Aqueous-PREP: A Pragmatic Randomized Trial Evaluating Preoperative Aqueous Antiseptic Skin Solutions in Open Fractures

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Purpose: Our objective was to compare the effectiveness of aqueous 10% povidone-iodine versus 4% chlorhexidine gluconate (CHG) for the antiseptic skin preparation of open fracture surgery.

Methods: A cluster-randomized multiple crossover clinical trial was conducted at 14 hospitals in the United States, Canada, and Spain. All patients receiving surgical fixation for an open extremity fracture were eligible for enrollment. Each participating site used their randomly allocated antiseptic solution for all eligible patients during the initial 2 months of recruitment. The sites then switched to the opposite antiseptic, alternating between the study solutions every 2 months. The primary outcome was surgical-site infection (SSI), and the secondary outcome was unplanned fracture-related reoperation within 1 year.

Results: 1640 patients were enrolled. The mean age of the study participants was 45 years (standard deviation [SD] 18) and 62% were male. 38% of included fractures were Gustilo-Anderson type IIIA injuries. Surface contamination was reported in 26% of the open wounds and 10% contained contamination embedded in the deep tissues. There were 783 open tibia fractures and 75% of all included fractures occurred in the lower extremity. Temporary fracture stabilization was used for 22% of the participants. 35% of participants received intrawound topical antibiotics and the median duration of perioperative intravenous antibiotics was 3.0 days (interquartile range [IQR] 2.0). As of January 4, 2022, 92% of participants have completed follow-up for the primary SSI outcome at 3 months and 87% of eligible participants have completed the 12-month assessment. Final follow-up for the trial will be closed in June 2022 with full data analysis ready for presentation at the 2022 OTA Annual Meeting.

Conclusion: The optimal antiseptic skin solution for open fracture surgery remains unknown. This large multicenter clinical trial will provide definitive evidence to determine if the choice of an aqueous antiseptic skin solution can decrease SSI and unplanned reoperations for open fracture patients.