associated with a lower, though not statistically significant, rate of surgical site infection following lower limb open reduction and internal fixation. Significant modifiable risk factors included BMI >25 kg/m^2, operative duration >3 hours, and perioperative blood transfusion. *Staphylococcus aureus* was the predominant causative organism. Larger randomized controlled trials are warranted to definitively establish the efficacy of this simple, low-cost intervention.

Declarations

Ethical Approval

Ethical approval was obtained from the ethical committee of Dala Orthopaedic Hospital, Kano, Kano State of Nigeria, to conduct the study.

Author Contribution

We attest to the fact that all authors have participated in the research, read the manuscript, and attest to the validity and legitimacy of the data. All authors have been directly involved with the various aspects of the study.

Conflicts of Interest

The authors declare that they have no conflict of interest.

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