Gentamicin-Coated Nail Is Effective Fracture-Related Infection Prophylaxis in Open Tibial Fractures

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Purpose: Fracture related infection (FRI) has been vastly described as a complication of open fracture. Risk is increased secondary to high-energy trauma, which frequently is associated with soft-tissue damage in this segment. Among surgical alternatives, the gentamicin-coated nail (GCN) is available. Its prophylaxis use is theory-based, preventing bacterial colonization and avoiding secondary biofilm formation. GCN is indicated in patients at high risk of presenting FRIs, such as those with open fractures. There are a couple of studies with a small sample of patients to validate its use clinically. The purpose of this study is to test the efficacy of GCN as a prophylactic method of FRI in a tibial open fracture.

Methods: In a mixed cohort study, a prospective group of patients managed with GCN, as compared to a retrospective group of patients managed with non-gentamycin-coated nails (NGCNs). Inclusion criteria were patients with open tibial fracture, surgical stabilization with GCN or NGCN, and follow-up of at least 6 months. The treatment protocol for every patient included: less than 3 hours for antibiotic prophylaxis initiation, less than 24 hours for surgical irrigation and debridement, pin holiday if time frame between external fixator and definitive fixation was more than 14 days, and, if required, local or microvascular coverage flaps as soon as possible. Traumatic amputation, protocol violation, and loss of follow-up were the exclusion criteria. Demographic variables, comorbidities, use of external fixation (EF), need of pin holiday, days with EF, flap coverage, time to flap coverage, open or closed reduction, and FRI incidence were studied. Later we evaluated any confounding variables in the association between GCN and FRI. Statistical analysis was done in Stata, v14.0, with P<0.05 as significance level.

Results: 214 patients were included, of whom 74 underwent GCN and 140 NGCN. No statistical differences were found in age, diabetes, obesity, requirement and type to flap coverage, days with EF, or reduction type. Smoke habit prevalence was higher in the GCN group (35.14% vs 20.93%, P = 0.02) and pin holiday was higher in the GCN group (13.79% vs 2.09%, P < 0.01). We found no association between pin holiday and FRI incidence (P = 0.46). EF use was higher in the NGCN group (72.14 vs 40.54%, P < 0.01), without any association between EF and FRI incidence (P = 0.23). There was a statistically significant association between use of GCN and FRI incidence being lower in the GCN group (1.35% vs 8.57%, P = 0.03). We found no confounding variables between GCN and FRI.

Conclusion: The use of GCNs in open tibial fracture provides an effective prophylactic method to reduce the risk of presenting FRIs at 6-month follow-up.

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.