Paint-Only Is Equivalent to Scrub-and-Paint in Preoperative Preparation of Abdominal Surgery Sites

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BACKGROUND: Antiseptic preoperative skin site preparation is used to prepare the operative site before making a surgical incision. The goal of this preparation is a reduction in postoperative wound infection. The most straightforward technique necessary to achieve this goal remains controversial.

STUDY DESIGN: A prospective randomized trial was designed to prove equivalency for two commonly used techniques of surgical skin site preparation. Two hundred thirty-four patients undergoing nonlaparoscopic abdominal operations were consented for the trial. Exclusion criteria included presence of active infection at the time of operation, neutropenia, history of skin reaction to iodine, or anticipated insertion of prosthetic material at the time of operation. Patients were randomized to receive either a vigorous 5-minute scrub with povidone-iodine soap, followed by absorption with a sterile towel, and a paint with aqueous povidone-iodine or surgical site preparation with a povidone-iodine paint only. The primary end point of the study was wound infection rate at 30 days, defined as presence of clinical signs of infection requiring therapeutic intervention.

RESULTS: Patients randomized to the scrub-and-paint arm ($n = 115$) and the paint-only arm ($n = 119$) matched at baseline with respect to age, comorbidity, wound classification, mean operative time, placement of drains, prophylactic antibiotic use, and surgical procedure (all $p > 0.09$). Wound infection occurred in 12 (10%) scrub-and-paint patients, and 12 (10%) paint-only patients. Based on our predefined equivalency parameters, we conclude equivalence of infection rates between the two preparations.

CONCLUSIONS: Preoperative preparation of the abdomen with a scrub with povidone-iodine soap followed by a paint with aqueous povidone-iodine can be abandoned in favor of a paint with aqueous povidone-iodine alone. This change will result in reductions in operative times and costs. (J Am Coll Surg 2005;201:737–741. © 2005 by the American College of Surgeons)

The purpose of preoperative surgical skin site preparation is to reduce bacterial cell count of the skin to reduce likelihood of postoperative wound infection. A variety of skin-preparation agents and methods are available for achieving these goals and the techniques for preoperative cleansing of the skin vary among hospitals and surgeons.

Competing Interests Declared: None.

Received May 7, 2005; Accepted May 18, 2005.

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Updated surgical guidelines recommend both mechanical cleansing and painting with povidone-iodine or chlorhexidine gluconate.[1] Standard preoperative skin preparation used by many hospitals includes a 5-minute scrub with povidone-iodine soap followed by a paint with aqueous povidone-iodine. This method is extremely effective in reducing bacterial skin count but has some potential drawbacks.[2] The method is time-consuming and can result in pooling of detergent under the patient or in intertriginous folds, resulting in irritation. Scrubbing components of the skin preparation can also result in higher bacterial skin counts because it releases the bacteria harbored in the pores and follicles of the dermis.[3]

A variety of alternative skin-preparation agents and methods are available and the techniques for preopera-

ISSN 1072-7515/05/$30.00
doi:10.1016/j.jamcollsurg.2005.05.023

tive cleansing of the skin vary among hospitals and surgeons. Numerous studies have favorably compared with the efficacy of these alternative preparations to the standard iodophor scrub-and-paint method, in terms of a reduction in bacterial skin counts.[3-7] Use of chlorhexidine-gluconate spray, iodophor-in-alcohol paint, and market soap scrub with alcohol paint have all been compared with the standard iodophor scrub-and-paint in prospective randomized trials.[5-7] None of these trials demonstrated differences in infection rates between the different preparation methods. One prospective randomized study of orthopaedic surgical patients compared with effectiveness of standard iodophor scrub-and-paint with iodophor paint alone.[3] There were no infections in either arm of the study, but the study was underpowered to prove equivalency between the two preparations and methods. Because of the potential advantages of eliminating the scrubbing component of the iodophor skin preparation, we decided to perform a trial to prove equivalence of the two preparation methods.

METHODS

In a Comprehensive Cancer Center, 234 surgical patients were consented and entered into a prospective randomized trial of preoperative skin preparation. Eligible patients were those undergoing elective abdominal operation. Exclusion criteria included: active infection at the time of operation, neutropenia defined as a white blood cell count of $< 2{,}000$ or an absolute neutrophil count of < 500, history of skin reaction to iodine, and anticipated use of prosthetic material as part of the surgical procedure.

Before preoperative skin preparation, patients had all gross foreign material removed from the skin using a dry sponge and tape remover, if necessary. A razor was used to remove hair from the operative site. Patients were randomized in blocks with equal allocation to the two preoperative preparation arms. Randomization slots were not reused. Patients randomized to the iodophor scrub-and-paint arm underwent a vigorous 5-minute scrub using urethane sponges saturated with povidone-iodine detergent (available iodine 0.75%). Detergent was then absorbed with a blotting towel, before painting the operative site with aqueous povidone-iodine solution (available iodine 1.0%), which was allowed to air-dry. Patients randomized to the paint-only arm underwent painting of the operative site with aqueous povidone-iodine solution (available iodine 1.0%) only. Single application of aqueous povidone-iodine solution was also allowed to air-dry. For this study, we used all or part of the E-Z PREP 270 Tray (Becton Dickinson AcuteCare). Use of perioperative IV antibiotics was left to the discretion of the operating surgeon. Infection was defined by clinical criteria as presence of wound erythema or purulence requiring therapeutic intervention within the first 30 days after the surgical procedure. Study participants were not instructed to shower with any antibacterial agent before the operation.

The study was designed as an equivalency trial with wound infection rate as the primary end point. Wound infection rates between the two groups were compared using methods outlined by Rodary and colleagues,[8] which test for one-sided equivalence between treatments in a randomized clinical trial. The study was designed prospectively with the expectation that paint-only might have a higher rate of infection than scrub-and-paint. Testing a one-sided equivalence hypothesis involves calculation of the one-sided confidence interval for treatment difference such that, if the confidence limit is less than a prespecified threshold, one can conclude that the two treatments are equivalent. For this trial, we considered 6% (absolute difference) as the maximum acceptable difference in infection rates between groups that could support an equivalence hypothesis. If the one-sided confidence interval for the difference in infection rates could exclude a difference of $\geq 6\%$, then we could conclude equivalence of infection rates between the two preparations. Additional analyses included multivariate logistic regression analysis to identify factors predictive for infection. Data from this study was analyzed using SAS statistical software. This study was approved and conducted under the oversight of the Institutional Review Board at the City of Hope National Medical Center in Duarte, CA.

RESULTS

The study accrued 234 patients who were randomized to the iodophor scrub-and-paint arm ($n = 115$) or the paint-only arm ($n = 119$). Randomization slots were not reused, which resulted in a slight imbalance between the two arms from ineligible patients or patients who withdrew consent. The two groups of patients were well matched for predictors of postoperative wound infection (Table 1). The p values for comparing mean age, number of obese and diabetic patients, operative time, and mean American Society of Anesthesiologists (ASA)