Three Weeks Versus Six Weeks of Antibiotic Therapy for Diabetic Foot Osteomyelitis: A Prospective, Randomized, Noninferiority Pilot Trial, Gariani K, Pham TT, Kressmann B, et al. *Clin Infect Dis*. 2021;73(7):e1539-e1545.

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Level of Evidence: 2

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Diabetic foot osteomyelitis (DFO) is associated with high financial costs, recurrences, and lower extremity amputations and has a high potential for poor outcomes. Many clinicians treat DFO with a long course of antibiotic therapy (>6 weeks). Yet, the use of prolonged therapy for DFO has risks of side effects, development of antibiotic resistance, and costs. The authors of this study designed a pilot randomized controlled trial comparing short vs long duration of systemic antibiotic therapy for DFO.

Relative short (3 weeks) vs long (6 weeks) duration of antibiotic therapy for diabetic foot infections (DFI) were prospectively compared. The study assessed clinical remission of DFO at 2 months after the end of treatment (EOT). Inclusion criteria included age >18, diabetes mellitus, having undergone appropriate debridement of all necrotic tissue, and the presence of DFO. Exclusion criteria were DFO associated with an implant, having antibiotic therapy within 96 previous hours, total clinical amputation of all infected tissue, complete destruction of bone beyond the cortical level, or remote infection of any type requiring >21 days of another antibiotic therapy.

Among 93 enrolled patients, 44 were randomized to the 3-week arm and 49 to the 6-week arm. The medial number of surgical debridements was 1. In the intention-to-treat (ITT) population, remission occurred in 37 (84%) of the patients in the 3-week arm compared with 36 (73%) in the 6-week arm. The number of adverse events (AE) was similar in the 2 study arms (17/44 vs 16/49), as were the remission incidences in the per-protocol (PP) population (33/39 vs 32/43). Using multivariate analysis, treatment with the shorter antibiotic course was not significantly associated with remission.

In this randomized controlled pilot trial, a post-debridement systemic antibiotic therapy course for DFO of 3 weeks gave similar (and statistically non-inferior) incidences of remission and AE to a course of 6 weeks. Limitations of this study included being a pilot study, the fact that antibiotic agents are only 1 part of the multifaceted treatment of DFO, minimal study follow-up period after treatment of 2 months, the RCT included DFO episodes in which the subject underwent a partial amputation (removing a substantial part of infection), and with 63 different microbiological constellations used among the 93 episodes they cannot compute the role of each pathogen on the likelihood of remission.
