

Safety Profile of
Seven-Day Antibiotic Irrigation for the Treatment of Chronic Periprosthetic Joint Infection: A Prospective Randomized Phase II Comparative Study

Bryan Donald Springer¹, Nicolas Santiago Piuizzi, Carlos A Higuera Rueda, Ian Savage Elliott², Brian C de Beaubien
¹Orthocolorina, ²Tulane School of Medicine

INTRODUCTION:

Periprosthetic joint infection (PJI) remains a major complication following total joint arthroplasty. This study evaluated the safety of a novel method of local delivery of antibiotics compared to a standard two-stage exchange.

METHODS:

This was a Phase II, multicenter, prospective randomized trial of a 7-day two-stage exchange arthroplasty with local antibiotics compared to a standard two-stage exchange. The experimental group included irrigation using 80 mg tobramycin daily followed by hourly irrigation using 125 mg of vancomycin. The control group received an antibiotic loaded cement spacer with vancomycin and tobramycin. Both groups received 12 weeks of systemic antibiotics. Safety measures included: Adverse events, peak vancomycin/tobramycin concentrations, blood transfusion, and mortality. Total operative times for both groups were recorded.

RESULTS:

Thirty-seven patients were randomized to the experimental group and 39 to control. There was no difference in baseline demographics. There were no antibiotic medication related adverse events. In total, 188 vancomycin peak measurements taken in the experimental group, 127 samples had detectable serum level concentrations (69%), with all concentrations well below the acceptable trough threshold of 20 mg/mL. Of the 103 tobramycin peak measurements, there were 46 samples with detectable levels (45%), with all well below the maximum peak threshold of 18-24 mg/mL. There was no difference in the amount of blood transfused per subject (p=0.4188). Two deaths occurred in each group. [The overall OR time was significantly less in the experimental group \(p=0.0068\). All subjects in the experimental group were successfully reimplemented between 7-10 days compared to 73% of in the control group.](#)

DISCUSSION AND CONCLUSION:

Local antibiotic delivery method is safe with minimal systemic antibiotic exposure (SAE). There was no difference in the rates or severity of SAEs between groups. Further research is being conducted to examine the efficacy of PJI eradication using local antibiotic irrigation.