Validation for the “Six Hour Rule” for the Severe Open Tibia Fracture
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Purpose/Background: The “six hour rule” serves as the accepted time frame for the initial irrigation and debridement to minimize septic complications after severe open tibia fractures. This study examined the validity of this traditional care paradigm in Gustilo-Anderson grade IIIB open tibia shaft fractures, which represent a subset of open fractures in which greater infection rates are expected.

Methods: This is a retrospective cohort study of grade IIIB open tibial shaft fractures treated at 2 Level I trauma centers from 2001-2013 by 5 attending surgeons. Fractures were treated initially with serial irrigation and debridement and vacuum-assisted closure device, and definitively with intramedullary nail, plate and screw fixation, or external fixator. Mean follow-up was 15 months (range, 2 to 61 months). Time to surgery was defined as time from arrival to the start of the case. Transfers were excluded as the time spent at outside hospitals could not be quantified. Data were analyzed using SPSS with Pearson chi-squared test.

Results: A total of 77 grade IIIB open tibial shaft fractures presented in the 13-year period; 15 transfers were excluded, 10 cases were excluded due to lack of follow-up, 2 due to death, 2 due to insufficient data in record, and 1 due to conversion to below the knee amputation. Of the remaining 47 cases, 77% underwent initial debridement within 6 hours. Mean patient age was 38 years (range, 17-67 years); mean time to debridement was 5 hours 39 minutes (range, 51 minutes-43 hours). Reoperation for infection was required in 5.6% of cases treated within 6 hours and 36.4% of cases treated after 6 hours. The exact 2-sided significance of the Pearson chi-squared test comparing infection rate between these groups was $P = 0.021$ with an odds ratio of 6.1.

Conclusion: Initial open fracture care within 6 hours of admission significantly reduces the infection rate in grade IIIB open tibial shaft fractures. Cases that are delayed more than 6 hours have an odds ratio of infection of 6.1 relative to those that are not.

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.