Paper Session: Program Highlights

A Prospective Randomized Trial to Assess Oral (PO) Versus IV Antibiotics for the Treatment of Postoperative Wound Infection After Extremity Fractures (POvIV)

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Purpose: Part of the treatment of fracture-related infections (FRIs) has historically involved 6 weeks of IV antibiotics. However, IV antibiotics are costly and create risk of complications including deep vein thrombosis (DVT), line clotting, and sepsis not expected with oral (PO) antibiotics. Basic science data and retrospective clinical studies comparing PO versus IV antibiotics support the use of PO antibiotics, but there areno high-quality clinical data investigating this question for FRIs. This study evaluates the effectiveness and complications of treatment of FRI with PO or IV antibiotics in addition to operative debridement and other standard practices. Our hypothesis is that PO antibiotics are non-inferior (equivalent) to IV antibiotics in the treatment of FRI.

Methods: This study was a phase III, randomized clinical trial to investigate the effectiveness of PO versus IV antibiotics following surgery for FRI. The study population included patients aged 18-84 years being treated for a wound infection after internal fixation of a fracture or joint fusion. All infections were treated with at least 1 surgical debridement. Participants were block randomized (within centers) in a 1:1 ratio to either PO or IV antibiotics at discharge following initial standard of care antibiotic treatment during the inpatient stay. Follow-up was scheduled for 2 weeks, 6 weeks, 3 months, 6 months, and 1 year after discharge following hospitalization to treat the infection. The primary outcome was the number of study injury-related surgical interventions by 1 year. Secondary outcomes include, but are not limited to, infection recurrence and infection with a new pathogen. We consider PO to be non-inferior to IV if the difference in mean number of additional procedures within 1 year is less than or equal to 0.67. A sensitivity analysis will be conducted to focus on infection-specific outcomes.

Results: The study randomized 233 eligible patients at 22 Level-I and II trauma centers to either PO (n = 115) or IV (n = 118) arms. The study sample was largely male (77%) and non-Hispanic white (65.2%), with a mean age of 45.9 years(± SD [standard deviation] 13.8). Most fractures (61.8%) were of the tibia/fibula. Additional fractures included femur (9%), humerus (7%), and radius/ulna (6%). The median follow-up time among all 233 patients was 51.9 weeks.

Conclusion: This study addresses a crucial question in treating the difficult but unfortunately common complication of FRI. The final analysis will be released at the annual meeting and should provide important information regarding the effectiveness and complications of PO versus IV antibiotics for the treatment of FRI.