

## ORIGINAL ARTICLE

# Skin Antisepsis before Surgical Fixation of Extremity Fractures

The PREP-IT Investigators\*

## ABSTRACT

**BACKGROUND**

Studies evaluating surgical-site infection have had conflicting results with respect to the use of alcohol solutions containing iodine povacrylex or chlorhexidine gluconate as skin antisepsis before surgery to repair a fractured limb (i.e., an extremity fracture).

**METHODS**

In a cluster-randomized, crossover trial at 25 hospitals in the United States and Canada, we randomly assigned hospitals to use a solution of 0.7% iodine povacrylex in 74% isopropyl alcohol (iodine group) or 2% chlorhexidine gluconate in 70% isopropyl alcohol (chlorhexidine group) as preoperative antisepsis for surgical procedures to repair extremity fractures. Every 2 months, the hospitals alternated interventions. Separate populations of patients with either open or closed fractures were enrolled and included in the analysis. The primary outcome was surgical-site infection, which included superficial incisional infection within 30 days or deep incisional or organ-space infection within 90 days. The secondary outcome was unplanned reoperation for fracture-healing complications.

**RESULTS**

A total of 6785 patients with a closed fracture and 1700 patients with an open fracture were included in the trial. In the closed-fracture population, surgical-site infection occurred in 77 patients (2.4%) in the iodine group and in 108 patients (3.3%) in the chlorhexidine group (odds ratio, 0.74; 95% confidence interval [CI], 0.55 to 1.00;  $P=0.049$ ). In the open-fracture population, surgical-site infection occurred in 54 patients (6.5%) in the iodine group and in 60 patients (7.3%) in the chlorhexidine group (odds ratio, 0.86; 95% CI, 0.58 to 1.27;  $P=0.45$ ). The frequencies of unplanned reoperation, 1-year outcomes, and serious adverse events were similar in the two groups.

**CONCLUSIONS**

Among patients with closed extremity fractures, skin antisepsis with iodine povacrylex in alcohol resulted in fewer surgical-site infections than antisepsis with chlorhexidine gluconate in alcohol. In patients with open fractures, the results were similar in the two groups. (Funded by the Patient-Centered Outcomes Research Institute and the Canadian Institutes of Health Research; PREPARE ClinicalTrials.gov number, NCT03523962.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Dr. Sprague can be contacted at [sprags@mcmaster.ca](mailto:sprags@mcmaster.ca) or at the Division of Orthopedic Surgery, Department of Surgery, McMaster University, 293 Wellington St. N., Suite 110, Hamilton, ON, Canada. Dr. Slobogean can be contacted at [gslobogean@som.umaryland.edu](mailto:gslobogean@som.umaryland.edu) or at the Center for Orthopedic Injury Research and Innovation, Department of Orthopedics, University of Maryland School of Medicine, R. Adams Cowley Shock Trauma Center, 22 S. Greene St., Baltimore, MD 21201.

\*A complete list of the PREP-IT Investigators is provided in the Supplementary Appendix, available at [NEJM.org](http://NEJM.org).

Drs. Sprague and Slobogean contributed equally to this article.

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