Comparative Effectiveness of Skin Antiseptic Agents in Reducing Surgical Site Infections: A Report from the Washington State Surgical Care and Outcomes Assessment Program

Timo W Hakkarainen, MD, MS, E Patchen Dellinger, MD, FACS, Heather L Evans, MD, MS, FACS, Farhood Farjah, MD, MPH, Ellen Farrokhi, MD, FACS, Scott R Steele, MD, FACS, Richard Thirlby, MD, FACS, David R Flum, MD, MPH, FACS, for the Surgical Care and Outcomes Assessment Program Collaborative

BACKGROUND: Surgical site infections (SSI) are an important source of morbidity and mortality. Chlorhexidine in isopropyl alcohol is effective in preventing central venous-catheter associated infections, but its effectiveness in reducing SSI in clean-contaminated procedures is uncertain. Surgical studies to date have had contradictory results. We aimed to further evaluate the relationship of commonly used antiseptic agents and SSI, and to determine if isopropyl alcohol has a unique effect.

STUDY DESIGN: We performed a prospective cohort analysis to evaluate the relationship of commonly used skin antiseptic agents and SSI for patients undergoing mostly clean-contaminated surgery from January 2011 through June 2012. Multivariate regression modeling predicted expected rates of SSI. Risk adjusted event rates (RAERs) of SSI were compared across groups using proportionality testing.

RESULTS: Among 7,669 patients, the rate of SSI was 4.6%. The RAERs were 0.85 ($p = 0.28$) for chlorhexidine (CHG), 1.10 ($p = 0.06$) for chlorhexidine in isopropyl alcohol (CHG+IPA), 0.98 ($p = 0.96$) for povidone-iodine (PVI), and 0.93 ($p = 0.51$) for iodine-povacrylex in isopropyl alcohol (IPC+IPA). The RAERs were 0.91 ($p = 0.39$) for the non-IPA group and 1.10 ($p = 0.07$) for the IPA group. Among elective colorectal patients, the RAERs were 0.90 ($p = 0.48$) for CHG, 1.04 ($p = 0.67$) for CHG+IPA, 1.04 ($p = 0.85$) for PVI, and 1.00 ($p = 0.99$) for IPC+IPA.

CONCLUSIONS: For clean-contaminated surgical cases, this large-scale state cohort study did not demonstrate superiority of any commonly used skin antiseptic agent in reducing the risk of SSI, nor did it find any unique effect of isopropyl alcohol. These results do not support the use of more expensive skin preparation agents. (J Am Coll Surg 2014;218:336–344. © 2014 by the American College of Surgeons)

CME questions for this article available at http://jacscme.facs.org

Disclosure Information: Authors have nothing to disclose. Timothy J Eberlein, Editor-in-Chief, has nothing to disclose.

Financial support: SCOAP is a program of the Foundation for Healthcare Quality and is supported by a grant from Washington State's Life Science Discovery Fund and Agency for Healthcare Research and Quality Grant Number 1 R01 HS 20025-01. None of the authors has any financial or personal conflicts of interests pertaining to this work. This work was supported by NIH training grant 1T32DK070555-01A1.

Received August 17, 2013; Revised November 13, 2013; Accepted November 20, 2013.

From the Departments of Surgery, University of Washington Medical Center (Hakkarainen, Dellinger, Evans, Farjah, Flum) and Virginia Mason Medical Center (Thirlby), Seattle, WA; the Department of Surgery, Madigan Army Medical Center (Steele), Tacoma, WA; and the Department of General and Vascular Surgery, Providence Medical Center (Farrokhi) Everett, WA.

Correspondence address: Timo W Hakkarainen, MD, MS, University of Washington, Department of Surgery, 1959 NE Pacific St, Box 356410, Seattle, WA 98105-6410. email: timoh@uw.edu

Surgical site infections (SSIs) are an important source of morbidity and mortality, occurring in approximately 500,000 patients in the United States each year.[1] They increase mortality, hospital length of stay (LOS), and costs of care.[2] Several methods attempt to reduce the incidence and deleterious effects of SSIs. Chlorhexidine in 70% isopropyl alcohol skin antisepsis has been shown to be effective in preventing central venous catheter-associated infections and is currently recommended by the Centers for Disease Control (CDC) as the agent of choice for this indication.[3] No such recommendation exists for surgical procedures overall. Preoperative skin antisepsis varies among and within hospitals.

