Oral Antibiotics Reduce Reinfection Following 2-stage Exchange: A Multi-center, Randomized Controlled Trial

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Introduction: A substantial number of patients develop recurrent periprosthetic joint infection (PJI) following two-stage exchange arthroplasty. The purpose of this multicenter randomized controlled trial was to determine if 3 months of oral antibiotics would decrease the risk of failure following a two-stage exchange.

Methods: We invited all members of the Knee Society to participate in the trial. Following Institutional Review Board approval seven centers enrolled patients who were randomized to receive three months of oral antibiotics or no further antibiotic treatment after operative cultures following the second stage reimplantation were negative. Oral antibiotic therapy was tailored to the original infecting organism(s) in consultation with an Infectious Disease specialist. Priori power analysis determined that 77 patients per group would be required to demonstrate a reduction in infection recurrence from 16% to 4% ($\beta=0.80$ and $\alpha=0.05$). A logrank survival curve was used to analyze the primary outcome of reinfection.

Results: 53 Patients were randomized to the antibiotic group and 41 in the control group; 14 were excluded for protocol deviations (most commonly discontinuation of antibiotics prior to 90 days) leaving 40 patients in each group with a mean follow up of 16.3 months in the antibiotic and 11.4 months in the control group. PJI followed a TKA in 41 patients and a THA in 39. Mean age, BMI, sex distribution and Charlson index were similar amongst the groups suggesting appropriate randomization. There have been two failures in the antibiotic group compared to eight amongst controls (5% vs 20%; $p=0.0232$ using log rank survival curve analysis). Seven of the 8 failures in the control group were with new organisms and both failures in the antibiotic group were with the same organism.

Conclusions: This multicenter randomized trial suggests that at short-term follow-up, the addition of three months of oral antibiotics significantly improved infection-free survival.