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Skin antisepsis with chlorhexidine-alcohol versus povidone iodine-alcohol, with and without skin scrubbing, for prevention of intravascular-catheter-related infection (CLEAN): an open-label, multicentre, randomised, controlled, two-by-two factorial trial.

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Abstract

BACKGROUND: Intravascular-catheter-related infections are frequent life-threatening events in health care, but incidence can be decreased by improvements in the quality of care. Optimisation of skin antisepsis is essential to prevent short-term catheter-related infections. We hypothesised that chlorhexidine-alcohol would be more effective than povidone iodine-alcohol as a skin antiseptic to prevent intravascular-catheter-related infections.

METHODS: In this open-label, randomised controlled trial with a two-by-two factorial design, we enrolled consecutive adults (age ≥18 years) admitted to one of 11 French intensive-care units and requiring at least one of central-venous, haemodialysis, or arterial catheters. Before catheter insertion, we randomly assigned (1:1:1:1) patients via a secure web-based random-number generator (permuted blocks of eight, stratified by centre) to have all intravascular catheters prepared with 2% chlorhexidine-70% isopropyl alcohol (chlorhexidine-alcohol) or 5% povidone iodine-69% ethanol (povidone iodine-alcohol), with or without scrubbing of the skin with detergent before antiseptic application. Physicians and nurses were not masked to group assignment but microbiologists and outcome assessors were. The primary outcome was the incidence of catheter-

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FINDINGS: Between Oct 26, 2012, and Feb 12, 2014, 2546 patients were eligible to participate in the study. We randomly assigned 1181 patients (2547 catheters) to chlorhexidine-alcohol (594 patients with scrubbing, 587 without) and 1168 (2612 catheters) to povidone iodine-alcohol (580 patients with scrubbing, 588 without). Chlorhexidine-alcohol was associated with lower incidence of catheter-related infections (0.28 vs 1.77 per 1000 catheter-days with povidone iodine-alcohol; hazard ratio 0.15, 95% CI 0.05-0.41; p=0.0002). Scrubbing was not associated with a significant difference in catheter colonisation (p=0.3877). No systemic adverse events were reported, but severe skin reactions occurred more frequently in those assigned to chlorhexidine-alcohol (27 [3%] patients vs seven [1%] with povidone iodine-alcohol; p=0.0017) and led to chlorhexidine discontinuation in two patients.

INTERPRETATION: For skin antisepsis, chlorhexidine-alcohol provides greater protection against short-term catheter-related infections than does povidone iodine-alcohol and should be included in all bundles for prevention of intravascular catheter-related infections.

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