There are 2 major classes of skin antiseptic agents commonly used in the United States: chlorhexidine-based agents and iodophor-based agents. These 2 classes are further divided into agents that include an alcohol agent—typically

ISSN 1072-7515/13/$36.00
http://dx.doi.org/10.1016/j.jamcollsurg.2013.11.018

Abbreviations and Acronyms

CERTAIN = Comparative Effectiveness Translational Network
CHG = chlorhexidine
IPA = isopropyl alcohol
LOS = length of stay
PVI = povidone-iodine
RAERs = risk-adjusted event rates
RCT = randomized controlled trial
SCOAP = Surgical Care and Outcomes Assessment Program
SSI = surgical site infection

isopropyl alcohol (IPA)—and those that do not. The relatively small body of literature examining the impact of preoperative antiseptic agents on risk of SSI has produced mixed results. A systematic review of chlorhexidine-based antisepsis vs iodophor-based antisepsis found chlorhexidine (CHG) to be the superior agent.[4] Maiwald and Chan[5] also found evidence to support the use of chlorhexidine in isopropyl alcohol over aqueous iodophor preparations, but noted that the effect was incorrectly attributed to chlorhexidine exclusively, rather than to the combination of chlorhexidine and alcohol in the majority of papers. Darouiche and colleagues[6] found 2% chlorhexidine-gluconate in 70% IPA (CHG+IPA) reduced the risk of SSI by 41% compared with povidone-iodine (PVI). However, Swenson and colleagues[7] reported no significant difference between iodophor-based antisepsis in combination with alcohol (PVI+IPA or iodine povacrylex in 74% IPA [IPC+IPA]) compared with CHG+IPA.

Despite this inconsistency in the literature, proper antisepsis plays a pivotal role in reducing SSI, and further clarifying the optimal strategy has the potential to affect the incidence of SSIs. There is also a significant cost differential between antiseptic agents, and costs should be considered alongside benefits. The aims of this study were to further evaluate the comparative effectiveness of 4 commonly used surgical skin antiseptic agents in a general surgery population and to determine if IPA has any unique effect on the risk of SSI.

METHODS

Study design

The Comparative Effectiveness Translational Network (CERTAIN) is an Agency for Healthcare Research and Quality-funded research platform directed from the University of Washington's Surgical Outcomes Research Center. The CERTAIN applies skills in comparative evaluation to prospective data collection activities across Washington State. For this research question, CERTAIN assembled a prospective cohort of patients who underwent surgery from January 2011 to June 2012 in Washington State, whose care was monitored through the Surgical Care and Outcomes Assessment Program (SCOAP). We included patients for whom preoperative antiseptic agent data were available. Patients who received more than 1 class of antiseptic agent were excluded. Patients undergoing appendectomies were excluded because the SCOAP data collection is abbreviated for these patients and the typical LOS is less than 24 hours, limiting assessment for SSI. This prospectively gathered clinical registry includes more than 50 Washington State hospitals. For this study, data from 47 SCOAP hospitals were available during the evaluation period. Records from SCOAP were used to obtain demographic, laboratory, anthropometric, procedure, and clinical characteristics, as well as laboratory values, operation type, level or urgency, and perioperative information deemed to be relevant to the risk of SSI.

Data source

The SCOAP is a physician-led surveillance and response system for surgical quality. Its mission is to improve the quality of surgical care by reducing variations in outcomes and processes of care using benchmarking initiatives and data sharing between participants. The SCOAP system monitors the incidence of SSI in participating hospitals by collecting data on factors relevant to SSI. Examples include perioperative patient temperature, appropriate antibiotic prophylaxis, perioperative glucose levels, comorbidities, and type of preoperative antisepsis used. It also includes information on the diagnosis of SSI before discharge. Data are captured for specific procedures performed at participating hospitals. These include bariatric procedures, colectomy, appendectomy, hysterectomy, and for a subset of hospitals, oncologic surgical procedures related to the breast (mastectomy only), lung, esophagus, liver, pancreas, kidney, and prostate. This research project was reviewed and approved by the University of Washington Human Subject Division Institutional Review Board.

Definitions

Data definitions for SCOAP variables are publically available (http://www.scoap.org). Beginning in 2011, SCOAP added an SSI data metric, and abstracters were trained to review the medical record for diagnosed SSIs, as well as information about reintervention including reopening of wound edges, antibiotics for treatment of infection, abscess drainage, drain placement, or reoperation. For the purposes of this study, a patient was considered to have