Paper - Annual Meeting

Paper Session: Program Highlights

Supplemental Perioperative Oxygen to Reduce Surgical Site Infection After High-Energy Fracture Surgery (OXYGEN Study)

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Purpose: Surgical site infection (SSI) after fracture fixation surgery remains challenging. One low-cost, readily available technique to reduce infection rates is the use of a higher concentration of oxygen during the perioperative period. While there is some literature investigating this concept in other surgical specialties, high-level evidence in fracture surgery does not exist. Our hypothesis was the use of higher concentration of perioperative oxygen in a high-risk population with tibial pilon, tibial plateau, and calcaneus fractures would reduce the rate of deep SSI within 6 months of fracture fixation.

Methods: This study was a phase III, prospective, double-blind randomized clinical trial. Patients were aged 18 to 80 years with tibial plateau, tibial pilon, and calcaneus fractures definitively treated with plate and screw fixation. To ensure study injuries had a higher risk of infection, eligible fractures had to be either open (Gustilo-Anderson Types I, II, or IIIA) or treated in a delayed fashion due to swelling or a high-risk fracture pattern. Participants were block-randomized (within center and fracture type) in a 1:1 ratio to either 30% (control group) or 80% (intervention group) FiO2 in the operating room and for up to 2 hours in the recovery room. Follow-up was scheduled for 2, 12, and 26 weeks after fixation with a patient phone interview at 52 weeks. The primary outcome measure was clinically important infections, defined as deep or superficial SSI within 6 months of injury based on Centers for Disease Control and Prevention (CDC) criteria. All outcomes were adjudicated by central independent adjudication committee.

Results: The study randomized 1136 patients at 29 Level-I trauma centers. The patient population was typical of trauma patients in the United States; they were more commonly male (68%) and non-Hispanic white (73%), with a mean age of 45.4 years (14.3 standard deviation). Most (84%) fractures were closed, while 58% of the open fractures were Type IIIA. Follow-up rates were high, with 90% of participants having follow-up to the 6-month clinical visit window. Median follow-up duration was 367 days.

Conclusion: This study is one of the largest prospective randomized multicenter trials conducted to date within orthopaedic trauma. The results of this trial should provide a definitive answer as to whether this low-cost treatment option can help reduce the burden of SSI in both military and civilian patients. Additional data cleaning queries and follow-up medical record reviews are currently in process and final results will be presented at the OTA annual meeting.